

DECISION JAWATANKUASA TEKNIKAL PENGGELASAN DAN PENDAFTARAN (JKTPP) YEAR 2024

List of products (Medical device risk classification)

NO	DEVICE NAME	DEVICE INTENDED USE*	DESCRIPTION OF MEDICAL DEVICE *	DECISION FROM COMMITTEE	REMARKS
1	ALLPLEX™ GI-HELMINTH(I)) ASSAY	Allplex™ GI-Helminth(I) Assay is a qualitative in vitro test for the single or multiple detection of Enterocytozoon spp. / Encephalitozoon spp. (EN), Strongyloides spp. (ST), Hymenolepis spp. (HY), Ascaris spp. (AS), Taenia spp. (TA), Trichuris trichiura (TT), Ancylostoma spp. (AN), Enterobius vermicularis (EV) and Necator americanus (NA) in human stool specimens from individuals with symptoms of gastroenteritis or infectious diarrhea.	Multiplex real-time PCR system for detection of Enterocytozoon spp. / Encephalitozoon spp. (EN), Strongyloides spp. (ST), Hymenolepis spp. (HY), Ascaris spp. (AS), Taenia spp. (TA), Trichuris trichiura (TT), Ancylostoma spp. (AN), Enterobius vermicularis (EV) and Necator americanus (NA) in human stool specimens.	Class B, Rule 6 (IVD)	These devices present a moderate individual risk as they are not likely to lead to an erroneous result that would cause death or severe disability, have a major negative impact on patient outcome or put the individual in immediate danger.
2	INFLATION DEVICE	The Inflation device product is intended to help balloon catheter to expand in the intervention operation.	Inflation device is composed of pressure gauge, sleeve, plunger, handle, extension tube and stopcock. Inflation device is single used connect to balloon catheter in the intervention operation.	Class A, Rule 4	The device is non-invasive which do not touch the patient

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3	Iron Stain Kit	The Iron Stain Kit is intended for use in the detection of ferric iron in tissues, blood smears, or bone marrow smears. Ferric iron is normally found in small amounts in bone marrow and the spleen. Abnormally large deposits may be seen in hemochromatosis and hemosiderosis. This product is based on the Prussian Blue reaction in which ionic iron reacts with acid ferrocyanide producing a blue color.	The Iron Stain Kit is intended for use in the detection of ferric iron in tissues, blood smears, or bone marrow smears. Ferric iron is normally found in small amounts in bone marrow and the spleen. Abnormally large deposits may be seen in hemochromatosis and hemosiderosis. This product is based on the Prussian Blue reaction in which ionic iron reacts with acid ferrocyanide producing a blue color.	Class B, Rule 6 (IVD)	This device is specific stain use in the detection of ferric iron in tissues, blood smears, or bone marrow smears
4	NYLON POLISHING BRUSH	For cleaning and polishing natural teeth. For single-use only	Nylon brush fix to metal holder	Class B, Rule 5	All invasive medical devices with respect to body orifices (other than those which are surgically invasive) that are intended to be connected to an active medical device in Class B or a higher class, are in Class B.

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5	DISPOSABLE SUCTION SPONGE SWAB/TOOTHBRUSH	It is used for respiratory suction and oral care of patients in medical institutions to relieve the discomfort of bad breath and sticky saliva in the oral cavity of patients due to bacterial growth.	Disposable Suction Sponge Swab/Toothbrush comes with many different sizes. composed of suction joints, negative pressure controllers, suction tubes, and suction heads. this product is single use overall sensation of relaxation.	Class B, Rule 5	All invasive medical devices with respect to body orifices that are intended to be connected to an active medical device in Class B, are in Class B, rule 5
6	Alternating Bubble Mattress with Adjustable Pump System	Alternating Bubble Mattress with Adjustable Pump System is intended for the treatment and prevention of pressure sore stage in short term and domiciliary therapies	Alternating Bubble Mattress with Adjustable Pump System is designed for the treatment and prevention of pressure sore stage in short term and domiciliary therapies. The PVC mattress is composed of 130 x 70 cm - high bubble cells, which is particularly comfortable. It is fixed to the bed by extra flaps on both top and bottom side. Besides that, it is easy to install, maintain and use due to the function of comfort range adjustment. The pump can be hung to the end of the bed by using 2 hooks provided.	Class A, Rule 12	The intended use is for general use only and not for specific therapeutic claim.
7	VENTANA ANTI-HELICOBACTER PYLORI	VENTANA anti-Helicobacter pylori (SP48) Rabbit Monoclonal Primary Antibody is intended for laboratory	Helicobacter pylori is a gram-negative bacteria that can colonize the human gastric mucosa and cause the	Class B, Rule 6 (IVD)	

