GL-06: Medical Devices Product Classification Guide

Medical Devices Cluster

October 2023
Revision 2

All Rights Reserved, Health Sciences Authority

CONTENTS

1. **INTRODUCTION**
   - i. Objective
   - ii. Definitions
   - iii. Intended Purpose

2. **PRODUCTS WITH MEDICAL RELATED PURPOSE**
   - i. Sterilisation or Disinfection
   - ii. Contact Lens Care Products
   - iii. Products used in Hospital or Laboratories
   - iv. Ophthalmic Products
   - v. Solutions or Media for Tissues/Cells
   - vi. Others

3. **GENERAL PURPOSE PRODUCTS**

4. **ASSISTIVE TECHNOLOGY PRODUCTS**

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

6. **PERSONAL PROTECTIVE EQUIPMENTS (PPE)**



All Rights Reserved, Health Sciences Authority

Revision History

Guidance Version (Effective Date) [3 latest revisions]	Revision
GL-06: Revision 1 (26 November 2021)	R1
R2 ►GL-06: Revision 2 (02 October 2023)	R2

**Where applicable, changes and updates made in each document revision are annotated with or within the arrow symbol "►". Deletions may not be shown.*

All Rights Reserved, Health Sciences Authority

INTRODUCTION
Objective

- Medical device (MD) is defined in the First Schedule of the Health Products Act (HPA) and products that meet this definition are regulated as MDs by HSA. However, for certain products, it may be challenging to interpret whether or not it would be classified as an 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 an MD in some countries, it will also be an MD in Singapore. This is not the case and the definition of MD should always be consulted, when determining the classification.

- Products falling outside the **scope of the MD regulatory controls** may still be a regulated product:
  - 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).

All Rights Reserved, Health Sciences Authority

INTRODUCTION
Objective

- Medical device (MD) is defined in the First Schedule of the Health Products Act (HPA) and products that meet this definition are regulated as MDs by HSA. However, for certain products, it may be challenging to interpret whether or not it would be classified as an 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 an MD in some countries, it will also be an MD in Singapore. This is not the case and the definition of MD should always be consulted, when determining the classification.

- Products falling outside the **scope of the MD regulatory controls** may still be a regulated product:
  - 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).

All Rights Reserved, Health Sciences Authority

INTRODUCTION

MD Definition (First Schedule of HPA)

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

All Rights Reserved, Health Sciences Authority

INTRODUCTION

Intended Purpose

- In order to determine whether a product is considered an MD, 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).

All Rights Reserved, Health Sciences Authority

PRODUCTS WITH MEDICAL RELATED PURPOSE

Sterilisation or disinfection

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

All Rights Reserved, Health Sciences Authority

PRODUCTS WITH MEDICAL RELATED PURPOSE

Contact Lens Care Products

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)	**May be Medical Device**	Multipurpose solutions with intended purposes that includes disinfection or storage 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.

All Rights Reserved, Health Sciences Authority

PRODUCTS WITH MEDICAL RELATED PURPOSE

Products Used in Hospital/Laboratory

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

PRODUCTS WITH MEDICAL RELATED PURPOSE → **GENERAL PURPOSE PRODUCTS** → **ASSISTIVE TECHNOLOGY PRODUCTS** → **PRODUCTS FOR SPORTS/PHYSICAL FITNESS/GENERAL HEALTH** → **PERSONAL PROTECTIVE EQUIPMENT (PPE)**

1) STERILISATION OR DISINFECTION | 2) CONTACT LENS CARE PRODUCTS | 3) PRODUCTS USED IN HOSPITAL/ LABORATORY | 4) OPTHALMIC PRODUCTS | 5) SOLUTIONS OR MEDIA FOR TISSUES/CELLS | 6) OTHERS

All Rights Reserved, Health Sciences Authority

PRODUCTS WITH MEDICAL RELATED PURPOSE

Products Used in Hospital/Laboratory

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

All Rights Reserved, Health Sciences Authority

PRODUCTS WITH MEDICAL RELATED PURPOSE

Ophthalmic Products

PRODUCT(S)	CLASSIFICATION	REMARKS
R2 ► Eye drops or eye irrigation solution (primary mode of action is physical: lubricating or physical washing)	**Medical Device**	Examples: - Lubricating or moisturising eye drops for relief of dry, irritated eyes - Eye drops or irrigation solution for relief of irritated eyes (due to particles such as dust or smoke) via physical washing of eye surface
Eye drops (primary mode of action via osmosis)	**Not Medical Device**	An example is eye drops intended for temporary relief of corneal edema.
Emergency eye washes	**Not Medical Device**	Emergency eye washes intended solely for washing of chemical spills/ splash. ◄

All Rights Reserved, Health Sciences Authority

PRODUCTS WITH MEDICAL RELATED PURPOSE

Ophthalmic Products

PRODUCT(S)	CLASSIFICATION	REMARKS
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.

