

**PRELIMINARY LIST OF BORDERLINE/ MD OR NON MD CLASIFICATION OF MEDICAL DEVICE**

Harmonized

<b>NO.</b>	<b>PRODUCT NAME</b>	<b>DESCRIPTION</b>	<b>Borderline with/ MD or non MD</b>	<b>AMDTC Decision</b>
5 <sup>th</sup> 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 Product Owner 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 Product Owner 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

NO.	PRODUCT NAME	DESCRIPTION	Borderline with/ MD or non MD	AMDTC Decision
				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, parasympatholytics, prostaglandins, non steroisal anti-inflammatory drugs (NSAIDs), antibiotics, antifungal or	Medical Device Borderline with Medicine	Medical Device if specifically intended to be used for lubricating, disinfecting, cleaning, rinsing or, when appropriate, hydrating contact

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		topical anesthetics. Eye drops sometimes do not have medications in them and are only lubricating and tear-replacing solution.		lenses 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	A therapeutic tool which can generate vibration waves, can help	Medical Device or non Medical Device	Medical Device

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	Stimulator	reduce and relieve aches and fatigue on the body.		
10.	Bed Matres	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/ MD or non MD	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/ MD or non MD	Medical Device
13.	Laser	Used to treat skin disorders and providing tangible cosmetic alterations to the skin	Borderline with/ MD or non MD	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/ MD or non MD	Medical Device
15.	Admission Kit	Intended use during admission in the hospital. Contains, towel, toothbrush, glass, measuring cup, medicine cup, etc.	Borderline with/ MD or consumer products	Non Medical Device
16.	Gadgets (ex. Cellphone) with	Cellphones are being used in the telecommunication with	Borderline with/ MD or non MD	Non Medical Device

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	health and medical applications	applications in health monitoring such as heart rate		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/ MD or drugs	Non Medical Device  Medical Device , if there are no biological/pharmacological/metabolic 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 MD or non Md	Non Medical Device , if General Laboratory Purposes  Medical Device , if use for IVD, IVF
19.	Laboratory products (pipettes, graduated	Intended use for the preparation of specimen, aspirating and dispensing	Borderline with MD or not MD	Non Medical Device , if General

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	cylinder, slides, beakers, etc.)	specific volumes in the microlitre scale		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/ MD 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/ MD or non MD	Medical Device , if intended for disinfecting Medical Device s
22.	Hand Gloves	The intended use is to reduce bacterial transfer	Borderline with/ MD or non MD	Medical Device if with medical purpose
23.	Mobile application for the communication	This application allows storing data on each moment of contraction during delivery.	Borderline with/ MD or non MD	Non Medical Device

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	between patient and caregivers while giving birth			
24.	Software for information management and patient monitoring	Intended to route and store Medical Device data	Borderline with/ MD or non MD	Medical Device if used to monitor the patient data.  Non MD if used only for data storage.
25.	Wound treatment products	Intended use to treat wounds.	Borderline with/ MD or drugs	Medical Device
26.	Lubricant	Intended use to reduce friction or to ease penetration	Borderline with/ MD or non MD	Medical Device
27.	Medical Oxygen gas	Indication as gases used for medical purposes (examples: oxygen used to help breathing)	Borderline with/ MD 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/ MD 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

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				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	Medical Device or non Medical Device	Non Medical Device  Medical Device if used to refrigerate



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		items due to quality issues and not degrade.		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	Borderline with/ MD or non MD	Medical Device

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		a dressing type where the povidone iodine additive is permanently bound to the textile substrate. The povidone iodine has antimicrobial activity.		
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 dialyser or a haemodialysis system	Medical Device or non Medical Device	Medical Device
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 relief 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, then it is classified as

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				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	Medical Device	Medical Device

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		remains to be absorbed by the specific anatomy/application and does not contain an antimicrobial agent		
44.	Peritoneal dialysis dialysate	It is used for the exchange of solutes across the peritoneum of the patient (in this case, used as a semi-permeable membrane)	Drug	Non Medical Device
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 vessels 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 classified as Drug-device combination. b. If the beads are sold separately from the drug, it will 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	Medical Device

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			medicine	
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	Medical Device Borderline with Medicine (Device-drug combination product)	Medical Device

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		<p>substance) in various clinical settings. The device may also be used to protect a patient from heat/flame during a surgical procedure.</p>		
52.	General-body orifice lubricant	<p>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 catheterisation, probing, endoscopy, changing fistula catheters, intubation and prevention of iatrogenic injuries to the rectum and colon. Eg: ancillary local anaesthetic: lidocaine</p>	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	<p>For diagnostic purpose Eg: - X-ray/ MRI contrast media - NMR enhancing agents - Ophthalmic diagnostic agents - Carrier solutions to stabilize microbubbles for ultrasound imaging</p>	Drug	Non Medical Device

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		- Radiopharmaceuticals for diagnostic use		
		As diagnostic test kit consist 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	a. To be used in anaesthesia and inhalation therapy, including their primary containers  b. 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 Device s. (eg. alcohol, chlorhexidine, iodine, cetrimide)	Medical Device	Medical Device

