

MEDICAL DEVICES PRODUCT CLASSIFICATION GUIDE

Medical Devices Cluster

November 2021

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Objective

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- Medical device (MD) is defined in the First Schedule of the Health Products Act (HPA) and products that meet this definition are regulated as MD by HSA. However, for certain products, it may be challenging to interpret whether or not it would be classified as a MD, within the scope of the MD definition. This document has been developed to aid with classification of some of these more challenging products.
- Many a time it is incorrectly assumed that because a product is considered a MD in some countries, it will also be a medical device in Singapore. This is not the case and the definition of MD should always be referred to, when determining the classification.
- Products falling outside the **scope of the MD regulatory controls** may still be regulated:
 - as Health Products under other Product Categories (such as Therapeutic Product, or Cosmetic Products) under the Health Products Act, or
 - under other legislation (e.g. Radiation Protection Act, Consumer Protection (Fair Trading) Act, etc).

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MEDICAL DEVICE means:

a) Any instrument, apparatus, implement, machine, appliance, implant, reagent for *in vitro* use, software, material or other similar or related article that is intended by its manufacturer to be used, whether alone or in combination, for humans **for one or more of the specific purposes of** –

- Diagnosis, prevention, monitoring, treatment or alleviate of disease;
- Diagnosis, monitoring, treatment or alleviation of, or compensation for, an injury;
- Investigation, replacement, modification or support of the anatomy or of a physiological process, *mainly for medical purposes*;
- Supporting or sustaining life;
- Control of contraception;
- Disinfection of medical devices; or
- Providing information by means of *in vitro* examination of specimens derived from the human body, for medical or diagnostic purposes,

and which does not achieve its **primary intended action in or on the human body by pharmacological, immunological or metabolic means**, but which may be assisted in its intended function by such means; and

b) **The following articles:**

- Any implant for the modification or fixation of any body part;
- Any injectable dermal filler or mucous membrane filler
- Any instrument, apparatus, implement, machine or appliance intended to be used for the removal or degradation of fat by invasive means

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Intended Purpose

- In order to determine whether a product is considered a medical device, the following should be considered:
 - A. The *intended purpose* of the product taking into account the way the product is designed and/or presented.
 - If the intended purpose fits the [MD definition](#) in the First Schedule of Health Products Act (HPA), then it would be subject to control as a medical device in Singapore.
 - B. The *primary mode of action* by which the intended purpose is achieved.
 - For a medical device, the primary mode of action by which the intended purpose is typically achieved is by physical means (including mechanical action, replacement of, or support of the anatomy or of a physiological process).

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Sterilization or disinfection

PRODUCT(S)	CLASSIFICATION	REMARKS
Hand or skin antiseptic wipes, hand sanitizers	Not Medical Device	
Disinfectant or Sterilant <i>for medical device</i>	Medical Device	
Sterilization pouch specifically intended by its product owner to be used together with the sterilizer for <u>re-sterilization</u> of medical device	Medical Device	Note: sterilization pouch used for the packaging and sterilization of a medical device <u>prior to the supply of the device</u> is part of the materials used in manufacturing process, and hence would not be classified as a Medical Device.

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PRODUCT(S)	CLASSIFICATION	REMARKS
Rinsing solutions for contact lens	Not Medical Device	
Cleaning solutions, Enzyme Tablet, or Liquid for protein removal of contact lens	Not Medical Device	
Contact lens multipurpose solution (such as for cleaning, disinfecting, rinsing, and/or storing of contact lens)	<u>May be Medical Device</u>	Multipurpose solutions with intended purposes that includes <u>disinfection</u> or <u>storage</u> of contact lens will be classified as MD.
Hydrating, Lubricating, or Rewetting solutions (to be instil in the eyes while wearing contact lens)	Medical Device	Intended for use to hydrate or lubricate, and to reduce friction between the lens and eyes.

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Products Used in Hospital/Laboratory

PRODUCT(S)	CLASSIFICATION	REMARKS
Laboratory equipment for: - <i>In-vitro diagnostic (IVD)</i> use or - <i>In-vitro fertilisation (IVF)</i>	Medical Device	Examples: - Incubators, centrifuges, or analysers <i>for IVD use</i> - <i>IVF</i> pipettes, transfer catheters or needles.
Blood bags (empty) and blood bags (containing anticoagulant/preservatives)	Medical Device	

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PRODUCT(S)	CLASSIFICATION	REMARKS
Blood refrigerator, or freezer	Medical Device	Intended to preserve blood and blood products by <i>storing</i> them at cold or freezing temperature <i>for eventual infusion/ transfusion</i> .
Vaccine/Pharmaceutical/ Medical Refrigerator (<u>not</u> intended for freezing or storing blood bags)	Not Medical Device	Intended 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.

