Decision Jawatankuasa Teknikal Pendaftaran Year 2023 - List of products (Medical device or Non-medical device)

NO	PRODUCT NAME	PRODUCT INTENDED USE*	DESCRIPTION OF PRODUCT*	DECISION FROM COMMITTEE	REMARKS
1	Non-sterile patient clothing	The main intended use of patient clothing is to keep patients warm and comfortable during hospitalization or temporary examination. It can also be worn by patients and other people, which helps to respect the privacy of patients during hospitalization. In some cases, it is simple to protect the wearer from splashes of potentially contaminated liquids and active particles to reduce the risk of infection transmission, especially in the case of epidemics or pandemics.	Patient Clothing is a kind of apparel provides effective prevention of infective agents. It is soft, breathable, comfortable and skin-friendly while maintaining a certain strength. On the basis of certain strength, patient clothing has the character of comfortability.	Non-Medical Device	Does not meet the definition of medical devices.
2	Allergoff® Spray	Allergoff® Spray is designed to protect against harmful impact of allergens present in house dust. It inhibits allergy development and soothes the symptoms of allergy. It neutralizes allergens commonly found it house dust.	Allergoff® Spray neutralizes allergens, glues airborne allergens together and reduces the risk of allergens inhalation. It supports the treatment of allergy symptoms, such as bronchial asthma, atopic dermatitis, allergic rhinitis. It inhibits allergy development and soothes the symptoms of allergy. It reduces intake of anti-allergic drugs.	Non-Medical Device	Does not meet the definition of medical devices.

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3	Scope pants	SCOPE PANTS are pants for patients needing coverage or warmth during examination, diagnostic testing, or surgical procedures.	SCOPE PANTS are pants for patients needing coverage or warmth during examination, diagnostic testing or surgical procedures.	Non-Medical Device	Does not meet the definition of medical devices.
4	SunSCAN 3D	The SunSCAN 3D, model 1234, is intended for radiotherapy dosimetry measurements and export of those measurements for commissioning a Treatment Planning System (TPS) computer. It is also intended for periodic beam Quality Assurance (QA) tests as defined by the medical physicist responsible for the QA program.	The SunSCAN 3D, model 1234, is intended for radiotherapy dosimetry measurements and export of those measurements for commissioning a Treatment Planning System (TPS) computer. It is also intended for periodic beam Quality Assurance (QA) tests as defined by the medical physicist responsible for the QA program.	Non-Medical Device	Does not meet the definition of medical devices.
5	Ear / eye drop	Storage of liquid medicine.	Eye / ear drop is a bottle with an insert that comes with a tiny hole. It is used especially for administering liquid medicine into the eyes by drops.	Non-Medical Device	Does not meet the definition of medical devices (Storage Bottle for eye drop).
6	Invisishield Long Instrument Pouch	Invisishield Long Instrument Pouch is intended to be used as a long instrument pouch for CV, orthopedic, neurologic and general procedures.	Invisishield Long Instrument Pouches feature three long compartments for cauteries or catheters. - New high-tack, aggressive adhesive for better adhesion to linen or nonwoven materials. - Heavy, low-glare matte-finish film.	Non-Medical Device	Does not meet the definition of medical devices.

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			- Use for CV, orthopedic and neurologic procedures.		
7	Needle Counting Mat	This a simple counting needle easily for surgeon to counting needle after a surgery finish. The needle will hock on the sponge with adhesive area in order to secure and easily do the counting progress.	A single use device for counting needle during surgery holding the needle during the operation.	Non-Medical Device	Does not meet the definition of medical devices.
8	Disfec mat	Placed on at the entrance or where it is needed in a hospital to trap microbes, viral particles as well as to have cidal effects for the microbs and viral particles. commonly in operation theatre(OT), ICU, NICU, LABS, CSSD, CCU, BURN UNITS and other required places. The antiviral and antimicrobial mats have elements that destroys virus, bacteria and fungi.	ANTI MICROBIAL & ANTI VIRAL MAT with Didecyl Dimethyl Ammonium Chloride + BIS3 Aminopropyldodecylamin + with Chlorhexidine and Detergency-adjuvant enzymes, spread into 30 layers of polyfilms combined to 1 unit and followed by the measurements of size115x45cm, 30-layers, 115x60cm, size115x 90cm.	Non-Medical Device	Does not meet the definition of medical devices.
9	Transfer board	Transfer boards also known as sliding boards are commonly rigid, flat boards made of wood or plastic. The board acts as a bridge to allow individuals to move from one seated surface to another such as moving from a wheelchair to a bed.	A transfer board is a piece of equipment that helps you transfer (move) from one surface to another. For example, from bed to chair, or from wheelchair to toilet. The boards come in different shapes, colours and sizes. They are also sometimes known as banana boards or slide boards.	Medical Device	

