Decision Jawatankuasa Teknikal Pendaftaran Year 2023 - List of medical device risk classification

NO	DEVICE NAME	DEVICE INTENDED USE*	DESCRIPTION OF MEDICAL DEVICE*	DECISION FROM COMMITTEE	REMARKS
1	HydraFacial Syndeo	The device is intended to abrade (exfoliate) the upper layers of the skin. Indication: • Mild to moderate acne, i.e. acne vulgaris, comedonal acne (blackheads and whiteheads). • Superficial acne scarring.	The HydraFacial Syndeo system is a device for non-invasive skin treatment that includes an accessory box, handpiece kit and lymphatic kit.	Class B, Rule 9(i)	
2	QLAB Quantification Software	Philips QLAB, QLAB ISITE, QLAB for 3rd party apis, QLAB for xcelera, QLAB for view forum are intended for analyzing diagnostic images or fluid flow of the human body. The QLAB quantification software is intended to be installed, used, and operated only in accordance with the safety procedures and operating instructions given in the product user information, and only for the purposes for which it was designed.	Philips QLAB advanced ultrasound quantification software is available either as a stand-alone product that can function on a standard pc, on board a dedicated workstation, or on-board Philips ultrasound systems. The QLAB quantification software application package is designed to view and quantify image data acquired on Philips ultrasound products.	Class B, Rule 10(i)	

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3	Dosicair flowrate controller	Allow the administration of intraveneous solutions by gravity.	Dosicair flowrate controller is a flowrate regulator composed of 2 cylinders in polycarbonate and a silicon seal. It can come in the form of a simple graduation or a double graduation flowrate regulator. Tubing are in PVC with a male luer lock connector for the inferior extremity connected to the patient. Tubing upstream of the flowrate regulator - Dosicair can be an extension line with a female luer lock connector or an infuser with spike and drop chamber / micro-drop chamber, depending the references. Tubing downstream of the flowrate regulator - Dosicair can be with a needleless or needle injection site or 3-ways stopcocks depending the references.	Class B, Rule 2	
4	Root Canal Preparation EDTA Cream	SoftPrep is a 17% aqueous EDTA solution. Provides rapid cleansing and enlarging of canals. Chelating agent assists in instrumentation of root canal and also lubricates to minimize binding and breaking of files.	SoftPrep is a 17% aqueous EDTA solution. Provides rapid cleansing and enlarging of canals. Chelating agent assists in instrumentation of root canal and also lubricates to minimize binding and breaking of files.	Class B, Rule 6	
5	SCHEU dental orthodontic accessories	The Hawley retainer design feature a cuspid to cuspid labial wire that retain the anterior teeth to hold them in place and two clasps for retention. The labial wire incorporates two omega loops for adjustment to maintain treatment or make minor movement of the anterior	Orthodontic accessories.	Class B, Rule 5	Intended for long-term use.

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		teeth as needed. The incorporation of expansion screw for variety of expansion and single tooth movement.			
6	Stryker AHTO suction/irrigation pump system	The Stryker AHTO Suction/Irrigation Pump System is a surgical fluid management system that utilizes a sterile disposable tube set (known as the "AHTO tube set") and a capital piece of equipment that contains the motor and controls flow rate into the AHTO tube set (known as the "console" or "AHTO suction/irrigation pump"). The AHTO Tube set is designed to be used with the AHTO Suction/Irrigation Pump (ref 250-070-601) and a laparoscopic probe or tip to allow for controlled irrigation and suction during laparoscopic surgical procedures.	The AHTO suction/irrigation pump is designed to be used with the AHTO tube set and a laparoscopic probe or tip to allow for controlled irrigation and suction during laparoscopic surgical procedures. The tube set is a sterile, single use and disposable unit that is easy to set up and use. Some AHTO tube sets are supplied with a disposable suction/irrigation tip.	Class B	

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7	Vaginal dilator	Amielle comfort : Ameille comfort is intended to treat women suffering from vaginismus and dyspareunia. Patients follow a course of treatment during which time they introduce a selection of different sized dilators into the vagina. Treatment may continue until the patient is happily able to participate in full sexual intercourse. Vaginismus : Vaginismus is the involuntary spasm of the muscles in the vaginal wall which makes penetration for sexual intercourse either impossible or extremely painful. The condition can be induced by the following factors : psychological induced (most often as a result of childhood sexual abuse, rape or fear of sexual intercourse).the result of gynaecological surgery. Due to an anatomical anomaly. Dyspareunia : Dyspareunia is pain experienced during penetration and sexual intercourse. Often it is caused by a physical problem but may also be attributable to psychological problems. If left untreated, it may lead to vaginismus.	The Amielle comfort device is designed to assist in the care of women undergoing treatment within the fields of gynaecology, obstetrics, oncology and radiotherapy and those receiving sex therapy for the treatment of vaginismus and dyspareunia. Sexual dysfunction is common in women undergoing treatment in the vaginal area. In addition to the physical effects of such treatment, patient fears about resuming sexual activity may lead to psychological problems. Amielle comfort is intended to be used for self treatment for painful sexual intercourse and post vaginal surgery. A full set of Amielle comfort comprises of 4 white, smooth, hollow penile shaped cones, which are graduated in size and length, and a universal twist and lock handle to aid manipulation of the cones, and a tube of water-soluble lubricating jelly to enable easier insertion.	Class A, Rule 5	

