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MEDICAL DEVICE GUIDANCE DOCUMENT

HARMONISED BORDERLINE PRODUCTS IN ASEAN

Medical Device Authority
MINISTRY OF HEALTH MALAYSIA

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PREFACE

This Guidance Document was prepared by the Medical Device Authority (MDA) to help the industry and healthcare professionals in their quest to comply with the Medical Device Act (Act 737) and the regulations under it.

This Guidance Document shall be read in conjunction with the current laws and regulations used in Malaysia, which include but not limited to the following-

a) Medical Device Act 2012 (Act 737);
b) Medical Device Regulations 2012.

In this Guidance Document, the following verbal forms are used:

— “shall” indicates a requirement;

— “should” indicates a recommendation;

— “may” indicates a permission; and

— “can” indicates a possibility or a capability.

Irrespective of the requirements of this Guidance Document, MDA has the right to request for information or material, or define conditions not specifically described in this document that is deemed necessary for the purpose of regulatory control.

MDA has put much effort to ensure the accuracy and completeness of this guidance document. In the event of any contradiction between the contents of this document and any written law, the latter should take precedence.

MDA reserves the right to amend any part of the guidance document from time to time.

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HARMONISED BORDERLINE PRODUCTS IN ASEAN

1. Introduction

The ASEAN Medical Device Directive (AMDD) is the Agreement that reflects a legal and institutional framework for the ASEAN Community to harmonise medical devices regulation in the region. It is a common medical device directive in ASEAN among Member States. This Agreement came into force on 1 January 2015. As one of the Member States, Malaysia has signed this Agreement on 23 April 2020.

The definition of medical device that has been specified in the Article 2 of AMDD is in line with the definition stipulated in Section 2 of Medical Device Act 2012 (Act 737). This definition determines the scopes of regulatory control in Malaysia.

The Act also specifies the responsibility of the manufacturer to classify a medical device based on the level of risk it poses, its intended use and the vulnerability of the human body in accordance with the prescribed manner in Section 3.

In the AMDC meeting, member states discuss product classification based on a harmonized definition. The goal is to ensure that products are regulated under a harmonised regulatory framework, facilitating easier entry into the ASEAN market.

2. Scope

This guidance document provides the list of borderline products whether they are medical devices or non-medical devices based on their intended purpose as claimed by the manufacturer which is harmonised in ASEAN.

This guidance document will be updated on a yearly basis to reflect the latest decisions of the ASEAN Medical Device Committee (AMDC).

3. Terms and definitions

For the purposes of this document, the terms and definitions in Act 737, the regulations under it and the following terms and definitions apply.

3.1 borderline products

Products that are difficult to distinguish from a medical device, for example products that might be medicines, cosmetics, food supplements, biocidal products or personal protective equipment. These products are called borderline products until their status of medical device or non-medical device has been decided.

[Source: asean.org]

3.2 ASEAN

Association of Southeast Asian Nations, or ASEAN, is a political and economic union of 10 member states in Southeast Asia, which are Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand and Vietnam.

[Source: asean.org]

3.3 Intended use/ purpose

The objective intent of the manufacturer regarding the use of a product, process or service as reflected in the specifications, instructions and information provided by the manufacturer.

3.4 Manufacturer

As defined in Section 2 of Act 737.

3.5 Medical device

(a) any instrument, apparatus, implement, machine, appliance, implant, in-vitro reagent or calibrator, software, material or other similar or related article intended by the manufacturer to be used, alone or in combination, for human beings for the purpose of:

(i) diagnosis, prevention, monitoring, treatment or alleviation of disease;
(ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
(iii) investigation, replacement or modification, or support of the anatomy or of a physiological process;
(iv) support or sustaining life;
(v) control of conception;
(vi) disinfection of medical device; or
(vii) providing information for medical or diagnostic purpose by means of in-vitro examination of specimens derived from the human body, which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its intended function by such means; and

(b) any instrument, apparatus, implement, machine, appliance, implant, in-vitro reagent or calibrator, software, material or other similar or related article, to be used on the human body, which the Minister may, after taking into consideration issues of public safety, public health or public risk, declare to be a medical device by order published in the Gazette.

4. Harmonised Borderline Products in ASEAN

4.1 General Requirements

Harmonised borderline products listed are in accordance with the definition of medical device and agreed upon by the ASEAN Medical Device Committee (AMDC). The list of harmonised borderline products has been published in the www.asean.org.

The list of borderline products that are classified as medical device or non-medical device are as listed in Annex A.

ANNEX A

LIST OF HARMONISED BORDERLINE PRODUCTS (MEDICAL DEVICES OR NON-MEDICAL DEVICE)

NO.	PRODUCT NAME	DESCRIPTION	BORDERLINE (MEDICAL DEVICE or NON-MEDICAL DEVICE	ASEAN DECISION
5th AMDTC				
1.	Micropipette	The standard laboratory equipment used to measure and transfer small volumes of liquids.	Medical Device or Non-medical Device	Non-medical Device unless manufacturer state it for IVD purposes
2.	Culture Media or Petri dish with culture media	Any material prepared for the growth of bacteria or other microorganism in a laboratory.	Medical Device or Non-medical Device	Non-medical Device, unless manufacturer state it for IVD and IVF purposes
3.	Disinfectant/ antiseptic for dental	Disinfectants or antiseptics for dental that contain materials: chlorhexidine gluconate, iodine, formaldehyde, Sodium hypochloride	Medical Device Borderline with Medicine	Depends on the mode of action of the active ingredient. If it is physical mode of action then it is a Medical Device. But if it is pharmacological action, the it is classified as medicine.
4.	EDTA Solution	EDTA Solution buffered to neutral pH used for preparation of root canals by rapid cleansing and enlarging of root canals.	Medical Device Borderline with Medicine	Depends on the mode of action of the active ingredient. If it is physical mode of action then it is a Medical Device. But if it is pharmacological action, the it is classified as medicine.
5.	Mentholated bandage	Mentholated bandage is a bandage containing menthol usually used to relieve pain.	Medical Device Borderline with Medicine	Non-medical Device
6.	Eye drops	Eye drops are saline – containing drops used as an ocular route to administer. Depending on the condition being treated, they may contain steroids, antihistamines, sympathomimetics, beta receptor blockers, parasympathomimetics,	Medical Device Borderline with Medicine	Medical Device if specifically intended to be used for lubricating, disinfecting, cleaning, rinsing or, when appropriate, hydrating contact lenses and tear-replacing solution