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Ophthalmic Products

PRODUCT(S)	CLASSIFICATION	REMARKS
Eye drops (primary mode of action is physical: lubricating or physical washing)	Medical Device	Examples: - Lubricating or moisturizing eye drops for relief of dry, irritated eyes - Eye drops for relief of irritated eyes via physical washing of eye surface
Eye bath or Eye wash (primary mode of action is physical: mechanical irrigation)	Medical Device	An example is the saline eye wash intended for irrigation of the eyes, during emergency.

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Fluorescein Ocular strips	Medical Device	For evaluating the fit of contact lenses (works via staining of tear film).
	Not Medical Device	Intended for use to enhance visualisation of anatomy for diagnostic purposes.
Fluorescein eye drop	Not Medical Device	Intended for use as diagnostic agent for eye conditions and/or fitting of contact lens.

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PRODUCT(S)	CLASSIFICATION	REMARKS
Contact lens with corrective function (powered contact lens)	Medical Device	
Non-corrective contact lens (zero powered contact lens)	Not Medical Device	Decorative lens with no corrective function, used to change the colour or appearance of the eyes. Refer to Regulatory Guidelines For Devices for Modification of Appearance or Anatomy [1]
Non-corrective contact lens labelled <u>with</u> medical claims	Medical Device	Some non-corrective contact lens may have a medical purpose, to treat a number of congenital or traumatic conditions. An example is UV blocking contact lenses which claims to protect against transmission of harmful UV radiation to the cornea and into the eye, to alleviate photophobia in albinism.

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PRODUCT(S)	CLASSIFICATION	REMARKS
Cell culture media for cell or tissue therapy	Not Medical Device	Considered as processing reagents.
Organ preservation solution	Not Medical Device	Comparable to processing reagents. An example is solution for preserving of corneal material prior transplant.

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PRODUCT(S)	CLASSIFICATION	REMARKS
In vitro fertilisation (IVF) media for: <ul style="list-style-type: none"> Sperm preparation Follicle Aspiration Rinsing Fertilization Embryo Culture Embryo Transfer 	Medical Device	Replacement or modification of a physiological process.
In vitro diagnostic (IVD) culture media	Medical Device	Labelled for IVD use. For definition of IVD product, please refer to Guidance on Risk Classification of IVD Medical Devices (GN-14) [2] .

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PRODUCT(S)	CLASSIFICATION	REMARKS
Cold laser therapy (for pain management and/or to accelerate healing)	Medical device	
Liposuction Machine	Medical Device	Intended to remove fats from the body using suction (by <u>invasive</u> means). Refer to Regulatory Guidelines For Devices for Modification of Appearance or Anatomy [1]
Sitz bath	Medical Device	Generally intended for pain relief.
Medical gases such as oxygen for breathing and anaesthetic gases (supplied in cylinders)	Not Medical Device	

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PRODUCT(S)	CLASSIFICATION	REMARKS
Acupuncture Needles, Electro-acupuncture machines	Medical Device	
Dental aligners, Dental retainers for use after orthodontic treatment	Medical Device	
In-vivo diagnostic agents such as x-ray contrast media and gases for lung function test	Not Medical Device	

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PRODUCT(S)	CLASSIFICATION	REMARKS
Hot or cold packs, Heat pads, Hot or cold water bottles	Medical Device	Generally intended for pain relief.
	Not Medical Device	Labelled with specific intended purpose to <u>exclude</u> these products from being a medical device. An example is heat pads labelled for keeping warmth in cold weather.

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PRODUCT(S)	CLASSIFICATION	REMARKS
Peritoneal dialysis solution	Not Medical Device	
Hemofiltration solution	Not Medical Device	Note: It is a replacement/substitution solution used in renal replacement therapy, where the exchange of solutes is by convection (hemofiltration).
Haemodialysis solution	Medical Device	Note: Exchange of solutes is by diffusion, across a semi-permeable membrane.

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PRODUCT(S)	CLASSIFICATION	REMARKS
Pressure or gas regulators for medical gases (to control flow rate)	Medical Device	
Female intimate hygiene products (primary mode of action is via <i>restoration of vaginal pH</i>)	Not Medical Device	An example is douche or gel intended to restore natural pH in vagina, for symptomatic relief of vaginal irritation, or infections.