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10	Pedal exerciser	To assist someone who may be temporary or permanently disabled for exercising lower or upper limbs at seated position.	To assist someone who may be temporary or permanently disabled for exercising lower or upper limbs at seated position.	Medical Device	
11	Wound and skin wash glove	Used for cleansing and care for bedridden and intensive care patient.	Used for cleansing and care for bedridden and intensive care patient.	Non-Medical Device	Does not meet the definition of medical devices.
12	Handpiece cleaning & lubrication system	Automatically cleans and lubricates up to 3 handpieces at one time with a touch of a button.	Automatically cleans and lubricates up to 3 handpieces at one time with a touch of a button. Both high speed and low speed handpieces are processed thoroughly in a single cycle.	Non-Medical Device	Does not meet the definition of medical devices.
13	Microbial mat	Placed on at the entrance or where it is needed in a hospital to trap dust as well as to have cidal effects for the microbs in tagged. Commonly in operation theatre (OT), ICU, NICU, labs, sterile dept. CCU,burn units and required places. The microbial mats have antibacterial element and destroys bacteria and fungi.	Anti microbial mat with active component 2-n-octyl-4-isothiazolin (OIT) spread into 30 layers of polyfilms combined to 1 unit and followed by the measurements of 60cm x 120cm and 90cm x 120cm.	Non-Medical Device	Does not meet the definition of medical devices.

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14	KANGZHU vacuum cupping/ CAREZOE vacuum cupping	Promote free passage in human channels and collaterals, eliminate wind evil and wetness evil, expel coldness-evil and remove toxins, curesiswases and strengthen human body etc.	Kangzhu vacuum cupping series products are pushed out by beijing kangda world appliance medical center cast away such disadvantage of ancient cupping therapy as inconvenience in operation ,getting burn easily ,limited treating sites, and limited scope of applications, and change the dispelling air b fire to air exhaust b vacuum, allowing the cupping device sucked on the surface acupoints of the body to cause local congestion.	Medical Device	
15	ATMOS S 61 SERVANT INSTRUMENTS	ATMOS S 61 SERVANT INSTRUMENTS are used in instrument management. They are used for instrument deposit and heating, as well as storage room for examination and therapy devices.	ATMOS S 61 SERVANT INSTRUMENTS are used in instrument management. They are used for instrument deposit and heating, as well as storage room for examination and therapy devices. They are supplied non-sterile and intended for multiple use.	Non-Medical Device	Does not meet the definition of medical devices.
16	PainChek®	PainChek is a software system which is comprised of the following components: a) PainChek App b) PainChek Portal PainChek is intended to be used to assess and monitor pain in people who cannot verbalise such as people with dementia or communication difficulties. The PainChek App is a point-of-care	PainChek is a software system which is comprised of the following components: a) PainChek App b) PainChek Portal PainChek is intended to be used to assess and monitor pain in people who cannot verbalise such as people with dementia or communication difficulties. The PainChek App is a point-of-care	Medical Device	

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		application which uses a smart-device camera to capture a short video of a person's face, this is then analysed in real-time using facial recognition technology to detect nine muscle movements - these are indicative of the presence of pain. This data is then combined with non-facial pain cues including movements, behaviours and vocalisations and inputted into the App to allow the automatic calculation of a pain severity score. The App has a graphing function which allows monitoring the person's pain over time. The App also includes an (optional) self-reporting Numeric Rating Scale (NRS) feature for documenting the pain reported by people who are able to articulate and self-report the extent of their pain. PainChek assessments should be conducted by a person that is trained on how to use the App.	application which uses a smart-device camera to capture a short video of a person's face, this is then analysed in real-time using facial recognition technology to detect nine muscle movements - these are indicative of the presence of pain. This data is then combined with non-facial pain cues including movements, behaviours and vocalisations and inputted into the App to allow the automatic calculation of a pain severity score. The App has a graphing function which allows monitoring the person's pain over time. The App also includes an (optional) self-reporting Numeric Rating Scale (NRS) feature for documenting the pain reported by people who are able to articulate and self-report the extent of their pain. PainChek assessments should be conducted by a person that is trained on how to use the App.		
17	DMC Cold Gel	DMC Cold Gel is intended to alleviate pain, to relieve tension in the back, lumbar, neck	DMC Cold Gel contains alcohol and menthol, with cooling effect, first decrease the skin temperature and pain	Medical Device	The percentage of menthol is too small

