

DECISION JAWATANKUASA TEKNIKAL PENGGELASAN DAN PENDAFTARAN (JKTPP) YEAR 2024

List of products (Medical device or Non-medical device)

NO	PRODUCT NAME	PRODUCT INTENDED USE*	DESCRIPTION OF PRODUCT*	DECISION FROM COMMITTEE	REMARKS
1	BIOESTA DENTURE CLEANSING AND WHITENING TABLET	Cleansing and whitening of denture	Round effervescent tablet with double sheet consists of green and white color and green dot, smooth surface and mint odour	Non-Medical Device	Does not meet the definition of medical devices. **The intended use of the tablet only for cleaning and whitening not for disinfecting
2	WEARABLE BREAST PUMP	Electrically powered wearable single breast pump consisting of the following key components: a flange, linker, silicone diaphragm, pump motor, USB cable, valve, milk collector, and bra adjustment buckle. It is designed to work in the user's bra and has a rechargeable battery so it can be used hands-free without any external power cords.	Powered breast pump, to express and collect milk from lactating women. The device is intended for a single user.	Non-Medical Device	Does not meet the definition of medical devices. Not medical device Intended to be used by lactating women to express and collect milk from their breasts. Medical device 1. Intended for lactating women to express and store milk from their breast to complement breastfeeding also to prevent

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					engorgement of the breast lump 2. Breast pumps for treatment of inverted nipples
3	Comfort Cool Refreshing	Devices intended to relief by having heating or cooling feeling from patch.	A single-use device in 12X15 cm pad.	Non-Medical Device	Does not meet the definition of medical devices.
4	OPST TM Advanced OP Tape	Medline tape is intended to close the extremity of a stockinette and to attach cable/tubes on the drape in the sterile field.	This device provides ease to the healthcare professional to perform the surgical procedure by providing the easy access of devices/instruments, helping to maintain the cleanliness and sterile field so surgeon can perform the surgical procedure without any disturbance.	Medical device	
5	Sleep Patch Patchure Natural Herb Patch	Device is intended to bring on sleep. It is designed to help calm the nervous system, the mind and stimulate an overall sensation of relaxation.	Device is an external use patch intended to bring on sleep. It is designed to help calm the nervous system, the mind and stimulate an overall sensation of relaxation.	Non-Medical Device	Does not meet the definition of medical devices.

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6	Probe Cover Kit	Used to cover equipment, maintain the sterile field and prevent potential contamination for the patient during medical examination	Single use device used to maintain the sterile field and prevent potential contamination for the patient during medical examination	Medical device	A sterile wrap, 30x30 cm, contains: - 1 probe cover - external ultrasound - 1 ultrasound gel*, 20g - external use - 2 rubberbands - tighten probe
7	Genius™ Tympanic Probe Covers	The device is intended to prevent cross contamination between patients by acting as sanitary barrier between the thermometer and ear canal	The probe covers are held in a cassette stored in the thermometer base. To load a probe cover on the thermometer, firmly push the probe tip into the probe cover. When installed on the thermometer, the probe cover film should be smooth with no holes, tears, or wrinkles. After the reading has been taken, eject the probe cover by pressing the eject button. Probe covers should be disposed of properly after use. In order to help prevent and control infection, always use a new	Non-Medical Device	Does not meet the definition of medical devices.

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			probe cover before taking a reading.		
8	Disposable Curve Monitor Drape	To cover equipment to help maintain a sterile field.	Disposable sterile drapes to cover touchscreen display of Curve.	Medical device	GD HARMONISED BORDERLINE PRODUCTS IN ASEAN: Equipment cover and Equipment sleeves for operating theatre - To cover equipment for operating theatre. (Medical device)
9	EASY-VAC GASKET	EASY-VAC GASKET IS A FORMING SHEET FOR DOING MOLD. AFTER MOLD DONE USING FOR WHITENING TRAY.SPLINT IS HARDER THAN BLEACHING	EASY-VAC GASKET IS A FORMING SHEET FOR DOING MOLD. AFTER MOLD DONE USING FOR WHITENING TRAY.	Non-Medical Device	Does not meet the definition of medical devices.
10	11" ICE BAG	COLD THERAPY: Use cold for sprains, strains, bruises, and other injuries. To help relieve pain and swelling: rest, apply ice, compression, and elevate (R.I.C.E)	11" Ice Bag is reusable and to apply cold for sprains, strains, bruises, and other injuries. This product provide excellent cold therapy effect	Medical device	specific primary intended purpose
11	Invisishield™ Long Instrument Pouch	Intended to place instruments and used swabs/gauzes/sutures during surgical procedure	Single use device used for infection control practices in healthcare industry	Non-Medical Device	Does not meet the definition of medical devices.