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	(SP48) RABBIT MONOCLONAL PRIMARY ANTIBODY	use in the qualitative immunohistochemical detection of Helicobacter pylori by light microscopy in sections of formalin-fixed, paraffin-embedded gastric biopsy tissue stained on a Benchmark IHC/ISH instrument.	development of peptic ulcers and gastritis. Long term infection and irritation by the organism results in a specific humoral immunologic response that is thought to lead to gastric carcinogenesis and gastric lymphoma. VENTANA anti-Helicobacter pylori (SP48) Rabbit Monoclonal Primary Antibody (VENTANA anti-H. pylori (SP48) antibody) may aid in the diagnosis of H. pylori infection in gastric endoscopic biopsies.		
8	Condac 37%	Condac 37% is water-based gel containing Phosphoric acid at 37%, with low viscosity and thixotropic properties. It is blue, which makes it easier to be visualized and controlled during the application. It mixes well with water which allows it to be easily removed after the etching. The content of phosphoric acid (orthophosphoric) allows for each a good chemical treatment of the surface.	Condac 37% is water-based gel containing Phosphoric acid at 37%, with low viscosity and thixotropic properties. It is blue, which makes it easier to be visualized and controlled during the application. It mixes well with water which allows it to be easily removed after the etching. The content of phosphoric acid (orthophosphoric) allows for each a good chemical treatment of the surface.	Class B, Rule 5	

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9	QUIDEL TRIAGE® PLGF SYSTEM	<p>The intended uses for Quidel Triage® PLGF Test, Quidel Triage® PLGF Controls, and Quidel Triage® MeterPro® are described below.</p> <p>The Quidel Triage® PLGF Test is a fluorescence immunoassay to be used with the Quidel Triage Meter for the quantitative determination of Placental Growth Factor (PLGF) in EDTA anticoagulated plasma specimens. The test is used in conjunction with other clinical information as an aid in the diagnosis of preterm pre-eclampsia and as an aid in the prognosis of delivery, in women presenting with signs & symptoms of pre-eclampsia after 20 weeks and prior to 35 weeks of gestation.</p> <p>QuidelTriage® PLGF, Control 1 and Control 2 The Quidel Triage® PLGF Controls are assayed materials to be used with the Quidel Triage® PLGF Test and the Quidel Triage® Meter® to</p>	<p>The Quidel Triage PLGF Test is a single use fluorescence immunoassay to be used with the Quidel Triage Meter for the quantitative determination of Placental Growth Factor (PLGF) in EDTA anti-coagulated plasma specimens.</p> <p>The test procedure involves the addition of several drops of an EDTA anticoagulated plasma specimen to the sample port on the Test Device. After addition of the specimen, the specimen reacts with fluorescent antibody conjugates and flows through the Test Device by capillary action. The presence of a target analyte causes the corresponding fluorescent antibody conjugate to bind to the discrete zone specific to that analyte.</p> <p>The Test Device is inserted into the Quidel Triage Meter (hereafter referred to as Meter). The meter is programmed to automatically perform the analysis after the sample has reacted with the reagents within the Test Device. The analysis is based on the amount of fluorescence the Meter detects within a</p>	Class C, Rule 3 (IVD)	<p>Intended to be used for measure the quantity level of Placental Growth Factor (PLGF).</p> <p>Guidance Document: Class C, Rule 3 To monitor levels of medicines, substances or biological components, when there is a risk that an erroneous result will lead to a patient management decision resulting in an immediate life-threatening situation for the patient</p>