		parasympatholytics, prostaglandins, non stroisal anti-inflammatory drugs (NSAIDs), antibiotics, antifungal or topical anesthetics. Eye drops sometimes do not have medications in them and are only lubricating and tear-replacing solution.		
7.	Artificial tears	Artificial tears are lubricant eye drops used to treat the dryness and irritation associated with deficient tear production in keratoconjunctivitis sicca (dry eyes). They are also used to moisten contact lenses and in eye examinations.	Medical Device Borderline with Medicine	Medical Device if there are no active ingredients and specifically intended to be used for lubricating and tear-replacing solution
8.	Lotion (example is for prevention of bed sores)	Moisturizing cream or skin protectant to treat skin gently to help prevent bed sores.	Medical Device Borderline with Medicine	Depends on the mode of action of the active ingredient. If it is physical mode of action then it is a Medical Device. But if it is pharmacological action, the it is classified as medicine.
9.	Personal Combinational Stimulator	A therapeutic tool which can generate vibration waves, can help reduce and relieve aches and fatigue on the body.	Medical Device or Non-medical Device	Medical Device
10.	Bed Mattress	heat therapy device with infrared remote, can help reduce and relieve aches and fatigue on the body.	Medical Device or Non-medical Device	Medical Device
11.	Needle for tattooing	Used in the context of cultural or individual.	Borderline with/ Medical Device or Non-medical Device	Non-medical Device
12.	Needle used in the acupuncture	Thin needles are inserted through the skin in which practitioners stimulate specific points on the body.	Borderline with/ Medical Device or Non-medical Device	Medical Device
13.	Laser	Used to treat skin disorders and providing tangible cosmetic alterations to the skin.	Borderline with/ Medical Device or Non-medical Device	Medical Device if there are any medical claim. Non-medical Device, if for aesthetic/ cosmetic purposes.
14.	Liposuction machine	Intended to remove fats from the body using suction.	Borderline with/ Medical Device	Medical Device

			or Non-medical Device	
15.	Admission Kit	Intended use during admission in the hospital. Contains, towel, toothbrush, glass, measuring cup, medicine cup, etc.	Borderline with/ Medical Device or consumer products	Non-medical Device
16.	Gadgets (ex. Cellphone) with health and medical applications	Cellphones are being used in the telecommunication with applications in health monitoring such as heart rate.	Borderline with/ Medical Device or Non-medical Device	Non-medical Device The Application/ Software is Medical Device
17.	Tissue replacement of biological origin	Regeneration and remodeling of tissue in vivo for the purpose of repairing, replacing, maintaining, or enhancing organ function, and the engineering and growing of functional tissue substitutes in vitro for implantation in vivo as a biological substitute for damaged or diseased tissues and organs. It is either (1) manufactured from human tissue; (2) manufactured from animal tissue, or (3) blood substitutes and expander.	Borderline with/ Medical Device or drugs	Non-medical Device Medical Device, if there are no biological/ pharmacological/ metabolical action, non-viable and manufactured from animal tissue.
18.	Laboratory equipments (microscope, centrifuge, etc.)	Intended use in the preparation and analysis of specimen.	Borderline with Medical Device or Non-medical device	Non-medical Device, if general laboratory purposes. Medical Device, if use for IVD, IVF
19.	Laboratory products (pipettes, graduated cylinder, slides, beakers, etc.)	Intended use for the preparation of specimen, aspirating and dispensing specific volumes in the microlitre scale.	Borderline with Medical Device or not Medical Device	Non-medical Device, if general laboratory purposes Medical Device, if use for IVD, IVF
20.	Eye drops	Intended use in the alleviation of soreness, discomfort or irritation caused by environmental factors (such as dust, heat, smoke, etc.).	Borderline with/ Medical Device or drugs	Medical Device if specifically intended to be used for lubricating, disinfecting, cleaning, rinsing or, when appropriate, hydrating contact lenses and tear-replacing solution.
21.	Washing solutions used for pathogenic microorganisms	Intended use for disinfection.	Borderline with/ Medical Device or Non-medical Device	Medical Device, if intended for disinfecting Medical Devices

22.	Hand Gloves	The intended use is to reduce bacterial transfer.	Borderline with/ Medical Device or Non-medical Device	Medical Device if with medical purpose
23.	Mobile application for the communication between patient and caregivers while giving birth	This application allows storing data on each moment of contraction during delivery.	Borderline with/ Medical Device or Non-medical Device	Non-medical Device
24.	Software for information management and patient monitoring	Intended to route and store Medical Device data.	Borderline with/ Medical Device or Non-medical Device	Medical Device if used to monitor the patient data. Non-medical Device if used only for data storage.
25.	Wound treatment products	Intended use to treat wounds.	Borderline with/ Medical Device or drugs	Medical Device
26.	Lubricant	Intended use to reduce friction or to ease penetration.	Borderline with/ Medical Device or Non-medical Device	Medical Device
27.	Medical Oxygen gas	Indication as gases used for medical purposes (examples: oxygen used to help breathing).	Borderline with/ Medical Device or drugs	Non-medical Device
28.	Gingival gel	Indicated use for gingivitis, gingival bleeding and other inflammatory and traumatic conditions where the gingival mucosa requires increase concentration of hyaluronic acid.	Borderline with/ Medical Device or drugs	Medical Device Depends on the mode of action of the active ingredient. If it is physical mode of action then it is a Medical Device. But if it is pharmacological action, the it is classified as medicine.
29.	Contrast Media	Used in radiodiagnostic procedures.	Medical Device Borderline with Medicine	Non-medical Device
30.	Microscope	Used in a variety of fields to view objects or organisms that are not visible with the naked eye. These devices are useful in biology, clinical and medicine to study or analyze specimens, such as bacteria, cells and body tissues.	Medical Device or Non-medical Device	Non-medical Device, if general laboratory purposes Medical Device, if use for IVD, IVF