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12	MAT SENSOR (SOLT SYSTEM)	A piece of sensor pad that can detect patient weight when patient is laying on top of it. The MATSENSOR will trigger the alarm when the pad detects no weight on top of it, ie when the patient falls from the bed	<ul style="list-style-type: none"> • Display monitor x 1 • Mat sensor x 1 • Nurse pager (c/w a charger plug) x 1 • Electronic box with cancel button x 1 *black box with fitting plug type	Non-Medical Device	Does not meet the definition of medical devices.
13	FD3000 Powered Table	The FD3000 is a motorised power table with a flat upholstered therapy surface optimised for patient comfort and compliance with medical device safety standards. The FD300 is a specially constructed table with an adjustable headpiece, a stationary thoraco-lumbar piece, and a moveable pelvic piece for the lower extremities.	The FD3000 is a specialized motorized table designed to assist chiropractors in administering the flexion-distraction technique, a recognized chiropractic method for alleviating back pain. This table enables precise and controlled movements essential for this therapeutic technique, contributing directly to its therapeutic outcomes.	Non-Medical Device	Does not meet the definition of medical devices.
14	STERILE ABSORBENT SHEET	To provide a clean or sterile area for any procedure	A form of sheet made from paper and plastic	Non-Medical Device	Does not meet the definition of medical devices. Product classification: Underpad is not medical device

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15	NEWMOM DISPOSABLE PAD FIXATOR	To hold the maternity sanitary pads, ordinary sanitary pads or incontinence pads in place.	To hold the maternity sanitary pads, ordinary sanitary pads or incontinence pads in place.	Non-Medical Device	Does not meet the definition of medical devices. Product classification: MDA/PC/2020/301 - SanNap Sanitary Napkin Loop is not medical device
16	BABY BOTTLE WARMERS	The device, designed for maintaining stable temperatures, utilizes resistors wrapped around an aluminum plate for this purpose. It is intended for use in hospitals, newborn units, and environments where breast milk is stored, with adjustable temperature settings ranging from +5°C to +55°C. The device is designed to ensure that breastmilk stored in cooler cabinets or at temperatures lower than human body temperature is heated until it reaches body temperature suitable for delivery.	The device is designed to ensure that breastmilk stored in cooler cabinets or at temperatures lower than human body temperature is heated until it reaches body temperature suitable for delivery	Non-Medical Device	Does not meet the definition of medical devices.

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17	Baclyser Hollow Fibre Membrane Filter	The filter is a CE-marked medical device and serves as an inline/terminal membrane filter to prevent nosocomial infections and diseases in immunocompromised or immunosuppressed patients by retaining all water-bound germs.	<p>The hollow fibres are fixed in the filter housing such that water is guided to the hollow fibres and filtered through their pores. The hollow fibres are fixed together in a fibre bundle in the filter housing so the water is led through the hollow fibres (cross flow) and is filtered through the pores of the fibres.</p> <p>The high-quality hollow fibre membrane offers reliable protection against waterborne germs and, in accordance with the definition of "sterile filtration", leads to a retention of the test germ <i>Brevundimonas diminuta</i> (<i>Brev.diminuta</i>) of 7 log steps per square centimetre of filter area [5, 6], i.e. to a germ retention of 99.99999 percent</p>	Non-Medical Device	<p>Does not meet the definition of medical devices.</p> <p>Product classification: (MDA/PC/2023/267, 26/07/2023)- NOT medical device: Intended to provide a total retention of waterborne bacteria, prevent contamination risk associated with conventional filters. Suitable for use for wound care, burn tubs, water birth, hand washing, regular baths and bottling of drinking water</p>

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18	FRESH + CLEAR PATCH	Fresh + Clear patch has a good energy conversion function taken medical glue as the carrier, a variety of natural aromatic plant extracts refreshing are included, better skin penetration and aroma, by the method of drug delivery through skin, the variety of active ingredients are transported to the skin, and then dispel the effects of alcohol, in addition to the volatile flavour, they can also act directly on the brain, to get an effect of refreshment.	Fresh + Clear patch is a new style Chinese medical plaster for external use to relieve the discomfort symptoms caused by drinking and reduce the harm of alcohol to the human body. Supplied non-sterile.	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*