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		Dyspareunia can be caused by the following factors : congenital vaginal deformities. Vaginal infections such as herpes, thrush or vaginitis, which could progress to inflammatory disease. Hormone abnormalities caused by menopause or endometriosis. Allergic reactions such as to contraceptives or the partner's sperm. Traumatic sexual experiences. Insufficient vaginal lubrication due to lack of stimulation during intercourse. The estimated population of vaginismus sufferers; approximately 0.17' % of women aged 75 to 64 years in the UK.			
8	Silagum comfort soft relining	Silagum-Comfort Soft Relining: Relining material for total, partial and implant-supported detures. Silagum-Comfort Soft Relining Primer: Bonding between standard PMMA based prothesis materials and Silagum Comfort Soft Relining. Silagum-Comfort Soft Relining Varnish: Post-processin of	Reline material.	Class A, Rule 5	

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		a prothesis relined with Silagum-Comfort.			
9	Bepanthen Itch Relief Cream	Bepanthen™ Itch Relief Cream is intended to relieve itch and redness caused by dry skin or atopic dermatitis (atopic eczema). Bepanthen™ Itch Relief Cream can be applied, several times a day, as needed on affected irritated non wounded skin. Bepanthen™ Itch Relief Cream is cortisone-free.	Bepanthen™ Itch Relief Cream is a white cream which with its cortisone free formula combines soothing of itch and regeneration of the skin barrier, helping your skin to heal diminishing the feeling to scratch.	Class B, Rule 1	
10	Oxygen hood	The Oxygen Hood ranges are all non-powered infant oxygen hoods. These devices are intended to be placed over the head of a neonate lying in the supine or prone position. They may be used within a cot, incubator, or overhead warming environment. They are used for the delivery of supplementary oxygen for neonates with lung disease. They may be used by neonates of all weights.	Manufactured from transparent acrylic, reusable oxygen hoods provide all round visibility of the patient. The edges of these oxygen hoods are hand polished for smoothness and aid effective cleaning. 1. Two side silicone window to access procedures easily. 2. Silicon rubber neck port adjustment to minimize the wastage of oxygen. 3. Silicon rubber neck port adjustment ensures can be used neonate/infant/pediatric patients. 4. Oxygen inlet port. 5. Optimal oxygen concentration and temperature control.	Class B, Rule 2	

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11	eVu TPS	The device is self regulation tool that commonly use in health physicians and specialists to encourage users to increase their relaxation response as they follow a breath pacer	A compact and light-weight portable sensor applied to a single finger, the device senses skin conductance, skin temperature, and heart rate. Patient/ subject can either follow the user-customizable breath pacer for relaxation, or other exercises provided by their health practitioner. Feedback provided (graphical, music and reward points) encouraging users to increase their relaxation response as they follow a breath pacer.	Class B, Rule 10(i)	Monitoring of vital physiological processes.
12	Central monitoring system	Monitoring multiple bedside devices at each patient in critical departments. Information collected will be broadcasted at nurse station in order caergiver can be responsed to the patient immediately when necessarily.	Central monitoring system software (CMS) is the medical information device that will be used in the clinical environment. CMS can be used in multiple networked monitors. CMS is responsible for collecting processed information from multiple bedside monitors.	Class C, Rule 10(i)	Monitoring of vital physiological processes.
13	KARL STORZ HOOK	The KARL STORZ hook is intended to distend the examination and operating field as well as to hold open and hold back tissue during surgical interventions in ENT medicine. The hook is designed for transient use in surgically invasive interventions.	The KARL STORZ hook is a reusable surgically invasive medical device, with differently shaped blunt or sharp surfaces that are equipped at one or both ends.	Class A, Rule 6	

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14	UW2000 Underwater chest drainage system	The UW2000 Underwater Chest Drainage System is intended to drain and temporarily store fluids drained from the thoracic space. It is a non-invasive device and connected to any type of inserted chest catheter. Drainage is by means of either gravity or by connecting the device to wall suction in the medical facility.	The UW2000 Underwater Chest Drainage System is a bottle and set of tubes that is used for the purpose of draining and temporary storing fluids during chest drainage procedure.The UW2000 Underwater Chest Drainage System is a common item, widely used by hospital to drain and temporarily store fluids drained from the thoracic space. It is a non-invasive device and connected to any type of inserted chest catheter. Drainage is by means of either gravity or by connecting to vacuum source. Adding water into the UW2000 Underwater Chest Drainage System will create a water seal, which prevents air form reentering into the pleural space, which is crucial during treatment for pneumothorax.	Class A, Rule 4	Non-invasive device and connected to any type of inserted chest catheter.
15	Disposable uterine sound	The device is use to measure the uterine cavity depth for accurate fundal placement of Intrauterine Contraceptive Device.	Disposable Uterine Sound (Gynaecology Instrument) is intended for probing a woman's uterus through the cervix, to approximately determine the depth of woman’s uterus. Uterine Sound is made up of Food contact grade High Density Polyethylene and is pack in individual gamma sterilised tyvek pouch with life spent of 5 years.	Class A, Rule 5	