31.	Centrifuge	A Laboratory device that is used for the separation of fluids, gas or liquid, based on density. Separation is achieved by spinning vessel containing material at high speed; the centrifugal force pushes heavier materials to the outside of the vessel.	Medical Device or Non-medical Device	Non-medical Device, if general laboratory purposes Medical Device, if use for IVD, IVF
32.	Vaccine/ pharmaceutical/ medical refrigerator	Design to store vaccines and other medical products at a stable temperature (prevent temperature fluctuations) to ensure an ideal cold temperature storage for sensitive items due to quality issues and not degrade.	Medical Device or Non-medical Device	Non-medical Device Medical Device if used to refrigerate other Medical Device (blood product)
33.	Control Reagent	A reagent blanks that routinely processed with samples. Laboratories include reagent blanks in the extraction, quantitation, and amplification processes to aid in monitoring potential contamination of reagents and/or supplies.	Medical Device or Non-medical Device	In Vitro Medical Device
34.	Calibrator Reagent	Used in all instruments of measurement to establish a reference point that assists instruments to produce accurate results.	Medical Device or Non-medical Device	In Vitro Medical Device
35.	General purpose reagent such as washing solution, detergent solution, buffer solution	GPRs based on 21 CFR 864.4010 (a) is a chemical reagent that has general laboratory application, that is used to collect, prepare and examine specimens from the human body for diagnostic purposes, and that is not labeled or otherwise intended for a specific diagnostic application.	Medical Device or Non-medical Device	Non-medical Device
36.	Plaster with povidone iodine	A wound dressing with povidone iodine is intended for use as a primary dressing for wounds. This is a dressing type where the povidone iodine additive is permanently bound to the textile substrate. The povidone iodine has antimicrobial activity.	Borderline with/ Medical Device or Non-medical Device	Medical Device
37.	Blood Bank Refrigerator	For channeling and storing liquids for infusion.	Medical Device or Non-medical Device	Medical Device
38.	Hemodialysis Dialysate	Intended use for the exchange of solutes with blood through a semi-permeable membrane in the	Medical Device or Non-medical Device	Medical Device

		dialyser or a haemodialysis system.		
39.	Allograft	a graft of tissue between individuals of the same species but of disparate genotype; types of donors are cadaveric, living-related, and living unrelated.	Medical Device or Biologics	Non-medical Device
40.	Aqueous cream product	As an emollient cream with moisturizing properties to promote healing and relied to the symptoms of skin dryness, impaired barrier function, skin problems/ diseases.	OTC Drug	Depends on the mode of action of the active ingredient. If it is physical mode of action then it is a Medical Device. But if it is pharmacological action, the it is classified as medicine.
41.	Blood bag containing anticoagulant/ preservation agent	To collect and preserve blood and its components (for use with cytapheresis device only) Note: not for direct intravenous infusion.	Medical Device borderline with medicine (Device-drug combination product)	Medical Device
42.	Catheter lock/ Flush solutions (eg: heparinised saline, sodium citrate solution)	As an anticoagulant for use as a catheter lock/ flush solution for flushing off catheters and cannulas to maintain catheter/ cannula patency and to prevent coagulation of blood or infection in the catheter. Note: It is not indicated for therapeutic use, contraindicated for direct systemic administration.	Medical Device	Medical Device
43.	Collagen Haemostatic agents (fibrillary or soft, pliable pad/ sponge or loose fibres)	A sterile, bioabsorbable device derived from animal collagen (eg: bovine or porcine collagen) designed to produce a rapid haemostasis through platelet activation/ aggregation (which initiates the haemostatic cascade leading to a fibrin clot) during a surgical procedure. It is applied directly to the wound where it remains to be absorbed by the specific anatomy/application and does not contain an antimicrobial agent.	Medical Device	Medical Device
44.	Peritoneal dialysis dialysate	It is used for the exchange of solutes across the peritoneum of the patient (in this case,	Drug	Non-medical Device

		used as a semi- permeable membrane).		
45.	Haemodialysis dialysate	It is used for the exchange of solutes with blood through a semi-permeable membrane in the dialyser of a haemodialysis system.	Medical Device	Medical Device
46.	Drug-eluting beads	It is an embolic agent which is intended to be loaded with a chemotherapy agent. Eg: Doxorubicin for the purpose of treatment of malignant hypervascularised tumors by embolization of vesses and occlusion of blood flow supplying malignant hypervascularised tumours and as a secondary action, delivers/elutes a local, controlled sustained dose of the chemotherapy agent directly to the tumours.	Medical Device borderline with medicine. a. if the beads and drug are packaged and sold together, it will be classified as Drug- device combination. b. If the beads are sold separately from the drug, it will be classified as Medical Device	Non-medical Device *Medical Device if the beads are sold separately
47.	Drug-eluting Stents (DES)	For use in angioplasty or coronary stenting procedures.	Medical Device borderline with medicine	Medical Device
48.	Drug-delivery products (eg: insulin prefilled pen/ syringes, asthma inhalers)	To administer pharmacologically active substance.	Medical Device Borderline with Medicine (Drug-device combination product)	Non-medical Device *Medical Device if the devices are sold separately
49.	Enteral Feeding Kit (containing Iodine Pack drug)	A collection of sterile devices that includes tubing and other materials intended to administer nutrient liquids directly into the stomach, duodenum or jejunum of a patient by means of gravity or enteral pump.	Medical Device Borderline with Medicine (Device-drug combination product)	Medical Device
50.	Aqueous/ vitreous humour replacement medium	It is used to assist in performing ophthalmic surgery (eg: to maintain the shape of the eyeball during the intervention, preserve tissue integrity, protect from surgical trauma, or to function as a tamponade during retinal reattachment.	Medical Device	Medical Device
51.	General purpose surgical or barrier drapes	A sterile protective covering made of natural or synthetic materials. To isolate a site of surgical incision or a surgical field from contamination (eg: microbial substance) in various clinical settings. The device may also be used to protect a patient from heat/flame during a surgical procedure.	Medical Device Borderline with Medicine (Device-drug combination product)	Medical Device