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		and shoulders, and any muscle related pains.	sensation following from physical exercise, fasten recovery and sore muscle.		and not be regulated by NPRA.
18	STF Load Check Holder	Simply place the indicator in the holder and place the device in the basket or tray of a washer-disinfector machine, after running a complete cycle, remove the indicator from the holder and examine for evidence of residual soil. The Browne STF Load Check indicator is printed with a bright red soil formula that is safe to handle, easy to see and therefore easy to interpret, and performs in an equivalent manner to typical debris / soils by providing a realistic challenge for the washer disinfector machines.	The Browne STF Load Check Holder has been carefully designed to hold the Browne STF Load Check indicator (order code 2315).	Non-Medical Device	Does not meet the definition of medical devices.
19	Lice cap	Med-cover lice cap in order to remove the remaining lice eggs in your head.	A thick cap that is impregnated with essential oils designed to eradicate head lice. It looks and feels just like a regular shower cap. The med-cover lice cap is different from mainstream head products as it doesn't contain the neurotoxins and pesticides that are often used to kill head lice.	Medical Device	Based on MDDCI Table, it classified as medical device due to acts solely by coating and/ or suffocating the lice and/ or its eggs.
20	Vomit bag	Vomit bag is used to contain the vomitus.	A single-use non-sterile vomit bag consists of one bag with an absorbent pad within	Non-Medical Device	Does not meet the definition of medical devices.

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			and a drawstring for closure. The bag can contain up to 1.5L volume of vomitus.		
21	EnziMed Standard	Low-foaming liquid enzymatic detergent for cleaning of reusable medical devices.	EnziMed Standard is a multi-enzymatic detergent designed for medical devices cleaning.	Non-Medical Device	Not intended to disinfect medical devices.
22	BESA MRI 3.0	Intended use of the software is to imports digital MRI data, segments and labels different brain and head tissues , transforms the MRI data into ACPC and Talairach spaces and renders the scalp and cortical surfaces.	BESA MRI is a stand-alone software to assist analysis of EEG and MEG data by providing tools for analysis segmentation of MRI data of human heads, coregistration of EEG and MEG sensor positions with MRI data.	Medical Device	
23	Water phantom systems	The PTW water phantom system (BEAMSCAN) is intended for dosimetry measurements in the context of a radiotherapy system. The device is intended to determine the beam characteristics of the radiotherapy system (beam data acquisition) during the commissioning and/or for periodic quality assurance procedures according to the QA plan of the responsible medical physicist.	The BEAMSCAN system is comprised of a PMMA tank with a moving mechanism and a radiation detector. Further main components are a lifting carriage with built-in electrometer and control unit with manual controller. The lifting carriage either includes a water reservoir or a separate reservoir is used. A positioning device can be mounted on top of the lifting carriage and allows the water phantom to be aligned manually. With additional options the PMMA tank can be removed from the lifting carriage. The	Non-Medical Device	Does not meet the definition of medical devices.

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			whole system is controlled by software for data display and processing.		
24	LED headlight system	Intended to provide illumination to aid visualization during minor surgical, diagnostic, or therapeutic procedure (this application is only to register their spare part.)	Surgical headlight that deliver cool and bright LED light for broad range of surgical procedures.	Non-Medical Device	Spare part only (not accessories)do not need to be registered. This product does not meet the definition of a medical device as set out in Section 2 of the Act.
25	Packaging bottles	HDPE packaging bottles are excellent for storage, shipping and packaging of liquid reagents.	PakGent packaging Bottles are ideal for specialty chemicals, diagnostics, biologicals, reagents, adhesives and veterinary pharmaceuticals. Lab Quality Wide-Mouth and Narrow-Mouth Bottles. PakGent Laboratory grade PP bottles are used for a variety of field applications and are autoclavable ((-80℃~121℃). Such containers are useful for most acids, bases and Alcohols. Excellent chemical resistance and are leak-proof when used with PakGent caps. Use only high made of quality laboratory grade plastic material, which can reliably reduce the content of lexes and extracts.	Non-Medical Device	Does not meet the definition of medical devices.