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58.	Peeling/ Exfoliator product	To improve skin texture due to unaesthetic skin appearance 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.	Cosmetic (Drug)	Non Medical Device
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	Medical Device Borderline with Medicine (Device drug	Medical Device



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		<p>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.</p>	combination product)	
62.	Wart Products (eg. pen applicator containing a caustic agent, cryogenic kit with refrigerant)	<p>a. Containing a caustic agent eg. trichloroacetic acid (TCA) that destroys warts by chemical coagulation of proteins.</p> <p>b. Cryotherapy which destroys warts by freezing them using a very cold substance eg: liquid nitrogen or refrigerant made from dimethyl ether and propane.</p>	<p>a. Drug</p> <p>b. Medical Device</p>	<p>a. Non Medical Device</p> <p>b. Medical Device</p>
63.	Comprising a matrix (eg. dressing, gauze, swabstick, plaster, sponge)	<p>a. To administer a medicinal substance to the wound eg: antimicrobial/ antiseptic agent for the purpose of controlling infection.</p> <p>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 eg: antimicrobial/</p>	<p>a. Drug</p> <p>b. Medical Device</p>	<p>a. Non Medical Device</p> <p>b. Medical Device</p>

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		antiseptic agent.		
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	Medical Device Borderline with Medicine (Device-drug combination product)	Medical Device

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		arterial catheters.		
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 materials/ transport utility/ transport soiled linen/clothing to the laundry	Not Medical Device	Non Medical Device
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	For tagging purpose, time markers is used to follow the precise part of	Not Medical Device	Non Medical Device

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	security tags, container label	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		
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

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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. CPAP also may be used to treat preterm infants whose lungs have not fully developed. The Wipes is use to disinfect the CPAP mask.	Medical Device	Medical Device if it is use for disinfecting
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	Drug	Non Medical Device

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		that soothes a cough and protect the airway.		
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
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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,	Medical Device or non-Medical Device	Non-Medical Device

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		disposable.		
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	Medical Device or drug	Medical Device

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		(HPMC)		
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	Medical Device or	Medical Device



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		anticoagulation	Drug	
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	Medical Device or	Non-Medical

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		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.	non-Medical Device	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

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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
7 <sup>th</sup> AMDTC				
124.	X-ray and Gamma Radiation Personal Dosimeter	For safety in work areas with radiation, such as radiation laboratory.	MD or non-MD	Non-Medical Device
125.	<i>X-ray Monitor</i>	Both static animated images in color and monochrome images from various medical instruments such as CT Scan, MRI, Digital Mammogram, Ultrasound, PET Scan. 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.	MD or non-MD	Medical Device
126.	<i>X-ray protective clothing such as Gown, Aprons, Collar, Glasses, Gloves</i>	<i>Use of industrial radiation protection</i>	<i>MD or non-MD</i>	<i>Non-Medical Device</i>

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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.	MD or non-MD	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.	MD 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.	MD 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.	MD or Non-MD	Non-Medical Device

<b>NO.</b>	<b>PRODUCT NAME</b>	<b>DESCRIPTION</b>	<b>Borderline with/ MD or non MD</b>	<b>AMDTC Decision</b>
131.	Facial imaging equipment	Device to check the condition such as oily skin or dry skin	MD or Non-MD	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.	MD or Non-MD	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	MD or Non-MD	Non-Medical Device
134.	Machine or equipment sprayed on water or mineral water	To keep the face moist	MD or Non-MD	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.	MD or Non-MD	Non-Medical Device

<b>NO.</b>	<b>PRODUCT NAME</b>	<b>DESCRIPTION</b>	<b>Borderline with/ MD or non MD</b>	<b>AMDTC Decision</b>
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.	MD or Non-MD	Non-Medical Device
137.	Baraku, Electronic Baraku, Electronic Cigarette		MD or Non-MD	Non-Medical Device
138.	Medical mask, Surgical Mask, Surgical respirators	For medical use	MD or Non-MD	Medical Device
139.	Disposable mask for Industry, Firefighter mask, Disposable dust mask	Not for medical use	MD or Non-MD	Non-Medical Device
140.	Nasal Strips	Expansion of respiratory tract makes breathing easier to reduce snoring	MD or Non-MD	Medical Device
141.	wrist strap, ankle strap	To specify the details of the patient or infant, such as surname, date of treatment, etc.	MD or Non-MD	Non-Medical Device
142.	Insoles or contain activated charcoal	Put on a shoe to keep your feet comfortable or reduce unwanted odors.	MD or Non-MD	Non-Medical Device