52.	General-body orifice lubricant	Lubricant intended to facilitate entry of a diagnostic or therapeutic device into a body orifice by reducing friction between the device and the body; Lubricant during catherisation, probing, endoscopy, changing fistula catheters, intubation and prevention of iatrogenic injuries to the rectum and colon. Eg: ancillary local anaesthetic: lidocaine.	Medical Device Borderline with Medicine (Device-drug combination product)	Medical Device
53.	Heat pad/ cooling pad	To relief aches and pains.	Medical Device	Medical Device
54.	In vivo diagnostic agents	For diagnostic purpose Eg: • X-ray/ MRI contrast media • NMR enhancing agents • Ophthalmic diagnostic agents • Carrier solutions to stabilize microbubbles for ultrasound imaging • Radiopharmaceuticals for diagnostic use	Drug	Non-medical Device
		As diagnostic test kit consists of drug and analyser, example Urea Breath Test.	Medical Device Borderline with Medicine (Drug-device combination product)	The Analyser Instrument is Medical Device The Urea Tablet is Drug
		As diagnostic analyser only (without drug).	Medical Device	Medical Device
55.	Medical gases	To be used in anaesthesia and inhalation therapy, including their primary containers. For in-vivo diagnostic purposes including lung function tests.	Drug	Non-medical Device
56.	Medicinal patch	To relieve fatigue, body aches, joint pains; to regulate hormone imbalance	Drug	Non-medical Device
57.	Preparations (including swabs/ wipes) containing antiseptics/ disinfectants/ antimicrobial substances	Intended for the disinfection of Medical Devices. (eg. alcohol, chlorhexidine, iodine, cetrimide).	Medical Device	Medical Device
58.	Peeling/ Exfoliator product	To improve skin texture due to unaesthetic skin appearance	Cosmetic (Drug)	Non-medical Device

		caused by pigmentation, post acne scars, photo damage, etc. (eg. Products containing glycolic acid and salicylic acid) Note: The ingredient and intended use should comply with the Guidelines for Control of Cosmetic Products in Malaysia.		
59.	Personal intimate hygiene	a. For female/male intimate hygiene Note: The product should be rinsed off. b. For symptomatic relief of vaginal irritation/infections by changing the vaginal pH.	a. Cosmetic (Drug) b. Drug	Non-medical Device
60.	Soft tissue filler/ Dermal filler	To correct cutaneous contour deformities of the skin (e.g., moderate to severe facial wrinkles and folds such as nasolabial folds, scars), particularly in cases of aging or degenerative lesions.	Medical Device Borderline with Medicine (Device drug combination product)	Medical Device
61.	Synthetic fluid tissue reconstructive material	As a submucosal implant in the urinary tract for urinary incontinence or vesicoureteral reflux. It may also be injected into the vocal cords to treat the effects of paralysis, atrophy, or scarring. After application, this device cannot be reused.	Medical Device Borderline with Medicine (Device drug combination product)	Medical Device
62.	Wart Products (eg. pen applicator containing a caustic agent, cyryogenic kit with refrigerant)	a. Containing a caustic agent eg. trichloroacetic acid (TCA) that destroys warts by chemical coagulation of proteins. b. Cryotherapy which destroys warts by freezing them using a very cold substance eg: liquid nitrogen or refrigerant made from dimethyl ether and propane.	a. Drug b. Medical Device	a. Non-medical Device b. Medical Device

63.	Comprising a matrix (e.g. dressing, gauze, swab stick, plaster, sponge)	a. To administer a medicinal substance to the wound e.g.: antimicrobial/ antiseptic agent for the purpose of controlling infection. b. To provide a protective layer/barrier to the wound and prevent microbial penetration and create healing environment. It may incorporate an ancillary medicinal substance e.g.: antimicrobial/ antiseptic agent.	a. Drug b. Medical Device	a. Non-medical Device b. Medical Device
64.	Topical preparation for application to a skin wound (e.g., abrasion, laceration, cut, ulcer)	To facilitate local haemostasis. It is available in various forms (e.g., gel, spray, powder, ointment, plaster/gauze pad) that can be applied directly to the wound where it forms a seal of transparent layer.	Medical Device	Medical Device
65.	Deep cavity wounds dressing for application to a surgical wound	To use as the wound covering material for deep body cavity to reduce the adhesion of surrounding tissues by applying to the surgical area.	Medical Device	Medical Device
66.	Intravascular catheter securement device containing antimicrobial/ antiseptic agent (e.g. chlorohexidine gluconate, CHG)	An intravascular catheter securement device is a device with an adhesive backing that is placed over a needle or catheter and is used to keep the hub of the needle or the catheter flat and securely anchored to the skin. The antimicrobial agent provides ancillary antimicrobial activity to reduce skin colonization and catheter colonization, suppress regrowth of microorganism's, and reduce catheter-related bloodstream infections (CRBSI) in patients with central venous or arterial catheters.	Medical Device Borderline with Medicine (Device-drug combination product)	Medical Device
67.	Surgical apparel	Example: shoe cover, surgical gown/apron, cap.	Medical Device	Medical Device
68.	Equipment cover and Equipment sleeves for operating theatre	To cover equipment for operating theatre.	Not Medical Device	Medical Device
69.	Trolley	A trolley to organize and storing medications and transporting to patient easily/ to transport medicine, instruments and disposable	Not Medical Device	Non-medical Device

		materials/ transport utility/ transport soiled linen/clothing to the laundry.		
70.	Examination stool	Stool for doctors to sit for examination purpose.	Not Medical Device	Non-medical Device
71.	Sleeper chair	A chair framework constructed from tublar steel and with pvc upholstery. Can be converted from a chair to a sleeper unit for sitting and temporary sleeping for hospital visitors.	Not Medical Device	Non-medical Device
72.	Urinary bottle holder	Stainless steel framework to hold urinal bottle.	Not Medical Device	Non-medical Device
73.	Dental bib	Dental cover for patient's body.	Not Medical Device	Non-medical Device
74.	Identity band, markers, padlock security tags, container label	For tagging purpose, time markers is used to follow the precise part of food through the entire GI tract and specifically in the bowel, whist, not influencing the performance of normal gastric and intestinal function, for surgical instrument container.	Not Medical Device	Non-medical Device
75.	Cart	Example: Medical cart, laundry cart, linen cart.	Not Medical Device	Non-medical Device
76.	Dental aprons		Not Medical Device	Non-medical Device
77.	Reclining chairs	Chairs for visitors and patient to rest.	Not Medical Device	Non-medical Device
78.	Plaster with Silver	It is used for sterilizing & protecting contamination of a wound site such as pressure ulcers, leg ulcer, diabetic ulcer, traumatic wounds, lacerations, donor and graft sites, burns, post-operative wound, and venous stasis ulcer.	Drug	Medical Device
79.	Test equipment's and refills	The equipment's and refills are for QC purpose.	Medical Device	Non-medical Device
80.	Sterilization Indicator	Sterilization indicator as accessories Example: steam sterilization, concentration of peracetic acid/ Peroxide.	Medical Device	Medical Device (Accessory)
81.	IVD Purpose Benchtop incubator	For cell culture purpose, only for IVD purpose.		Medical Device
82.	CPAP Mask Wipes	CPAP, or continuous positive airway pressure, is a treatment that uses mild air pressure to keep the airways open. CPAP typically is used by people who have breathing problems, such as sleep apnea.	Medical Device	Medical Device if it is use for disinfecting