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16	Throat spray	Keep throat mucous moist, to form a physical barrier between the mucous and the environment with a moist film and prevent microbial penetration. Silver ion is associated with significant microbial burden reduction.	Throat Spray is an antimicrobial barrier medical device with silver content.	Class B, Rule 5	Contains active ingredients.
17	Pipette	Pipette is meant for uterine diagnostic use. The device is used for obtaining differentiated endometrial tissue sample in an outpatient setting. The sample is used for a histological and cyotological diagnosis. Curette for curettage and evacuation of the endometrial contents during induced termination of pregnancy or after miscarriage or as a curative measure in cases of dysmenorrhea.	Pipette is a sterile, disposable sampling device. It consist of a 23.5cm long clear flexible tube with a 3.1mm od and an inside piston rod.	Class B, Rule 5	
18	Bacteria filter	Filter out any dirt or bacteria in the water for dialysis use. This filter will only be used if there is bypass in the reverse osmosis system and the filter will be changed immediately.	A single use device which is suitable for the filtration of liquid (e.g. water).	Class B, Rule 3	
19	Saline gel	The nasogel is a saline based water soluble gel. Saline nasal solution intended for moisturize, clear, clean, rinsing Nasal passage. Nasogel is either delivered in a spray or gel format.	Nasogel Spray is a drug-free saline based water-soluble nasal gel spray formulated with sodium hyaluronate to provide nasal moisture. NasoGEL provides moisture to hydrate and lubricate dry and irritated nasal passages	Class B, Rule 5	

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			caused by dry climate and indoor heat. It helps reduce nasal dryness experienced during air travel, oxygen & CPAP use, as well as dryness symptoms caused by atrophic rhinitis, post radiation therapy and sinus surgery.		
20	HEINE mini 3000 ophthalmoscope	HEINE mini 3000 ophthalmoscope is intended for transient examination of the media (cornea, aqueous humour, lens, vitreous humour) and retina of the eye. The instruments feature an optical examination system and an illumination unit powered by a battery or rechargeable battery. The product may only be used by qualified medical professionals and in professional healthcare facilities.	HEINE mini 3000 ophthalmoscope is intended for transient examination of the media (cornea, aqueous humour, lens, vitreous humour) and retina of the eye. The instruments feature an optical examination system and an illumination unit powered by a battery or rechargeable battery. The product may only be used by qualified medical professionals and in professional healthcare facilities.	Class A, Rule 12	
21	Kitazato IUI catheter	The kitazato IUI catheter is a sterile, single-use catheter for the infusion of washed spermatozoa into the uterine cavity. The catheter is made up of the shaft and the connector. The connector can be connected to a syringe. Washed spermatozoa are inhaled through tip of the shaft of the catheter connected to the syringe. During the injection procedure of the spermatozoa into the uterus, the shaft of catheter is introduced into the uterine cavity through the cervix, and	The kitazato IUI catheter is a sterile, single-use catheter for the infusion of washed spermatozoa into the uterine cavity. The catheter is made up of the shaft and the connector. The connector can be connected to a syringe. Washed spermatozoa are inhaled through tip of the shaft of the catheter connected to the syringe. During the injection procedure of the spermatozoa into the uterus, the shaft of catheter is introduced into the uterine cavity through the cervix, and then spermatozoa are infused into the uterine cavity.	Class A, Rule 6	

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		then spermatozoa are infused into the uterine cavity.			
22	UI Cube-electromagnetic stimulator	The UI CUBE is an electrically powered device intended for medical purposes that repeatedly contracts muscles by passing electrical currents through electrodes non-contacting the affected body area. And, in addition, the electro-magnetic stimulator is intended to provide entirely non-invasive electromagnetic stimulation of pelvic floor musculature for the purpose of rehabilitation of weak pelvic muscles and restoration of neuromuscular control for the treatment of urinary incontinence in human.	The UI CUBE is intended to help relieve the patient's muscular pain and suppress urination such as urinary incontinence has the function of magnetic stimulation. This UI CUBE consists of the Main Body for magnetic stimulation. The function of magnetic stimulation is operated with the parameter such as Strength Mode. These parameter cab be controlled by users on the LED Touch Panel.	Class B, Rule 9(i)	
23	MiPlatform	MiPlatform is an internet-based image management system intended to be used by trained professionals including but not limited to physicians, nurses and medical technicians. Retrieving and viewing Radiological Dicom images such at CT Scans, MRIs, X-rays , ultra sounds and writing radiological reports by radiologists.	Medical Image Management & Reporting Software for Radiologists and clinical use.	Class A, Rule 4	This device use for Retrieving and viewing only, not for treatment and diagnosis.