<b>NO.</b>	<b>PRODUCT NAME</b>	<b>DESCRIPTION</b>	<b>Borderline with/ MD or non MD</b>	<b>AMDTC Decision</b>
143.	Heel liners	Prevent bite shoes or to tighten. Without a purpose for medical use.	MD or Non-MD	Non-Medical Device
144.	Foot cushion	Supports shock and friction caused by foot pressure. Without a purpose for medical use.	MD or Non-MD	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	MD or Non-MD	Non-Medical Device
146.	Blade for shaving, Epilator hair removal, Temporary hair removal, Shaver, Machine or wax melting pot used to remove hairs		MD or Non-MD	Non-Medical Device
147.	Suture Needle for wound closer		MD or Non-MD	Medical Device
148.	Suture Needle for lifting	For lifting face, chin, body, etc.	MD or Non-MD	Medical Device
149.	Tattoo Machine	For cosmetics or for belief or religion	MD or Non-MD	Non-Medical Device
150.	Tattoo Needles, Tattoo Ink	For cosmetics or for belief or religion	MD or Non-MD	Non-Medical Device

<b>NO.</b>	<b>PRODUCT NAME</b>	<b>DESCRIPTION</b>	<b>Borderline with/ MD or non MD</b>	<b>AMDTC Decision</b>
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	MD or Non-MD	Non-Medical Device
152.	Ambulance, Emergency Vehicle, Mobile Medical Check-up Vehicle, Mobile X-Ray Vehicle, Mobile Dental Vehicle, Mobile Laboratory Vehicle		MD or Non-MD	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.	MD or Non-MD	Non-Medical Device
154.	Massage Bath Tub	Used in entertainment type massage parlor. To entertain or relax the user.	MD or Non-MD	Non-Medical Device
155.	Couch	For sleep to support the face. Body massage or for beauty	MD or Non-MD	Non-Medical Device



<b>NO.</b>	<b>PRODUCT NAME</b>	<b>DESCRIPTION</b>	<b>Borderline with/ MD or non MD</b>	<b>AMDTC Decision</b>
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.	MD or Non-MD	Non-Medical Device
157.	Disposable urinal	Urine bags are disposable. To use while traveling Stay overnight for general people, patient or disabled	MD or Non-MD	Non-Medical Device
158.	Thermometer in sauna	Installed in sauna to measure temperature.	MD or Non-MD	Non-Medical Device
159.	Hygrometer in sauna	Installed in Sauna Room to measure relative humidity.	MD or Non-MD	Non-Medical Device
160.	Motorized bed	For sleeping at home adjustable height, up, adjust the head or leg lift.	MD or Non-MD	Non-Medical Device
161.	Electric scooter	For driving to facilitate short trips. Used in places such as home, office, shopping mall, Exhibition Center Park	MD or Non-MD	Non-Medical Device
162.	Surgical warming blanket	Used to warm patients during surgery.	MD or Non-MD	Medical Device
163.	Heated underblanket	Use it on the mattress and cover	MD or Non-MD	Non-Medical

<b>NO.</b>	<b>PRODUCT NAME</b>	<b>DESCRIPTION</b>	<b>Borderline with/ MD or non MD</b>	<b>AMDTC Decision</b>
		sheets to make it. Mattress on warm bed Used in cold weather. Without the purpose of medical use.		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.	MD or Non-MD	Non-Medical Device
165.	Temperature Boiler	Connect with the mattress to adjust the temperature of the mattress to warm up. Used in cold weather.	MD or Non-MD	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.	MD or Non-MD	Non-Medical Device
167.	Application - Body fat	Not for medical purpose	MD or Non-MD	Non-Medical Device
168.	Models, Simulators and Medical Skills Training Products	The product is not actually available in patients or those with abnormalities.	MD or Non-MD	Non-Medical Device
169.	Microscope to see the tissue of the human body	Especially to diagnose diseases or injuries of humans.	MD or Non-MD	Medical Device

<b>NO.</b>	<b>PRODUCT NAME</b>	<b>DESCRIPTION</b>	<b>Borderline with/ MD or non MD</b>	<b>AMDTC Decision</b>
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.	MD or Non-MD	Non-Medical Device
171.	Product cover on microscope to prevent moisture.	To prevent moisture that causes fungus in the microscope.	MD or Non-MD	Non-Medical Device
172.	Electronic Tables	Electrical equipment or items use in hospitals, clinics or other places.	MD or Non-MD	Non-Medical Device
173.	Medicine Trolley, UD Dose Cart	To distribute medicine to each patient.	MD or Non-MD	Non-Medical Device
174.	Mobile Computer Cart	Can be moved to other places used in hospitals, clinics, offices.	MD or Non-MD	Non-Medical Device
175.	Device for patient or central pipeline system.	Flowmeter, Humidifier, Nebulizer, Suction Tube, Nasogastric Tube, Suction For Surgical Room	MD or Non-MD	Medical Device
<b>8<sup>th</sup> AMDTC</b>				
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	MD or non-MD	Non-Medical Device

NO.	PRODUCT NAME	DESCRIPTION	Borderline with/ MD or non MD	AMDTC Decision
177.	Rectal Cream/Suppository	Intended to soothes and moisturize the perianal area, relieves and rejuvenates 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	MD or non-MD	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 NOTE: components are, sodium carboxycellulose, elastomer, dioctyl adipate, hydrogenated petroleum resin	MD or non-MD	Medical Device
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	MD or non-MD	Non-Medical Device

NO.	PRODUCT NAME	DESCRIPTION	Borderline with/ MD or non MD	AMDTC Decision
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.	MD or non-MD	Non-Medical Device