		CPAP also may be used to treat preterm infants whose lungs have not fully developed. The Wipes is use to disinfect the CPAP mask.		
83.	Ward screening	To provide temporary or permanent privacy solution.	Not Medical Device	Non-medical Device
84.	Lice comb	To remove lice and lice eggs from human hair.	Medical Device	Non-medical Device
85.	Invasive blood pressure accessories	The invasive blood pressure adapter cables are intended to be used for connecting one or two invasive blood pressure transducers to get medical systems information technologies and datex-ohmeda monitoring equipment requiring rectangular 11-pin connector cable.	Medical Device	Medical Device
86.	Mayo table	Surgical mayo instrument stand.	Not Medical Device	Non-medical Device
87.	Lichensed Adult Syrup	Lichensed adult syrup acts as a barrier by creating a protective film that soothes a cough and protect the airway.	Drug	Non-medical Device
88.	Monitor cable	To connect the disposable pressure transducer to the patient monitor.	Medical Device	Medical Device System Accessory
89.	Cold laser therapy	Treatment of pain management, accelerate healing.	Medical Device	Medical Device
6th AMDTC				
90.	Diapers		Medical Device or Non-medical Device	Non-medical Device
91.	Milk bottle and Nipple		Medical Device or Food	Non-medical Device
92.	Breastmilk storage and freezing bags		Medical Device or Food	Non-medical Device
93.	Pacifiers		Medical Device or Non-medical Device	Non-medical Device
94.	Disposable breast pad		Medical Device or Non-medical Device	Non-medical Device
95.	Nasal Aspirator		Medical Device or Non-medical Device	Medical Device
96.	Urine bags and vomit in children or adults	Incorporation into a deodorant gel can be used at home or outdoors, disposable.	Medical Device or Non-medical Device	Non-medical Device
97.	Glasses frames	Glasses frames without lenses.	Medical Device or Non-medical Device	Non-medical Device

		Glasses frames that come with lens but no power.	Medical Device or Non-medical Device	Non-medical Device
98.	Sunglasses	Sunglasses that come with lens but no power.	Medical Device or Non-medical Device	Non-medical Device
99.	Spectacle lens has no power		Medical Device or Non-medical Device	Non-medical Device
100.	Semi-finished spectacle lens blank		Medical Device or Non-medical Device	Non-medical Device
101.	Powered contact lens	Soft and hard lens.	Medical Device	Medical Device
102.	Disinfecting Lens care solution		Medical Device or drug	Medical Device
103.	Ophthalmic Viscosurgical Device (OVD)	It contains substances with viscosity properties such as Sodium hyaluronate, Chondroitin sulfate, Hydroxypropylmethylcellulose (HPMC).	Medical Device or drug	Medical Device
104.	Keratome blade	For eye surgery.	Medical Device	Medical Device
105.	The eye surgery simulator	For education or lesson.	Medical Device or Non-medical Device	Non-medical Device
106.	Colour blindness tests	For diagnostic colour blindness.	Medical Device or Non-medical Device	Medical Device
107.	Optical lens manufacturing machine		Medical Device or Non-medical Device	Non-medical Device
108.	Lensmeter	Use by employee inspection department template at the lens manufacturing plant.	Medical Device or Non-medical Device	Non-medical Device
109.	Autopsy table, Autopsy saws, Morgue refrigerator, Body bag		Medical Device or Non-medical Device	Non- medical Device
110.	Sterile blood bag	Sterile empty blood bag.	Medical Device or Drug	Medical Device
111.	Collection blood tube	Empty collection blood tube.	Medical Device	Medical Device
		Collection blood tube with anticoagulation.	Medical Device or Drug	Medical Device
112.	Plasma Freezer, Blood product freezer		Medical Device or Non-medical Device	Medical Device
113.	Haematocrit Centrifuge	Spin the specimen from the human and obtain information from medical examinations or diagnostic purposes.	Medical Device or Non-medical Device	Medical Device
	Centrifuge for IVD	Spin the specimen from the human body.	Medical Device or Non-medical Device	Medical Device

114.	Platelet Additive Solution	To replace the plasma portion of the preparation and storage buffy coat- derived platelet concentrate orapheresis platelet units. To feed and maintain the condition of platelets.	Medical Device or Drug	Medical Device
115.	White blood cell type T-lymphocyte counting reagent	Used in conjunction with hematologic analytical automation.	Medical Device or Non-medical Device	Medical Device
116.	Control Solution	Control substances used to verify the accuracy of Medical Devices.	Medical Device or Non-medical Device	Medical Device if it is use for IVD
117.	Pedometer	Walking motion detector or step counter and tell the amount of energy and fat that is metabolized or tell the distance and time between walking or calorie processing used to plan a diet.	Medical Device or Non-medical Device	Non-medical Device
118.	Wristwatch	Measure heart rate, steps, body fat, Breathing rate/respiratory rate, mood, stress, deep sleep while exercising or daily life and not for medical purposes.	Medical Device or Non-medical Device	Non-medical Device
		Measure oxygen saturation, blood glucose, blood pressure, body temperature, ECG sensor.	Medical Device or Non-medical Device	Medical Device
119.	Treadmill	For exercise/ In fitness.	Medical Device or Non-medical Device	Non-medical Device
		For diagnostic cardiovascular.	Medical Device or Non-medical Device	Medical Device
120.	Bone cement		Medical Device or Drug	Medical Device
121.	Antibiotic Bone cement	Antibiotics such as Gentamicins.	Medical Device or Drug	Medical Device
122.	Vacuum Splint Kit	Prevents bones moving.	Medical Device	Medical Device
123.	Back support	Prevent back pain and bones move if bent or lift heavy or wrong for medical purposes.	Medical Device or Non-medical Device	Medical Device
7th AMDTC				
124.	X-ray and Gamma Radiation Personal Dosimeter	For safety in work areas with radiation, such as radiation laboratory.	Medical Device or Non-medical Device	Non-medical Device
125.	X-ray Monitor	Both static animated images in color and monochrome images from various medical instruments such as CT Scan, MRI, Digital Mammogram, Ultrasound, PET Scan.	Medical Device or Non-medical Device	Medical Device