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24	Richard wolf exploring probe with flexible tip	The exploring probes are used for palpating tissue. The use of the products is excluded on the central circulatory system or nervous system.	The exploring probes are used for palpating tissue. The use of the products is excluded on the central circulatory system or nervous system.	Class A, Rule 6	Intended use mention the use of the products excluded on the central circulatory system or nervous system.
25	HORIZON 6FA Regen Lab	General purpose laboratory centrifuge, intended for the density based separation of fluids through centripetal acceleration.	HORIZON 6FA RegenLab is a versatile line of centrifuges designed with 3 settings preprogrammed with the most convenient settings for ease of use. The cycle settings can be changed to accommodate custom settings. This general-purpose laboratory centrifuge may also be used to spin approved containers with biologics, chemicals (non-flammable, non-explosive, non-volatile, and non-highly reactive), and environmental samples.	Class A, Rule 5 (IVD)	
26	ACTIVHEAL® PHMB foam silicone border	The PHMB Silicone Wound Dressings are intended for use by healthcare professionals for the treatment of moderate to heavily exuding chronic and acute wounds that are infected or at the risk of infection. The dressings are for use during the healing process.	Activheal Silicone PHMB Foam Wound Dressing is a sterile wound dressing, which provides a moist wound healing environment. This absorbent dressing is designed for moderately to heavily exuding wounds. The soft flexible nature of the dressing allows it to conform easily. It contains the substance polyhexamethylene biguanide and provides a barrier to bacterial penetration through the dressing and prevents colonization and proliferation of bacteria within the dressing while in use for up to 7 days.	Class C, Rule 1	

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27	Icy Spray	Easi Cool Icy Spray intended for used as a first aid measure for muscle injuries. For relieving muscle aches and sprains	Easi Cool Icy Spray gives an instant blast of cooling sensation to relieve pain. It is ideal for sport first aid treatment. Spray around injuries such as sprains and aches. Easi Cool Icy Sprayl can be applied immediately after the sports injuries.	Class A, Rule 4	
28	Xtra Icy Spray	Easi Cool Xtra Spray is intended for use as a first aid measure for muscle injuries. For relieving muscle aches and sprains.	Easi Cool Xtra Spray gives an instant blast of cooling sensation to relieve pain. It is ideal for sport first aid treatment. Spray around injuries such as sprains and aches, Easi Cool Xtra Icy Spray can be applied immediately after sports injuries.	Class A, Rule 4	
29	CPR Bags disposable (CPR 2)	Provides emergency respiratory support by means of a face mask or a tube inserted into a patient airway.	Provides emergency respiratory support by means of a face mask or a tube inserted into a patient airway.	Class B, Rule 2	Connected to active device (oxygen tank).
30	PHANTASEE soft contact lens	Maxvue visions soft contact lenses for daily wear are indicated for the corrections of visual acuity in aphakic and not aphakic person with non-diseased eyes with myopia or hyperopia. The lens may be worn by persons who exhibit refractive astigmatism of 0.50 diopters or less where the astigmatism does not interfere with visual acuity. The lens is also used to enhance or alter the apparent colour of the eye. Eye care practitioners may prescribe the above lenses for frequent/planned	Maxvue Vision Sdn Bhd's soft contact lenses are hemispherical shells with moulded spherical base curves and lathe-cut front surfaces. The lenses are fabricated from a non-ionic polymer. The non-ionic lens material is a hydrophilic polymer of 2-hydroxyethyl methacrylate (2-hema) and cross-linked with crosslinking agent. The lenses are immersed in normal buffered saline solution.	Class C, Rule 5	

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		replacement wear, with cleaning disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be disinfected using a chemical disinfecting system.			
31	Neonatal PICC	Nutriline, Nutriline Twinflo and Premicath are PICC catheters for premature babies or neonates.	Nutriline, Nutriline Twinflo and Premicath are polyurethane PICC (peripherally inserted central catheter) used for short-term infusion (< 30 days) of total parenteral nutrition (TPN) or intravenous medications in premature babies and in neonates. Insertion sites are peripheral veins (basilic, cephalic, saphena...). • Premicath are 1Fr single-lumen catheters used for catheterization of very low weight premature babies or neonates • Nutriline are 2Fr, 3Fr or 4Fr single-lumen catheters for catheterization of premature babies or neonates. • Nutriline Twinflo are 2Fr double-lumen catheters, particularly recommended for administration of incompatible drugs.	Class D, Rule 7	
32	Jaw physiology evaluation system	The Tech in MotionTM hardware is an accessory for use with the TWIMTM medical software device to record and analyse mandibular kinematics to aid in the diagnosis, characterisation and therapeutic planning of occlusal patterns.	Medical device consists in a software medical device Twin in MotionTM (TWIM) intended to record and analyse mandibular kinematics to help diagnosis, characterization, and therapeutic planning of occlusion patterns. It presents several modules and a cloud service. And accessories hardware for use with the	Class A, Rule 12	

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			TWIMTM medical software device to record and analyse mandibular kinematics to aid in the diagnosis, characterisation and therapeutic planning of occlusal patterns. This hardware has several components: Opeartional cart (camera IR emission, touchscreen PC, An articulated mechanical structure with 4 wheels, Power management devices: power supply (PoE) and insulation transformer, Cables (RJ45 cables, power cables)) – Patient kit (Frontal tracker TIARA, Mandibular tracker support FORK, Mandibular tracker SMILI'IT, A pen tracker TALLY used by the dentist to acquire trackers positions, infrared reflection detected by the camera then transferred to the software, Reflective markers NAVEX).		
33	Activascrew	Devices of ActivaScrew™ are intended to be used by orthopaedic surgeons in hospitals. The devices of ActivaScrew™ are indicated for fixation of bone fractures, osteotomies, arthrodeses, bone grafts and osteochondral fractures in the presence of appropriate immobilization.	This design dossier covers the product group of non-cannulated and cannulated fully and partially threaded ActivaScrew™ ActivaScrew™ is available as fully threaded in different sizes, diameters 2.0, 2.7, 3.5 and 4.5 mm and lengths 12 - 90 mm. ActivaScrew™ Cannulated are available as fully and partially threaded, in different sizes, diameters 3.5, 4.0 and 4.5 mm and lengths 20 - 90 mm. The devices of ActivaScrew™ are bioabsorbable screws indicated for fixation of bone fractures, osteotomies, arthrodeses,	Class D, Rule 8	