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		<p>assist the end user in monitoring product performance.</p> <p>The Quidel Triage® MeterPro® is a portable fluorescence instrument used to measure the results of tests manufactured by Quidel Cardiovascular, Inc. The Quidel Triage® MeterPro® can be used in a laboratory or in a point-of-care setting.</p>	<p>measurement zone on the Test Device. A lesser amount of fluorescence detected indicates a lower concentration of analyte in the specimen. The results are displayed on the Meter screen in approximately 15 minutes. Results are stored in the Meter memory to display or print when needed. If connected, the Meter can transmit results to the lab or hospital information system.</p>		
10	PARAFFIN GAUZE DRESSING	Ideal for minor burns and wounds with superficial skin loss. It soothes and protects the wound to allow drainage onto a secondary absorbent dressing.	A Paraffin Gauze Dressings is a type of dressing that can be directly placed over minor wounds and burns. It serves as the first layer of protection, and also soothes the injury.	Class A, Rule 1	The device is non-medicated and applied for minor wounds
11	BlancOne® ULTRA+	<p>BlancOne® ULTRA+ is ideal for an in-office treatment of the most problematic intrinsic tooth discolorations, like those caused by pharmacological therapies and whitening of non-vital teeth.</p> <p>BlancOne® ULTRA+ is a medical whitening treatment to be used solely by dental professionals in the dental field.</p>	BlancOne® ULTRA+ is a tooth whitening gel based on 35% hydrogen peroxide and photo accelerators achieving a fast photochemical activation when irradiated by a suitable source of light. Use for medical purpose.	Class B, Rule 9(i)	The device is for treatment.

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12	NOVA LITE RAT LIVER, KIDNEY, STOMACH KIT	Indirect immunofluorescence is the reference method for screening and titration of circulating autoantibodies in human serum. Animal tissue sections, e.g. from rat, are generally preferred over other commonly-used substrates including human tissue sections and cell preparations; this is primarily due to the lack of interference from hla and/or other blood group antibodies. Using three different tissues (liver, kidney and stomach) enables autoantibodies to be more easily identified by comparing the results obtained with each tissue.	This product is intended for use in the screening and titration of circulating autoantibodies in human serum as an aid in the diagnosis and treatment of various autoimmune diseases. The four major autoantibodies detected are antinuclear antibodies (ana), antimitochondrial antibodies (ama), antismooth muscle antibodies (asma) and antigastric parietal cell antibodies (agpca).	Class B, Rule 6 (IVD)	
13	AUTO REFRACTOMETER	This instrument is used to measure the spherical refractive-power, cylindrical refractive power, the direction of astigmatic axis, the radius of curvature, the corneal astigmatic axis angle and the corneal refractory power.	The auto alignment function facilitates to get fine alignment and to start measurement automatically	Class A, Rule 12	Based on the brochure, the device does not provide a diagnosis of any condition or lack thereof or any recommendations for appropriate treatment

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14	PARAFFIN GAUZE DRESSING	Paraffin gauze dressing acts as a primary barrier between the wound and a secondary dressing, allowing wound fluid to pass into the secondary dressing. Suitable for use in the first aid management of minor burns & superficial wounds. It may also be used on minor burns, scalds, leg ulcers, donor and recipient graft sites, lacerations, abrasion, and other skin loss wounds.	Paraffin gauze dressing is a sterile non-medicated, paraffin-impregnated gauze made from open weave gauze. It is soft and the medical grade paraffin soothes and protects the wound. Paraffin gauze dressing is low adherent and has open weave base fabric which allows the wound to drain freely into an absorbent secondary dressing. Paraffin gauze dressing is a non-shedding, non-absorbant dressing and it is semi transparency makes the observation of wound site very easy.	Class B, Rule 1	Based on the CER provided, the aim of a dressing is to promote healing of the wound by providing a sterile, breathable and moist environment that facilitates granulation and epithelialization. This will then reduce the risk of infection, help the wound heal more quickly, and reduce scarring
15	Curacyn Wound & Skin Cleansing	Curacyn Wound & Skin Cleansing is a super-oxidized formulation, is specifically designed for debridement, irrigation, and moistening of acute wounds, ulcers, cuts, abrasions, and burns.	Curacyn Wound & Skin Cleansing is an advanced wound wash, debridement and irrigation solution. It is a super-oxidized, pH-neutral purified water-based solution. It contains reactive oxygen species in a stable formulation, has an extended shelf life and remains harmless to humans, animals and the environment.	Class A, rule 4	If the cleaning solution for instrument- Not Medical Device If the cleaning solution for wound- Medical Device