		Technical radiation is a visual validator. Radiologist is the reader with the interpretation of the image. And the doctor is the viewer. With the results of the examination. Analysis to plan for further treatment.		
126.	X-ray protective clothing such as Gown, Aprons, Collar, Glasses, Gloves	Use of industrial radiation protection.	Medical Device or Non-medical Device	Non-medical Device
127.	Shield protects radio waves from external environment into the diagnostic room.	To prevent radio interference from MRI, Used to provide the right place or environment for the MRI machine.	Medical Device or Non-medical Device	Non-medical Device
128.	Pastille or spray for people with symptoms hyposalivation or xerostomia used in conjunction with treatment mucositis due to radiation or high doses of chemotherapy.	To help moisturize, moisturize and cleanse the mouth for people with dry mouth. The mechanism of physical action.	Medical Device or Drug	Medical Device
129.	Dressing to reduce inflammation such as dry, itching, flaking, peeling irritated, pain, redness, heat from radiation therapy or first and second degree burns	The cover helps to keep the wound healed faster and mechanism is physical action.	Medical Device or Cosmetics	Medical Device
130.	Metal Detector, Seal Inspection, Weigh Inspection	Used in various industries such as medicine, food, cosmetics, medical equipment, automotive, plastics, etc.	Medical Device or Non-medical Device	Non-medical Device
131.	Facial imaging equipment	Device to check the condition such as oily skin or dry skin.	Medical Device or Non-medical Device	Non-medical Device
132.	Skin detector equipment	To see the size, pores, skin color, wrinkles, dryness, dark spots, and to be used as a guide to use cosmetics for cosmetic customers.	Medical Device or Non-medical Device	Non-medical Device
133.	Machine or device that has a brush or sponge (puff) that can rotate or shake	Use cleaning polish or for spread out of cream.	Medical Device or Non-medical Device	Non-medical Device

134.	Machine or equipment sprayed on water or mineral water	To keep the face moist.	Medical Device or Non-medical Device	Non-medical Device
135.	Products using BIA (Bioelectrical Impedance Analysis) working principle	Body measuring instrument It is intended for measuring and analyzing body composition such as body weight, fat mass, muscle mass Total body weight, body mass index, body fat percentage, body fat. The body's metabolic rate, waist to hip ratio. Body age estimate Compare the age of the body Exercise plan. Without a medical purpose or diagnosis.	Medical Device or Non-medical Device	Non-medical Device
136.	Motion Capture System	To record human movements, animals and inanimate objects. To study movement 3D animation simulation used in the entertainment industry, such as movies, movies, games, sports industry.	Medical Device or Non-medical Device	Non-medical Device
137.	Baraku, Electronic Baraku, Electronic Cigarette		Medical Device or Non-medical Device	Non-medical Device
138.	Medical mask, Surgical Mask, Surgical respirators	For medical use.	Medical Device or Non-medical Device	Medical Device
139.	Disposable mask for Industry, Firefighter mask, Disposable dust mask	Not for medical use.	Medical Device or Non-medical Device	Non-medical Device
140.	Nasal Strips	Expansion of respiratory tract makes breathing easier to reduce snoring.	Medical Device or Non-medical Device	Medical Device
141.	wrist strap, ankle strap	To specify the details of the patient or infant, such as surname, date of treatment, etc.	Medical Device or Non-medical Device	Non-medical Device
142.	Insoles or contain activated charcoal	Put on a shoe to keep your feet comfortable or reduce unwanted odors.	Medical Device or Non-medical Device	Non-medical Device
143.	Heel liners	Prevent bite shoes or to tighten. Without a purpose for medical use.	Medical Device or Non-medical Device	Non-medical Device
144.	Foot cushion	Supports shock and friction caused by foot pressure. Without a purpose for medical use.	Medical Device or Non-medical Device	Non-medical Device

145.	Tools or equipment for measuring the size and shape of individual feet	It is used to cut shoe or shoe to fit each foot.	Medical Device or Non-medical Device	Non-medical Device
146.	Blade for shaving, Epilator hair removal, Temporary hair removal, Shaver, Machine or wax melting pot used to remove hairs		Medical Device or Non-medical Device	Non-medical Device
147.	Suture Needle for wound closer		Medical Device or Non-medical Device	Medical Device
148.	Suture Needle for lifting	For lifting face, chin, body, etc.	Medical Device or Non-medical Device	Medical Device
149.	Tattoo Machine	For cosmetics or for belief or religion.	Medical Device or Non-medical Device	Non-medical Device
150.	Tattoo Needles, Tattoo Ink	For cosmetics or for belief or religion.	Medical Device or Non-medical Device	Non-medical Device
151.	Piercing Needles, Clamping device, grab jewelry	Use to pierce the ear, nose, mouth, tongue, navel, nipple or other areas to wear jewelry. And for beauty or for belief or religion.	Medical Device or Non-medical Device	Non-medical Device
152.	Ambulance, Emergency Vehicle, Mobile Medical Check-up Vehicle, Mobile X-Ray Vehicle, Mobile Dental Vehicle, Mobile Laboratory Vehicle		Medical Device or Non-medical Device	Non-medical Device
153.	The sheet or device records the time and temperature of the environment surrounding the product while it is being shipped.	For information on how to keep the product from damage from high or low temperatures.	Medical Device or Non-medical Device	Non-medical Device
154.	Massage Bath Tub	Used in entertainment type massage parlor. To entertain or relax the user.	Medical Device or Non-medical Device	Non-medical Device
155.	Couch	For sleep to support the face. Body massage or for beauty.	Medical Device or Non-medical Device	Non-medical Device