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			bone grafts and osteochondral fractures in the presence of appropriate immobilization. The ActivaScrew™ includes ActivaScrew™ ActivaScrew™ Cannulated and ActivaScrew™ Cannulated LAG. ActivaScrew™ is available fully threaded in different sizes, diameters 2.0, 2.7, 3.5 and 4.5mm and lengths 12 - 90 mm. The screws are delivered with the disposable metallic INSERTION ADAPTERS with AO/ASIF-compatible socket.		
34	Isorapid spray	Isorapid Spray is an aldehyde-free, ready-to-use surface disinfectant based on alcohols for the rapid spray and wipe disinfection and cleaning of non-invasive medical devices such as operating tables, gurneys, IV poles, and dental chairs. The low alcohol content of less than 50% reduces the potential for allergies or irritation whilst simultaneously increasing material compatibility. Isorapid Spray is fragranced with a fresh, floral perfume.	Ready-to-use disinfectant for the rapid disinfection and cleaning of non-invasive medical devices.	Class B, Rule 15	Disinfection of non-invasive.
35	Pulmonary function filter	The filter series is indicated for use in prevention of contamination of pulmonary function testing equipment and associated valves and hoses by aerosols and particulates which may be	The pulmonary function filter is a filtering device that connects the subject to the spirometer. The gas exhaled by the patient passes through the respiratory filter,and bacteria, viruses and other pathogens are	Class A, Rule 2	Not connected to active device.

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		present in a patient's exhaled gas volumes.	adsorbed in the filter, which can prevent the patient from cross-infecting, protect the instrument from damage, prolong the life, and reduce the frequency of cleaning and maintenance.		
36	Etest® antimicrobial susceptibility	Etest® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram negative and Gram positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation.	ETEST® is a manual, quantitative technique for the determination of antimicrobial susceptibility of non-fastidious Gram negative and Gram positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation.	Class C, Rule 3 (IVD)	
37	Peripheral inserted central venous catheter kit	The Kimal Peripherally Inserted Central Catheter Kit (PICC) are single use devices indicated for use in attaining peripheral access to the central venous for the purpose of: • Administration of vasoactive/inotropic drugs • Administration of incompatible medications • Administration of hypertonic solutions including total parental nutrition and blood transfusion	The Kimal Peripherally Inserted Central Catheter Kit (PICC) are single use devices for adult and paediatric use, indicated for attaining peripheral access to the central venous system and are only to be used by trained doctors or healthcare personnel. The adult catheter range includes catheters that resist high injection pressure. It is radiopaque and made from polyurethane. The catheter tube can be single, dual, or multi-lumen. Pressure resistant catheters (identified by	Class D, Rule 8	

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		• Frequent blood sampling • Powerful injection of contrast media (for pressure PICC's only).	purple colour) and indicated also for powerful injection.		
38	Disposable cytology brushes	This device is intended to be used with a flexible endoscope to aid physicians in collecting tissues from a patient for histologic examination.	This Device is used to collect tissues from patient for examination.	Class B, Rule 5	Invasive medical devices with respect to body orifices that are intended to be connected to an active medical device in Class B or a higher class, are in Class B.
39	INVISALIGN RETAINER SYSTEM	The Vivera Retainer System is indicated for maintaining and preventing movement of a patient's dentition.	The Vivera Retainers consists of a series of doctor prescribed, thin, clear, plastic removable orthodontic retainers that maintain and prevent movement of a patient's dentition.	Class B, Rule 5	For long- term use in the oral cavity.

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40	Refrigerator with freezer	The device is to preserving the pharmaceuticals, the vaccines, and the insulin or reagents.	The device is painted steel exterior, user friendly design and have alarm function. The temperature for refrigerator is 2-8oC; freezer is -20 - -40oC.	Class A, Rule 5 (IVD)	The intended use (The equipment serves for preserving the pharmaceuticals, the vaccines, and the insulin, culture products, reagents.), falls under IVD category.
41	BD DIFCO vibrio cholerae antisera	BD DIFCO vibrio cholerae antisera are recommended for use in slide agglutination tests for the identification and serotyping of vibrio cholerae.	BD DIFCO vibrio cholerae antisera are lyophilized, polyclonal rabbit antisera containing approximately 0.2% sodium azide as a preservative. BD DIFCO vibrio cholerae antiserum ogawa and BD DIFCO vibrio cholerae antiserum inaba are monospecific absorbed antisera.	Class C, Rule 3 (IVD)	