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26	Breath alcohol measuring system	The AlcoBlow® is a rapid screener which detect the presence or absence of alcohol in the body.	The AlcoBlow® is a rapid screener which detect the presence or absence of alcohol in the body.	Non-Medical Device	Does not meet the definition of medical devices.
27	QuickSuite Sahara Operating Table Sheets	Operating table sheets intended to be used as a moisture management system to help manage moisture and optimise the operating theatre workflow.	QuickSuite Sahara Operating Table Sheets is part of Medline's moisture management solution designed to manage moisture and optimise the operating theatre workflow. They help reduce clean-up time by absorbing and retaining fluids during procedures and keeping the patient and equipment dry. Medline's Sahara operating table sheets have a wicking function paired with an impervious backing, which promotes effective moisture management and the optimisation of the operating table's lifespan. Medline's Sahara operating table sheets have 3 layers. The quilted top layer made of non-woven polypropylene to ensure comfort and reduce linting. The middle absorbent layer reinforced by core polymer technology that rapidly wicks moisture away, maintaining skin integrity. And the impervious bottom layer that keeps all fluids away from the operating table. They also come with two types of backings.	Non-Medical Device	Does not meet the definition of medical devices.

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28	QA Ultrasound Device	Ultrasound Quality Assurance Device.	Ultrasound Quality Assurance Device.	Non-Medical Device	Does not meet the definition of medical devices.
29	Sterile cautery tip cleaner	Intended use are designed for intraoperative removal of charred residues left on diathermy tips following cauterization.	A form of pad combines with foam with abrasive material to assist in removing residues left on diathermy tips. This pad is not use directly in the procedure but the diathermy tips might be used during the surgical procedure. However, we are registering the pad only and not the diathermy tips. (May refer to the brochure attached for more information).	Non-Medical Device	Not intended to disinfect medical devices.
30	Vienna test system	The Vienna Test System is simple to use and requires no prior computer knowledge. The programs are clearly structured, enabling you to administer tests, evaluate the results and manage data very easily.	The Vienna Test System is the result of 25 years' experience in computerized psychological assessment. It comprises a wide selection of modern personality and ability tests, in forms which are continuously maintained and updated. The range of available tests is constantly being expanded – in addition to tests based on classical test theory, an increasing number of adaptive and multimedia tests are being developed to incorporate the benefits of innovative technologies and "modern" test theory.	Non-Medical Device	Does not meet the definition of medical devices. As mention in IFU, 'it is used to test or assess individuals in the areas of personnel selection and development, clinical neuropsychology, traffic psychology and sports psychology', and not specifically for patient.

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31	MICRO+ SMOKERLYZER	Micro+ Smokerlyzer products are breath carbon monoxide monitors intended for multi-patient use by healthcare professionals in smoking cessation programmes and research. They can also be used as an indicator of carbon monoxide poisoning in a healthcare environment.	The Micro+™ Smokerlyzer® products are breath carbon monoxide monitors intended for multi-patient use by healthcare professionals in smoking cessation programmes. The Micro+™ give a reading when the patient performs a breath test, for the patient to do this they must follow the instructions on the monitor by holding their breath and when indicated blowing slowing into the mouthpiece aiming to empty the lungs completely. The mouthpieces which are used is a D-piece and Steribreath mouthpiece. Once the patient has given a reading, the monitor will display a traffic light colour these are Green – Non Smoker, Amber – Borderline and Red – Addicted in various forms. This will give an indication to the healthcare professional how much carbon monoxide the patient has in their blood.	Medical Device	Intended use is for multipatient use by healthcare professionals.

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32	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.	Medical Device	This device is specially developed for medical applications.
33	Spatula	Spatula is used to mix dental materials.	Made of stainless steel.	Non-Medical Device	Does not meet the definition of medical devices.
34	Antegrade IR System	To provide a work surface over a supine patient for femoral transarterial diagnosis and intervention via Antegrade approach on an Angiography imaging table.	An ideal work surface for antegrade femoral approach.	Non-Medical Device	Does not meet the definition of medical devices (Intended use is for work surface).
35	Eye Shield	These Tungsten eye shields with aluminum caps are designed to protect the lens and cornea of the eye when treating the eyelid with electrons.	The Tungsten Eye Shield can use either the 0.5 mm or 1 mm thick anodized aluminum cap (both are included with each tungsten eye shield) to reduce the electron backscatter to the eyelid. The eye shield can be used without the aluminum cap when placed superficially.	Medical Device	This device are designed to protect the lens and cornea of the eye (meet the definition of a medical device).