156.	Swimming Pool Spa and Outdoor Spa	The pump system. Heating system water pressure system, ozone system, fountain system, music and LED lights are intended for soaking water to massage the body and help to relax. And can create atmosphere with music and light. Available at home, spa, clinic, hospital.	Medical Device or Non-medical Device	Non-medical Device
157.	Disposable urinal	Urine bags are disposable. To use while traveling Stay overnight for general people, patient or disabled.	Medical Device or Non-medical Device	Non-medical Device
158.	Thermometer in sauna	Installed in sauna to measure temperature.	Medical Device or Non-medical Device	Non-medical Device
159.	Hygrometer in sauna	Installed in Sauna Room to measure relative humidity.	Medical Device or Non-medical Device	Non-medical Device
160.	Motorized bed	For sleeping at home adjustable height, up, adjust the head or leg lift.	Medical Device or Non-medical Device	Non-medical Device
161.	Electric scooter	For driving to facilitate short trips. Used in places such as home, office, shopping mall, Exhibition Center Park.	Medical Device or Non-medical Device	Non-medical Device
162.	Surgical warming blanket	Used to warm patients during surgery.	Medical Device or Non-medical Device	Medical Device
163.	Heated underblanket	Use it on the mattress and cover sheets to make it. Mattress on warm bed Used in cold weather. Without the purpose of medical use.	Medical Device or Non-medical Device	Non-medical Device
164.	Thermal overblanket	Electric fields and magnetic fields within the product release heat to warm the body. Used in cold weather. Without the purpose of medical use.	Medical Device or Non-medical Device	Non-medical Device
165.	Temperature Boiler	Connect with the mattress to adjust the temperature of the mattress to warm up. Used in cold weather.	Medical Device or Non-medical Device	Non-medical Device
166.	Hot pad or Hot bag	Put on clothes Under the socks to warm the body. Suitable for those who need warmth in cold weather. Or those who play winter sports without the purpose of medical applications.	Medical Device or Non-medical Device	Non-medical Device
167.	Application - Body fat	Not for medical purpose.	Medical Device or Non-medical Device	Non-medical Device

168.	Models, Simulators and Medical Skills Training Products	The product is not actually available in patients or those with abnormalities.	Medical Device or Non-medical Device	Non-medical Device
169.	Microscope to see the tissue of the human body	Especially to diagnose diseases or injuries of humans.	Medical Device or Non-medical Device	Medical Device
170.	The microscope to see size, quantity and visualizes the internal structure of a small object.	For study or research such as cell, tissue, wood, rock, mineral, animal secretion, foam, snow, sample metal from the culture plate, plant, insect, small animal.	Medical Device or Non-medical Device	Non-medical Device
171.	Product cover on microscope to prevent moisture.	To prevent moisture that causes fungus in the microscope.	Medical Device or Non-medical Device	Non-medical Device
172.	Electronic Tables	Electrical equipment or items use in hospitals, clinics or other places.	Medical Device or Non-medical Device	Non-medical Device
173.	Medicine Trolley, UD Dose Cart	To distribute medicine to each patient.	Medical Device or Non-medical Device	Non-medical Device
174.	Mobile Computer Cart	Can be moved to other places used in hospitals, clinics, offices.	Medical Device or Non-medical Device	Non-medical Device
175.	Device for patient or central pipeline system.	Flowmeter, Humidifier, Nebulizer, Suction Tube, Nasogastric Tube, Suction for Surgical Room	Medical Device or Non-medical Device	Medical Device
		8th AMDTC		
176.	Anti-virus patch	Intended to be attached to cellphones, IDs, bags, etc. The device releases chlorine dioxide that eliminates respiratory viruses. Hence, preventing virus transmission.	Medical Device or Non-medical Device	Non-medical Device
177.	Rectal Cream/ Suppository	Intended to soothes and moisturize the perianal area, relieves and rejuvinates common signs of hemorrhoids, and relieve burning sensation or itchiness in the problematic area. NOTE: No drug components only emollient, emulsifying and film forming materials such as stearic acid, hipericum oil and beeswax.	Medical Device or Non-medical Device	Medical Device
178.	Pimple patch	With hydrocolloid technology to conceal the pimple, helps avoid bacterial contact, helps to dry out and flatten the surface level of the acne.	Medical Device or Non-medical Device	Medical Device

		Note: components are, sodium carboxycellulose, elastomer, dioctyl adipate, hydrogenated petroleum resin.		
179.	Diamond impregnated stone for trimming, zirconia polishers, polisher disc, CAD/CAM miling burss, milling unit, ultra vaccum, grind control basic unit	Intended to be used in the dental laboratory by a laboratory technician for the manufacture of dentures, crowns, and bridges.	Medical Device or Non-medical Device	Non-medical Device
180.	Oxygen recreational	Use supplemental recreational oxygen to help recover from stress in the body due to exertion. The oxygen seems to help recovery, give more stamina, and provide an energy boost when needed.	Medical Device or Non-medical Device	Non-medical Device
9th AMDTC				
181.	Medical drape	To be put on treatment table or bed during operation procedure and to prevent transfer of microorganisms, fluids and particles to the patients.	MD or non-MD	Medical Device
182.	Mattress	Combine a specific foam density with a nominal hardness that optimises pressure reduction and improves circulation and quality of sleep.	Medical Device or Non-Medical Device	Non-Medical Device
183.	Therapressure brush	To decrease the state of arousal (calm), normalize responses to touch, help the child relax and become more aware of his/her body to improve attention and purposeful movements.	Medical Device or Non-Medical Device	Non-Medical Device
184	Portable oxygen spray	Recreational portal canned oxygen can help improve stamina, increase endurance, and help muscles recover faster from soreness and fatigue.	Medical Device or Non-Medical Device	Non-Medical Device
185.	Air purifier	Air purifier that traps and eliminates bacteria and viruses found in the air, effectively reducing the risk of secondary infection and airborne transmission. For home use.	Medical Device or Non-Medical Device	Non-Medical Device
186.	Smartwatch	Measure skin temperature (only area that contact with	Medical Device or	Non-Medical Device