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16	Kaesar Compressors	The machine is intended solely for generating compressed air	Compressed air for dental Technology	Class A, Rule 12	
17	A-AMYLASE KIT, MULTI CONTROL AND MULTI SERA CALIBRATOR	<p>α-Amylase Kit (IFCC Method): In vitro test for the quantitative determination of α-Amylase (1, 4-α-D-glucanohydrolases) (α-AMY) activity in human serum, plasma or urine on Mindray BS series chemistry analyzers. It is intended to be used for diagnosis and monitoring the therapeutic effect of pancreatitis.</p> <p>ClinChem Multi Control: ClinChem Multi Control is used for quality control of quantitative determination of routine chemistry analytes by monitoring accuracy and precision of Mindray BS series chemistry analyzers and test ability of clinical laboratory.</p> <p>Multi Sera Calibrator: Multi Sera Calibrator is used for calibration of quantitative determination of routine chemistry analytes on</p>	<p>α-Amylases originate from various organs and are mainly produced by the pancreas (P-type) and the salivary glands (S-type). α-Amylases catalyze the hydrolytic degradation of polymeric carbohydrates, such as amylose, amylopectin and glycogen by cleaving 1, 4-α-glucosidic bonds into various fragments. The pancreatic amylase is produced by the pancreas and released into the intestinal tract; the salivary amylase is synthesized in the salivary glands and secreted into saliva. Because of its small molecular weight, the blood amylase is eliminated through the kidney and excreted into urine. Elevation of urine amylase activity reflects the rise of serum amylase activity. Measurement of α-amylase in serum and urine is mainly used for the diagnosis of pancreatic disorders, as well as for detecting the development of complications. Normally the α-amylases present low activity, in acute pancreatitis the blood amylase activity increases</p>	Class B, Rule 6 (IVD)	Amylase detection for pancreatitis

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		Mindray BS series chemistry analyzers.	<p>within 8-12 hours after onset of abdominal pain, peaks after approx. 12-24 hours. The blood amylase activity returns to normal values at the latest after 2-5 days, but the high urine amylase level will still last for 5-7 days.</p> <p>However, various nonpancreatic diseases, e.g. parotitis, renal insufficiency or pulmonary inflammation, can also increase amylase levels. To confirm pancreatic disorders, additional pancreas specific enzyme, lipase or pancreatic-α-amylase, is recommended to be determined at the same time.</p>		
18	FETAL MONITOR (FM-801)	The FM-801 monitor is for use during prenatal care, and for the monitoring of the physiological parameters during parturition. During the monitoring, the fetus activity is explained by fetal heart rate, uterine contraction pressure, and fetal movement.	The FM-801 monitor is made up of a fetal heart rate detector used in processing the signal of fetal heart rate, and a TOCO probe for monitoring the uterine contraction pressure and fetal movement of pregnant women.	Class C, Rule 10(i)	The device is continuously monitoring

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19	CARBIDE, CERAMIC POLISHER BURS	It is used to polish acrylic denture	It can be used with dental handpieces to polish Acrylic dentures and retainer. These devices do not make contact with teeth or patient, the usage is for the dentures.	Class A, Rule 12	The product that has been used for medical device is considered as medical device
20	DENTAL VARNISH	Prevention of tooth decay/treat of tooth hypersensitivity	CharmVarnish is a type of sodium fluoride varnish and it has orange flavor. This convenient disposable package offers easy mix, application and daily life immediately after the treatment. It is applied limited (less than 24 hours) by a dentist, dental hygienist or other health care professional. It is applied to the tooth surface for several minutes. It might be applied to enamel, dentin or cementum of the tooth. It has high concentration of fluoride as a salt and fluoride could help prevent decay, remineralise the tooth surface.	Class B, Rule 5	Treatment of hypersensitive teeth
21	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	The farstar hood is an acrylic, stackable, easy to clean, laboratory tested, neonatal headbox/oxygen hood. It is used for providing an oxygen-enriched environment for neonates with respiratory distress syndrome. The oxygen hood are advanced units with	Class B, Rule 2	May be connected to an active medical device in Class B or higher