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36	INSPIRE nCPAP bonnet	The INSPIRE nCPAP bonnet intended to ensure the nCPAP generator is comfortable and securely placed on the patient.	The inspire nCPAP bonnet is single-use, colour-coding for enables easy size selection and individually packaged. The bonnet is the basis for the application of the entire nCPAP system since it ensures the necessary stability.	Medical Device	This device are accessories for respiratory care system (meet the definition of a medical device).
37	Nurse Call System	Nurse call systems are designed to facilitate communication between patients and medical staff. It is intended for use in healthcare settings to allow patients to seek help or communicate their needs to caregivers.	The Nurse Call System is designed to facilitate communication between patients and healthcare providers. It is intended for use in healthcare facilities to allow patients to call for assistance or communicate their needs to nursing staff.	Non-Medical Device	Does not meet the definition of medical devices.
38	Super absorbent sticks	Intended to solidify body fluids in suction canisters. Can also be used with bedpans, urinals, vomit supports. Limits contamination by eliminating splashes, spills, cleaning and cross-contamination.	Super absorbent stick to solidify body fluids and limit contamination.	Non-Medical Device	Not intended to disinfect medical devices.
39	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.	Medical Device	

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40	Smart storage freezer	Is a Radio-Frequency Identification (RFID) product used to track Fresh Frozen Plasma (FFP) bags. It improves the storage of Fresh Frozen Plasma. The device do provide information to user. The SST-F tracks all bag movements into and out of a freezer or cold room and displays a stock status.	It composed of a mechanical structure (drawers + slides + mounting kit), RFID satellites (antennas) and calculator (embedded software + web interface).	Non-Medical Device	Does not meet the definition of medical devices.
41	Brillica Bianco	The Brillica system is a heat source that is intended to apply heat to a bleaching agent which is applied to intraoral teeth by light irradiation.	Brillica is a teeth whitening light. It presents a new style of teeth whitening through direct fitting to the mouthpiece. Even if the patient moves, the radiating position remains unchanged, assuring efficient treatment and minimizing the stress on the patient without intsructing the patient now to move.	Non-Medical Device	Does not meet the definition of medical devices This device specific for whitening (Whitening product classified as Non-Medical Device).
42	Surgical marking pen	The surgical marking pen is used for surgical marking on intact skin.	The surgical marking pen is made with gentian violet skin ink, sterile and used to define incision sites prior to surgery. It is intended for a single use and not made with natural rubber latex. The tip options are available depending on preference as well as the inclusion of rulers and/or labels.	Non-Medical Device	Does not meet the definition of medical devices.

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43	Wheelchair scale	This medical device is designed to be used in accordance with national regulations, to measure weight within specifications, for weight-related usage by professionals.	This medical device is designed to be used in accordance with national regulations, to measure weight within specifications, for weight-related usage by professionals. The device is designed to measure weight by pushing a patient seated in a wheelchair onto the measurement platform.	Medical Device	Designed for patient.
44	SurgiLem Circumcision Pants	SurgiLem Circumcision pants is intended to protects the circumcised area from outside and creates space for air circulation, thus assist in wound healing process. It is intended for home use.	Circumcision pants used to protects the circumcised area from outside and creates space for air circulation, thus assist in wound healing process.	Medical Device	This device assists in wound healing process.
45	PICA-SPIKE	This medical device is to eliminate the potential for any dangerous exposure to high-risk drugs by mantaining closed needle-free system during drug administration. This device too prevents any risk of leaks or spills.	• Intended to be used for multiple withdrawals or infusions of fluid • Universal spike for medication vial • Consist of air filter, hydrophobic bacterial filter • Vented spike for withdrawing fluids from vial or semi-rigids containers • Reduces contamination through safety snap cap • Ergonomic design • PVC Free, DEHP Free, Latex Free • Available in green, blue and red colour • Sterile with EtO, For Single use only.	Medical Device	

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46	Instrument Pouch	To place instruments and used swabs/gauzes/sutures during surgical procedure. This device will not be used during sterilization process.	Single use device used to maintain the cleanliness during surgical procedure.	Non-Medical Device	Does not meet the definition of medical devices.

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

Prepared on 13th Feb 2024.

Using justified text setting.