		smartwatch). Not intend to use for diagnostic or medical purpose.	Non-Medical Device	
10th AMDTC				
187.	Strip to check saliva acidity	To measure saliva acidity for diagnosis of teeth caries.	Medical Device or Non-Medical Device	Medical Device
188.	Microtube	Empty specimen container for centrifuge and PCR.	Medical Device or Non-Medical Device	Medical Device for IVD use Non-Medical Device for laboratory use
189.	Solution contains Trichloroacetic Acid (TCA)	Face skin peeling, removal of death cell.	Medical Device or Non-Medical Device	Non-Medical Device
190.	Solution contains lactic acid, glycolic acid, and salicylic acid	Face skin peeling, removal of death cell.	Medical Device or Non-Medical Device	Non-Medical Device
191.	3D Printer	To produce orthodontic models. For dental laboratory use.	Medical Device or Non-Medical Device	Non-Medical Device
		To fabricate Custom-Made Bones from non-degradable materials such as polymer or titanium.	Medical Device or Non-Medical Device	Non-Medical Device
		3D bioprinter - fabricate a dermal patch graft to treat scarred lesions from biomaterial such as patient's autologous tissues and cells.	Medical Device or Non-Medical Device	Non-Medical Device
192.	Allograft bone	Intended for replacement of damaged bone/ transplantation from: 6.1 morselized frozen bone 6.2 frozen bone 6.3 freeze-dried bone	Medical Device or Non-Medical Device	Non-Medical Device
193.	Device for production of acidic dialysis concentrate solution	Device contains the hemodialysis powder that is mixed with RO water and transferred to the storage tanks ready to be fed directly to the hemodialysis machines for the patient.	Medical Device or Non-Medical Device	Medical Device
194.	Equipment that releases Negative Ions	Intended for treatment of menstrual cramps, balance hormones, treatment of glaucoma.	Medical Device or Non-Medical Device	Medical Device
11th AMDTC				
195.	Heating & cooling massager	39°C heating mode helps to improve skin circulation and cleanse skin residues deeply by opening pores.	Medical Device or Non-Medical Device	Non-Medical Device

		36°C booster mode helps skin absorption of cosmetic with micro vibration. 13°C cooling mode makes your skin lower temperature immediately and keeps the optimal skin temperature. 5°C tightening mode with cold massage. Shrinks pores and makes skin elastic.		
196.	Antibacterial Surface Coating (Not for Medical Device coating)	Disinfection coating for surfaces, the material is silver or copper.	Medical Device or Non-Medical Device	Non-Medical Device
197.	Wound Antiseptics	Topical antiseptic wound cleansers aim to prevent infection due to wounds of the skin.	Medical Device or Non-Medical Device	Non-Medical Device
198.	Air disinfectant (hospital use)	Air cleaning liquid (disinfectant) which can be used by spraying it into the air so that it forms smoke or mist.	Medical Device or Non-Medical Device	Non-Medical Device
12th AMDTC				
199.	Software	1.1 Standalone software that intended to display, receive, collect, and store health data (such as blood pressure, blood glucose) with no processing or analysis for wellness.	Medical Device or Non-Medical Device	Non-Medical Device
		1.2 Standalone software that intended to collect patient medical data by connected directly with medical device and transmit the patient medical data to a doctor/physician for further consideration without processing and analyzing the data.	Medical Device or Non-Medical Device	Non-Medical Device
		1.3 Standalone software that intended to collect patient medical data by not connect to medical device (e.g. filling the information by user) and transmit the patient medical data to a doctor/physician for further consideration without processing and analyzing the data.	Medical Device or Non-Medical Device	Non-Medical Device
200.	Electronic cigarette	An electronic cigarette is an electronic device that simulates tobacco smoking.	Medical Device or Non-Medical Device	Non-Medical Device

201.	Sex toy	An object or device used for sexual stimulation or to enhance sexual pleasure.	Medical Device or Non-Medical Device	Non-Medical Device
202.	Telecare Alarm System	Intended to detect fall from hospital bed, general bed and alert to Central Monitoring Station e.g. hospital, elderly care, owner company.	Medical Device or Non-Medical Device	Non-Medical Device
203.	Fall Detection Devices	Wearable sensor devices (e.g. smartwatch, band) or ambient sensor device intended for fall detection.	Medical Device or Non-Medical Device	Non-Medical Device
204.	Phantom for Quality Assurance of Radiological Product	Intended as radiotherapy quality assurance for determination radiation dose from Medical linear accelerator (LINAC), Intended for calibration of the product.	Medical Device or Non-Medical Device	Non-Medical Device
13th AMDTC				
205.	Nasal Spray	Intended to be used for nasal cleaning containing deep sea salt water.	Medical Device or Non-Medical Device	Medical Device
206.	Wound cover gel/cream	Containing hyaluronic acid or sodium hyaluronate and has the following effects: Covering acute and chronic wounds (first and second degree burns, vascular and metabolic ulcers and pressure ulcers) and provide a moist wound environment free of bacteria.	Medical Device or Non-Medical Device	Medical Device
14th AMDTC				
207.	Reverse osmosis equipment	used in hemodialysis water treatment systems: produces water to dilute concentrates used in hemodialysis.	Medical Device or Non-Medical Device	Medical Device
208.	Sprays and creams help prolong sexual intercourse	The product does not contain pharmaceutical ingredients, containing Oat Amino Acids, Aloe Vera, Alfalfa Extract, Borago Officinalis Extract, Chamomile Extract, Clove Essential Oil.	Medical Device or Non-Medical Device	Non-Medical Device
209.	Dermal implant	For Treatment of facial contour deformities (such as asymmetry treatment) in case of tissue loss by accident or disease, to add volume into facial dermis for treatment of facial lipoatrophy. Contains PDO polydioxanone.	Medical Device or Non-Medical Device	Medical Device
210.	Nitric oxide Nasal spray	-an active barrier that shields and protects from airborne viruses found often in circulated air in open spaces, planes, trains, large shopping	Medical Device or Non-Medical Device	Medical Device

		centre and public transportation. -Use as a protective mechanical barrier against viruses within the nasal cavity.		

MEDICAL DEVICE AUTHORITY

MINISTRY OF HEALTH, MALAYSIA

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