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42	Prolactin and its calibrator	The CL-series PRL assay is a Chemiluminescent Immunoassay (CLIA) for the quantitative determination of prolactin (PRL) in human serum or plasma. The determination of prolactin is to be used as an aid in the diagnosis of male and female infertility and pituitary dysfunction, monitoring of male and female gonadal disorders and management of amenorrhea and galactorrhea. Mindray Prolactin Calibrators (PRL CAL) are intended to calibrate the quantitative prolactin (PRL) assay on Mindray CL-series Chemiluminescence Immunoassay Analyzer.	Prolactin (PRL) is a single chain polypeptide that is secreted by anterior pituitary cells, with a molecular weight of approximately 22,550 daltons. The major physiological function of prolactin is the initiation and maintenance of lactation in women. The secretion of prolactin is in a pulsed-wave mode. It reaches a secretion peak after falling asleep and maintains a high level during the sleep, while falls down when waken up.The normal levels of prolactin in healthy individuals are 5-25 ng/mL in women, while 1-20 ng/mL in men.3 Highly elevated level of prolactin is called hyperprolactinemia, a dysfunction of the system consisted of hypothalamus, pituitary gland and gonads. The major symptoms of hyperprolactinemia are galactorrhea, spano-menstruation or even amenorrhea in women, and also impotence, infertility in men. The quantitation of prolactin levels is of interest in evaluation and management of patients with hyperprolactinemia, such as galactorrhea and menorrhea. Various factors have been found to influence prolactin levels, such as severe physical activities, stimulations, drugs that interfere the metabolism or activities of dopamine, such as	Class B, Rule 6 (IVD)	

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			reserpine. In addition, constitutional deterioration of function of thyroid gland, renal failure can also increase prolaction levels. Mindray CL measurement system is composed of Mindray CL-series Chemiluminescence Immunoassay Analyzer, Mindray reagent kits, calibrators, and controls. Prolactin Calibrators contain prolactin (PRL) analyte. The mathematical relationship between the measured responses and the known analyte concentration establishes the calibration curve. It is used to convert Relative Light Units (RLUs) measured from samples to quantitative analyte concentration.		
43	TearCheck	Tearcheck is intended for Dry Eye Symptom examination.	TearCheck is an Active device intended for examination of dry eye syndrome caused by a deficiency in the lipid layer of the lachrymal film.	Class A, Rule 12	
44	Oxygen tubing	It is used to deliver supplemental oxygen to a patient or person in need of extra oxygen by oxygen mask . it is connected to an oxygen tank, a	It is used to deliver supplemental oxygen to a patient or person in need of extra oxygen by oxygen mask . it is connected to an oxygen tank, a portable oxygen generator, or a wall	Class B, Rule 2	This device connected to active device.

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		portable oxygen generator, or a wall connection in a hospital via a flowmeter. The oxygen flow from the tube.	connection in a hospital via a flowmeter. The oxygen flow from the tube.		
45	Movable swimming pool floor	To create the optimal exercise environment for the patient in aquatic rehabilitation.	In aquatic rehabilitation, a therapist should create the optimal exercise environment for the patient, water depth being one of the most important variables. This is why EWAC have created a movable swimming pool floor that is specially developed for medical applications. The pool design having unprecedented water permeability, movable pool floor offers the very best hygienic performance in the market. Very important with vulnerable patients.	Class A, Rule 4	This device is specially developed for medical applications.
46	VACUCLAVE 550	The steam sterilizer is mainly intended for use in the medical field, e.g. in physician and dental practices. The steam sterilizer is a small steam sterilizer according to EN 13060 and works with the fractionated vacuum method, which ensures effective steam penetration of the load with saturated steam. It is suitable for reprocessing instruments and materials that may come into contact with blood or body fluids during treatment. The steam sterilizer is not intended for use on patients or in the patient's	The steam sterilizer is a small steam sterilizer according to EN 13060 and works with the fractionated vacuum method, which ensures effective steam penetration of the load with saturated steam.	Class C, Rule 15	

NO	DEVICE NAME	DEVICE INTENDED USE*	DESCRIPTION OF MEDICAL DEVICE*	DECISION FROM COMMITTEE	REMARKS
		environment and is not intended for the sterilization of liquids.			
47	Balloon inflation device	Balloon inflation device is used in cardiovascular interventional operation and connected with balloon catheter. The balloon on the catheter can be accurately expanded and contracted by controlling the pressure value displayed on pressure gauge.	Balloon inflation device is used together with a balloon catheter for cardiovascular interventional surgery. Operate the balloon pressure pump to expand the balloon of the balloon catheter for a vascular dilation effect or stent implantation.	Class A, Rule 2	
48	ISEA spray	ISEA Nasal Spray can be useful in case of daily nasal hygiene, nasal congestion, dry, prolonged exposure to hot or air-conditioned environments, exposure to dust or smog. The presence of dexpanthenol makes ISEA spray particularly suitable for cases of sensitive and/or irritated nasal mucosa (as in common colds, allergic rhinitis, etc.).	ISEA nasal spray is an isotonic solution with Dead Sea salts and Dexpanthenol. It as well as being indicated for daily nasal hygiene, nasal congestion and colds, is particularly useful in case of dry sinuses.	Class B, Rule 5	Nasal solution sprays intended to penetrate, hydrate the nasal passages and sinus cavity for preventive or symptomatic nasal care are Class B.
49	DPP® Micro reader	The DPP® Micro Reader is a medical device used quantification, semi-quantification or qualification of test-line intensity. The device uses a camera to obtain a picture of the test strip and then analyses the line intensities to display a clear test result to the user.	The DPP® Micro Reader is a medical device used quantification, semi-quantification or qualification of test-line intensity. The device uses a camera to obtain a picture of the test strip and then analyses the line intensities to display a clear test result to the user.	Class A, Rule 5 (IVD)	Instruments specifically intended by the manufacturer for in vitro diagnostic procedures. These instruments are classified as class A, whereas reagents and kits