All Rights Reserved, Health Sciences Authority

PRODUCTS WITH MEDICAL RELATED PURPOSE

Ophthalmic Products

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 with 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.

All Rights Reserved, Health Sciences Authority

PRODUCTS WITH MEDICAL RELATED PURPOSE

Solutions/Media for Tissues/Cells

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.



All Rights Reserved, Health Sciences Authority

PRODUCTS WITH MEDICAL RELATED PURPOSE

Solutions/Media for Tissues/Cells

PRODUCT(S)	CLASSIFICATION	REMARKS
In vitro fertilisation (IVF) media for: • Sperm preparation • Follicle Aspiration • Rinsing • Fertilisation • 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].

All Rights Reserved, Health Sciences Authority

PRODUCTS WITH MEDICAL RELATED PURPOSE

Others

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 invasive 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**	

All Rights Reserved, Health Sciences Authority

PRODUCTS WITH MEDICAL RELATED PURPOSE

Others

PRODUCT(S)	CLASSIFICATION	REMARKS
R2 ► Emergency skin washes	**Not Medical Device**	Emergency skin washes intended solely for washing of chemical spills/ splash ◄
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**	

All Rights Reserved, Health Sciences Authority

PRODUCTS WITH MEDICAL RELATED PURPOSE

Others

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 exclude these products from being a medical device. An example is heat pads **labelled** for keeping warmth in cold weather.

All Rights Reserved, Health Sciences Authority

PRODUCTS WITH MEDICAL RELATED PURPOSE

Others

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.

All Rights Reserved, Health Sciences Authority

PRODUCTS WITH MEDICAL RELATED PURPOSE

Others

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 *restoration of vaginal pH)*	**Not Medical Device**	An example is douche or gel intended to restore natural pH in vagina, for symptomatic relief of vaginal irritation, or infections.



All Rights Reserved, Health Sciences Authority

PRODUCTS WITH MEDICAL RELATED PURPOSE

Others

PRODUCT(S)	CLASSIFICATION	REMARKS
Lubricants	**Medical Device**	Lubricants with a medical purpose. Examples: - Lubricant 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	Personal lubricants that is intended for a non-medical purpose (e.g. sexual comfort/ for pleasure). Note: Personal lubricants which *claims compatibility* to condom (e.g. *can be used with* 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.

PRODUCTS WITH MEDICAL RELATED PURPOSE | **GENERAL PURPOSE PRODUCTS** | **ASSISTIVE TECHNOLOGY PRODUCTS** | **PRODUCTS FOR SPORTS/PHYSICAL FITNESS/GENERAL HEALTH** | **PERSONAL PROTECTIVE EQUIPMENT (PPE)**

1) STERILISATION OR DISINFECTION

2) CONTACT LENS CARE PRODUCTS

3) PRODUCTS USED IN HOSPITAL/ LABORATORY

4) OPTHALMIC PRODUCTS

5) SOLUTIONS OR MEDIA FOR TISSUES/CELLS

6) OTHERS

All Rights Reserved, Health Sciences Authority

GENERAL PURPOSE PRODUCTS

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.

All Rights Reserved, Health Sciences Authority

GENERAL PURPOSE PRODUCTS

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]

All Rights Reserved, Health Sciences Authority

GENERAL PURPOSE PRODUCTS

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.

All Rights Reserved, Health Sciences Authority

GENERAL PURPOSE PRODUCTS

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**	

All Rights Reserved, Health Sciences Authority

GENERAL PURPOSE PRODUCTS

PRODUCT(S)	CLASSIFICATION	REMARKS
Laser equipment (for non-invasive lipolysis)	**Not Medical Device**	Intended to remove fats from the body (by non-invasive 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 *by healthcare professionals prior surgery* (on intact skin not relating to wound care), for cleaning of nails and/or hands.

All Rights Reserved, Health Sciences Authority

GENERAL PURPOSE PRODUCTS

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 *in vitro diagnostic (*IVD) devices, please refer to Guidance on Risk Classification of IVD Medical Devices (GN-14) [2].

All Rights Reserved, Health Sciences Authority

ASSISTIVE TECHNOLOGY PRODUCTS

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

All Rights Reserved, Health Sciences Authority

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**	

All Rights Reserved, Health Sciences Authority

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: • healthcare professional • patient who may contract illnesses or medical conditions from being exposed to potentially infectious bacteria

All Rights Reserved, Health Sciences Authority

PERSONAL PROTECTIVE EQUIPMENT (PPE)

PRODUCT(S)	CLASSIFICATION	REMARKS
Facemask/N95 respirator for non-medical purposes	**Not Medical Device**	Facemask/ N95 respirator labelled solely 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.

All Rights Reserved, Health Sciences Authority

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

All Rights Reserved, Health Sciences Authority

CONTACT INFORMATION

Medical Devices Cluster

Health Products Regulation Group

Health Sciences Authority

11 Biopolis Way, #11-03 Helios

Singapore 138667

www.hsa.gov.sg

All Rights Reserved, Health Sciences Authority