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		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.	modern functional design. The device is developed in accordance with the latest standards in medical device industry, they will provide users with years of reliable and trouble free service.		
22	YILMAZ MEDIKAL OVEM STERILE EPIDERMAL SKIN PRICK TEST APPLICATORS	The Yilmaz Medikal Skin Prick Test Applicators are used for allergen applications. Allergen liquids are applied on the skin epidermis when the allergy has not been known accurately but symptoms of clear allergy have been presented. The devices are to be used on people who will take the allergy tests except for pregnant, breastfeeding mothers and babies. The product is intended for professional use only.	The skin prick test applicators are to be used for skin tests. They are made of acrylic polymer that is biocompatible. The product is plastic, thus, the skin is punctured without bleeding and allergen contact is provided under the skin. The applicator/lancet is a sterile, single-use only medical device. Its pins are 2-3 cm from one another. Hence, the mixing of reactions is prevented during each allergic application. The applicator has an absorbent tipped and is sterile. The pricks are thin sticks that are made of flexible metal, wood or synthetic material. An absorbent head is present at one end of the tip that is used to perform the local applications on any surface.	Class B, Rule 6	
23	Operating Room Control System	Modular operating theater drives consistency and smooth flow	Provides better and easier control of the devices in the operating room from a	Class A, Rule 4	This device is only support to the main

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		during operations, reducing the risk while carrying out surgical procedures.	single location. The system is very flexible, open, modular, can be adjusted to comply the client's expectations and requirements, accordingly to the above shown solutions. Can be operated from wall mounted control panel or wirelessly from mobile device.		system which is not main system that control and monitor AGSS.
24	Hyalo4 Silver Spray	Treatment of non infected skin lesions (e.g. abrasions, grazes, cracked skin, cuts, small surgical wounds, localized first and second degree burns), in diabetic foot, athlete's foot and pressure sores.	HYALO4 SILVER SPRAY is a suspension spray for topical use containing hyaluronic acid, metallic silver and vitamin E. The hyaluronic acid and silver are combined in a matrix (kaolin and starch) with absorbent properties. Absorption of the exudate creates an environment that facilitates the natural tissue regenerating process, forming, together with hyaluronic acid and silver, a protective barrier against microbial penetration. The film-forming action of vitamin E, by assisting the reepithelialization process, favours restoration of the optimal skin moistening conditions.	Class B, Rule 1	The device is intended to be used of the is principally with wounds which have breached the dermis.
25	bO2ugie Boussignac	bO2ugie Boussignac are orotracheal guides for difficult intubation with oxygen injection,	Intubation introducers are used in situations where planned or unplanned (e.g. emergency) intubation proves	Class B, Rule 5	The device is connected to active device

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		<p>under the trade name bO2ugie Boussignac. The variety of sizes available covers the morphological requirements of patients ranging from newborn to adult.</p> <p>The bO2ugie Boussignac can be used as follows with endotracheal tubes of different sizes:</p> <ul style="list-style-type: none"> ■ 6-11: product code :5576.01 ■ 4-5.5: product code: 5576.02 ■ 2.5-3.5: product code: 5576.03 <p>The bO2ugie Boussignac has centimetric markings of 10 to 40 cm (product code: 5576.01) and centimetric markings of 1 to 30 cm (product code: 5576.02) and 1 to 20 cm (product code: 5576.03). Information regarding the size of endotracheal tubes to be used is also provided on the device itself. These devices are supplied with an oxygen biconical connector.</p> <p>These devices are sold sterile, in single packaging and for single use only.</p>	<p>difficult and in patients presenting with apnea. The bO2ugie Boussignac is an intubation introducer – an orotracheal guide used to position endotracheal tubes during difficult intubation, primarily for Mallampati or Cormack scores greater than 2. It is used to inject oxygen. In the event of spasm, decompression openings prevent any risk of barotrauma by allowing the oxygen to escape via the main tube.</p>		

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