NO	DEVICE NAME	DEVICE INTENDED USE*	DESCRIPTION OF MEDICAL DEVICE*	DECISION FROM COMMITTEE	REMARKS
					are classified in their own right.
50	croBEE 2.0 Nucleic Acid Extraction System	Device is intended for automated simultaneous nucleic acid extraction from a wide range of biological material. The instument is intended for molecular biology applications. This product is not intended for the diagnosis, prevention, or treatment of a disease. The intended user is trained staff or clinical laboratories. The croBEE 2.0 Nucleic Acid Extraction System is automated extracted instrument. The product is intended to be used in combination with myCROBE/croBEE 2.0 Universal Extraction Kit for human, fungi, bacterial and viral nucleic acids extraction from wide-range of biological materials.	An automated simultaneous nucleic acid extraction instrument, intended for molecular biology applications, used for DNA/RNA extraction from a wide range of biological materials.	Class A, Rule 5 (IVD)	Instruments specifically intended by the manufacturer for in vitro diagnostic procedures. These instruments are classified as class A, whereas reagents and kits are classified in their own right.

NO	DEVICE NAME	DEVICE INTENDED USE*	DESCRIPTION OF MEDICAL DEVICE*	DECISION FROM COMMITTEE	REMARKS
51	NextSeq 550Dx Instrument	The NextSeq 550Dx instrument is intended for sequencing of DNA libraries when used with in vitro diagnostic assays. The NextSeq 550Dx instrument is to be used with specific registered, certified, or approved in vitro diagnostic reagents and analytical software.	The NextSeq 550Dx instrument is intended for sequencing of DNA libraries when used with in vitro diagnostic assays performed on the instrument. The NextSeq 550Dx instrument is to be used with specific registered, certified or approved in vitro diagnostic reagents and analytical software. The instrument includes a dual boot configuration to enable the use of the instrument in either diagnostic (Dx) or research use only (RUO) mode. In vitro diagnostic sequencing assays, including the Germline and Somatic Variant Modules, are executed in diagnostic mode. Only IVD sequencing reagents can be utilized in diagnostic mode.	Class A, Rule 5 (IVD)	Instruments specifically intended by the manufacturer for in vitro diagnostic procedures. These instruments are classified as class A, whereas reagents and kits are classified in their own right.
52	Suction Tube	Suction tube is attached to a suction system, is used for the evacuation of blood, fluids & other tissue debris from the surgical site during a general or plastic surgical procedure.	Made of stainless steel with round and depressive holes.	Class B, Rule 5	Connected to an active medical device.

NO	DEVICE NAME	DEVICE INTENDED USE*	DESCRIPTION OF MEDICAL DEVICE*	DECISION FROM COMMITTEE	REMARKS
53	BREATH-O Correct	The Breath-O Correct is indicated for overnight wear for myopia and myopic astigmatism. It reshapes the cornea and provides improved vision after removing lenses.	Orthokeratology is defined as a vision correction method in which patients wear lenses thereby reshaping the cornea to improve uncorrected vision after they remove the lenses. Breath-O Correct is a lens of which the inside is designed in special shapes and is a high gas permeable hard contact lens for treatment of orthokeratology that is worn to reshape the cornea thereby providing refractivity with high predictability. The intended use of this lens is that patients repeatedly wear the lens while asleep thereby stabilizing the reshaping of the cornea to improve and maintain uncorrected vision during the day after they remove the lenses. Breath-O Correct comprises a special internal shape consisting of four curves. The central portion of the lens has a special structure. By wearing Breath-O Correct overnight, if flattens the anterior surface of the cornea to temporary improve unaided vision.	Class C, Rule 5	This device intended to be use continuously up to 30 days.
54	Implant Studio	Implant Studio® is indicated for use as a medical front-end software that can be used by medically trained professionals for the purpose of visualizing gray value images.It is intended for use as a pre-operative planning software for the placement of dental implant(s) based on imported CT image data, optionally aligned to an	Implant Studio is used as medical front-end software that can be used by medically trained professionals for the purpose of visualizing gray value images.	Class B, Rule 10(i)	Intended for diagnosis.