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PRODUCT(S)	CLASSIFICATION	REMARKS
Lubricants	Medical Device	<p>Lubricants with a medical purpose.</p> <p>Examples:</p> <ul style="list-style-type: none"> - Lubricant intended for use in medical procedures with medical devices such as endoscopes - Lubricant intended for use with condoms (medical device) to facilitate the function of condom - Vaginal lubricant intended for a medical purpose such as for treatment of vaginal dryness
	Not Medical Device	<p>Personal lubricants that is intended for a non-medical purpose (e.g. sexual comfort/ for pleasure).</p> <p>Note: Personal lubricants which <i>claims compatibility</i> to condom (e.g. <i>can be used with</i> condom) are not medical device as it is only to indicate the fact that it can be safely used in combination with (latex) condom. Such personal lubricants compatible for use with condoms (ie. latex) are not medical devices.</p>

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Products that serves multiple purposes may occasionally be used within a medical setting. These are not considered medical devices, *unless* the product is intended for a specific medical purpose.

PRODUCT(S)	CLASSIFICATION	REMARKS
Air Decontamination or Purification Units	Not Medical Device	Products intended to remove allergens (dust, pollen, etc) and/or to remove bacteria from the air in a specific area/room. They may be used in hospitals for air decontamination, aiming to reduce infection risks in intensive care units and operating theatres. Not for disinfection of medical devices.
Multipurpose general disinfectant	Not Medical Device	These products are intended for disinfecting various surfaces such as floors, walls and sanitary facilities. Not for disinfection of medical devices.
Multipurpose computer and printer	Not Medical Device	These products are not medical devices unless they are specifically intended* to be used in combination with a medical device as an accessory.

***Specifically intended** refers to a clear indication of such use in the information accompanying the medical device.

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PRODUCT(S)	CLASSIFICATION	REMARKS
Toothbrush, Toothpaste, Mouthwash, Dental floss	Not Medical Device	Primarily intended for basic oral hygiene and/or cleaning.
Denture cleansing tablets	Not Medical Device	
Dental disclosing solution/tablets	Not Medical Device	Generally used to disclose dental plaques on teeth.
Tooth whitening or bleaching products (Instruments and gel)	Not Medical Device	Tooth whitening instruments: refer to Regulatory Guideline for Devices for Modification of Appearance or Anatomy [1]

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PRODUCT(S)	CLASSIFICATION	REMARKS
Female hygiene products such as: Tampons, Menstrual Cup, Pads/sanitary towel	Not Medical Device	
Diapers (for baby and/ or adults) and Incontinence pads	Not Medical Device	Generally used to contain or absorb urine and waste.
Commodes and Bedpans (Body waste receptacles)	Not Medical Device	Generally used to contain body waste.
Gallipots, Kidney dishes	Not Medical Device	Generally intended for a variety of purposes such as containing fluids, mixing solutions, carrying or holding instruments prior to or during a procedure, and collecting body waste or other matters.

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PRODUCT(S)	CLASSIFICATION	REMARKS
Breast pumps	Not Medical Device	Generally, breast pumps are intended for milk extraction.
Sunscreens	Not Medical Device	
Insect repellent, Mosquito repellent or patches	Not Medical Device	
Lice comb	Not Medical Device	For removal of lice and lice eggs from human hair
Medicine spoons, Medicine droppers, Dispensers or Storage containers for pills, capsules and tablets	Not Medical Device	

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PRODUCT(S)	CLASSIFICATION	REMARKS
Laser equipment (for non-invasive lipolysis)	Not Medical Device	Intended to remove fats from the body (by <u>non-invasive</u> means). Refer to Regulatory Guidelines For Devices for Modification of Appearance or Anatomy [1]
Needles for tattooing	Not Medical Device	Refer to Regulatory Guidelines For Devices for Modification of Appearance or Anatomy [1]
Microneedles or dermal rollers (to create micro punctures on the skin) for skin rejuvenation or for scars	Not Medical Device	Refer to Regulatory Guidelines For Devices for Modification of Appearance or Anatomy [1]
Brushes, or Sponges for washing and/or cleaning of nails and/or hands	Not Medical Device	An example is brush or sponge for use <i>by healthcare professionals prior surgery</i> (on intact skin not relating to wound care), for cleaning of nails and/or hands.