NO	DEVICE NAME	DEVICE INTENDED USE*	DESCRIPTION OF MEDICAL DEVICE*	DECISION FROM COMMITTEE	REMARKS
		optical 3D surface scan. Virtual Crowns can be used for optimized implant positioning under the prosthetic aspect. The digital three-dimensional model of a surgical guide for guided surgery can be designed based on the approved implant position. This 3D data can be exported to manufacture a separate physical product.			
55	CORTISOL (CLIA)	Cortisol (CLIA): The CL-series Cortisol assay is a Chemiluminescent Immunoassay (CLIA) for the quantitative determination of Cortisol in human serum, plasma or urine. Measurements of cortisol are used in the diagnosis and treatment of adrenal gland related diseases. Cortisol Calibrators: Mindray Cortisol Calibrators (Cortisol CAL) are intended to calibrate the quantitative Cortisol assay on Mindray CL-series Chemiluminescence Immunoassay Analyzer. Mindray Immunoassay Multi Control is used for quality control by monitoring the accuracy and precision of Mindray CL-series Chemiluminescence Immunoassay Analyzer and test ability	These devices, Cortisol (CLIA) and Cortisol Calibrators are used in combination, Cortisol (CLIA) is used for the quantitative determination of Cortisol in human serum , urine or plasma, Cortisol Calibrators is used for calibration. They function together for quantitative determination of the same analyte as a whole measurement system. Mindray CL measurement system is composed of Mindray CL series Chemiluminescence Immunoassay Analyzer, Mindray reagent kits, calibrators, and controls. Mindray Immunoassay Multi control can be used to check whether QC result is within specified range or not. It is used with Mindray chemiluminescent immunoassays, including Insulin (CLIA), C-Peptide (CLIA), Dehydroepiandrosterone sulfate (CLIA), Cortisol (CLIA).	Class B, Rule 6 (IVD)	Intended use (for "determination/measurement for diagnosis").

NO	DEVICE NAME	DEVICE INTENDED USE*	DESCRIPTION OF MEDICAL DEVICE*	DECISION FROM COMMITTEE	REMARKS
		of clinical laboratory in the quantitative measurement of Immunoassay Multi analytes.			
56	Pulmonary function test filter	Act as mouthpieces & bacterial filter to prevent bacterial go into the spirometry lung function machine.	Pulmonary function test filter also known as pulmonary function testing (PFT) filter acts as a barrier to viral and bacterial cross-contamination. The electrostatic cotton (pall filter membrane) that do not promote the growth of mold, mildew, other fungi or bacteria.	Class B, Rule 2	Connected to an active medical device.
57	Lubricating jelly	X-Y Lubricating Jelly is a personal lubricant, for vaginal/or penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane	Material : Gel. -Non-greasy, Water soluble Odourless. Weight : 35gm and 100gm. Ingredients : Water, Glycerin, Hydroxyethylcellulose, Methylparaben. Warning : If irritation or discomfort occurs, discontinue use immediately and consult a doctor. This is not a contraceptive or spermicide. If you are pregnant or nursing, consult a doctor before use. Keep out of	Class B, Rule 5	Intended for short-term use.

NO	DEVICE NAME	DEVICE INTENDED USE*	DESCRIPTION OF MEDICAL DEVICE*	DECISION FROM COMMITTEE	REMARKS
		condoms. Directions : Apply desired amount to genitals, reapply as needed or desired.	children. Product is very slippery, clean spills immediately. Storage : Please store in a cool dry place, away from direct sunlight.		
58	FUJIFILM medical dry laser imager DRYPIX edge	Fuji Medical Dry Laser Imager DRYPIX EDGE (DRYPIX 8000) is a device that prints digital image data transferred via the DICOM network from the FCR/FDR Image Reader or DR, CT, MRI and other imaging modalities onto the Fuji Medical Dry Laser Image Film.	Fuji Medical Dry Laser Imager DRYPIX EDGE (DRYPIX 8000) is a device that prints digital image data transferred via the DICOM network from the FCR/FDR Image Reader or DR, CT, MRI and other imaging modalities onto the Fuji Medical Dry Laser Image Film.	Class A, Rule 12	
59	MONOFLUO™ PNEUMOCYSTIS JIROVECII (P. CARINII) IFA test kit	THE MONOFLUO™ PNEUMOCYSTIS IMMUNOFLUORESCENT ANTIBODY test kit is to be used for the detection of pneumocystis JIROVECII (P. CARINII) cysts and trophozoites in specimens collected from the respiratory tract.	THE MONOFLUO PNEUMOCYSTIS IMMUNOFLUORESCENT ANTIBODY test kit is to be used for the detection of pneumocystis JIROVECII (P.CARINII) cysts and trophozoites in specimens collected from the respiratory tract. The use of a direct, fluorescent-antibody procedure with induced sputum, bronchial wash or bronchoalveolar lavage samples provides a simple, highly-specific procedure for detection of pneumocystis JIROVECII. The murine monoclonal antibodies are chemically linked to fluorescein isothiocyanate conjugated (FITC) to produce a highly specific, direct, immunofluorescent reagent with a low level background fluorescence. In addition to binding with pneumocystis JIROVECII cysts, the monoclonal antibodies also bind specifically to pneumocystis JIROVECII trophozoites, sporozoites and the extracellular matrix. When	Class C, Rule 3 (IVD)	

NO	DEVICE NAME	DEVICE INTENDED USE*	DESCRIPTION OF MEDICAL DEVICE*	DECISION FROM COMMITTEE	REMARKS
			viewed with a fluorescence microscope, infected specimens fluoresce bright apple-green.		
60	Retainer	To maintain teeth alignment after completion of the customer's aligner treatment.	Custom made medical Grade/BPA Free thermoformed clear aligner plastic that maintains the user's teeth position based on prescription provided by the dentist.	Class B, Rule 5	IFU duration of use of the retainers is : -First 3 months-everyday, for 18-20 hours a day -Year 1-everyday,for 10-12 hours a day -Year 2-everyday for 8 hours at night -Year 3 & beyond-alternate day for 8 hours at night.

**The product intended use and description are based on the information submitted in the Medical Device Registration application in MeDC@St system.*

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