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PRODUCT(S)	CLASSIFICATION	REMARKS
Pipelines/ manifolds in hospital (for anaesthetics and other medical gases)	Not Medical Device	
Ceiling pendants, fixed installations, treatment rooms in hospitals (also including salt rooms or oxygen hyperbaric rooms outside of hospital setting)	Not Medical Device	Generally, infrastructures are not medical devices. However, if the fixtures include examination lights or gas flow control function (of medical gases) etc., please contact the Medical Devices Cluster with product information.
General Laboratory Equipment	Not Medical Device	General lab equipment not for In-vitro diagnostic use are not regulated as Medical Devices. For definition of <i>In-vitro diagnostic</i> (IVD) devices, please refer to Guidance on Risk Classification of IVD Medical Devices (GN-14) [2] .

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Assistive technology products are generally intended for *alleviation of*, or *compensation for disability*. They are designed to help individual with disability to overcome barriers they face in carrying out their daily living activities. Depending on the primary intended purpose, these products may be considered either medical devices or general consumer products.

The main determining factor will be whether there is a:

- (a) **direct link between the corrective function of the product and the individual with disability** and,
- (b) that there is **a stated medical purpose**

MEDICAL DEVICES	NOT MEDICAL DEVICES
Wheelchair	Alarm system in toilets/homes
Walking stick	Toilet equipment for disabled
Hearing Aid	Grab rails at doorways or stairs
Prosthetic Devices	Portable ramps

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PRODUCTS FOR SPORTS/PHYSICAL FITNESS /GENERAL HEALTH

In general, products intended for sport or leisure purposes are not considered as medical devices. Similarly, products intended for physical fitness, maintenance of general state of health (ie. weight management, recreational use, sleep management, detoxification, improving and enhancing flow of (qi) are not considered medical devices.

PRODUCT(S)	CLASSIFICATION	REMARKS
Gym equipment or Watch with a function to measure heart rate	May or May not be a Medical Device	Refer to Regulatory Guidelines for Telehealth Products [3] for determination of product classification.
Foot patch intended to maintain good health, promote good sleep, to soothe or relax muscle	Not Medical Device	
Bandages or support for sprains or injuries	Medical Device	

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PERSONAL PROTECTIVE EQUIPMENT (PPE)

- PPE are products that are generally worn to protect users from workplace hazards.
- The primary determining factor will be whether the product is **for use in a healthcare setting, or for a medical purpose.**

PRODUCT(S)	CLASSIFICATION	REMARKS
Gloves or gowns for non-medical purposes	Not Medical Device	Gloves or gowns intended for other purposes (outside of healthcare settings) such as food industry would not be considered as medical device.
Medical/ Examination/ Surgical gloves, Surgical/Isolation gowns	Medical Device	Gloves or gowns intended to be worn by healthcare personnel during medical/surgical procedures for the protection of: <ul style="list-style-type: none"> • healthcare professional • patient who may contract illnesses or medical conditions from being exposed to potentially infectious bacteria

PRODUCTS WITH
MEDICAL RELATED
PURPOSE

GENERAL
PURPOSE
PRODUCTS

ASSISTIVE
TECHNOLOGY
PRODUCTS

PRODUCTS FOR
SPORTS/PHYSICAL
FITNESS/GENERAL HEALTH

PERSONAL
PROTECTIVE
EQUIPMENT (PPE)

PERSONAL PROTECTIVE EQUIPMENT (PPE)

PRODUCT(S)	CLASSIFICATION	REMARKS
Facemask/N95 respirator for non-medical purposes	Not Medical Device	Facemask/ N95 respirator labelled <u>solely</u> for occupational uses would not be a medical device.
Medical/ Surgical Facemasks and N95 Respirators	Medical Device	Medical/ surgical facemasks and N95 respirators intended for use in healthcare settings.
Mouth guards for non-medical purposes	Not Medical Device	Mouth guards intended for sports purposes.

**PRODUCTS WITH
MEDICAL RELATED
PURPOSE**

**GENERAL
PURPOSE
PRODUCTS**

**ASSISTIVE
TECHNOLOGY
PRODUCTS**

**PRODUCTS FOR
SPORTS/PHYSICAL
FITNESS/GENERAL HEALTH**

**PERSONAL
PROTECTIVE
EQUIPMENT (PPE)**

References

- [1] Regulatory Guideline for Devices for Modification of Appearance or Anatomy
- [2] Guidance on Risk Classification of IVD Medical Devices (GN-14)
- [3] Regulatory Guidelines for Telehealth Products

Above References can be accessed online at:

<https://www.hsa.gov.sg/medical-devices/guidance-documents>

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