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MEDICAL DEVICE GUIDANCE DOCUMENT

GENERAL MEDICAL DEVICE - GROUPING

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;
c) Medical Device (Duties and Obligations of Establishments) Regulations 2019; and
d) Medical Device (Advertising) Regulations 2019.

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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GENERAL MEDICAL DEVICE – GROUPING

1. Introduction

Under the Medical Device Act 2012, the manufacturer or the Authorized Representative of the foreign manufacturer is required to register a medical device before importing, exporting or placing it in the Malaysia market.

There is a wide range of medical devices from a simple medical device to a highly complex and sophisticated medical device. The various components can be sold as a separate component, individual customized pack or group and can be categorized as SINGLE, FAMILY, SYSTEM and SET. Each of the categories mentioned can be submitted in the medical device registration application.

The purpose of this document is to provide guidance to determine the appropriate grouping for medical devices in the medical device registration application

2. Scope and application

This document applies to all products that fall within the definition of medical device that has been specified in the Guidance Document: Definition of Medical Device (MDA/GD/0006) excluding In-vitro Diagnostic Medical Device.

NOTE For grouping of IVD Medical Device, please refer to MDA/GD/0054. For dental devices grouping, please refer to MDA/GD/0069[1].

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 accessory

For the purposes of this guidance document, an accessory is an article that is intended specifically by its manufacturer to:

(a) be used together with a medical device to enable that device to be used in accordance with its intended purpose as a medical device; or

(b) augment or extend the capabilities of that device in fulfilment of its intended purpose as a medical device;

and therefore, should be considered as a medical device.

3.2 Authorised Representative (AR)

As defined in Section 2 of Act 737.

[1] Under development

3.3 constituent-component(s)

One of several possibly unequal subdivisions which together constitute the whole medical device to achieve the latter's intended purpose. A component may be known as a part but not a medical device in its own right.

3.4 intended use/purpose

As defined in Medical Device Regulations 2012.

3.5 manufacturer

As defined in Section 2 of Act 737.

3.6 proprietary name

A unique name given by the manufacturer to identify a medical device as a whole product, also known as the trade name or brand name.

3.7 registration holder

In relation to a registered medical device, means an establishment on whose application the medical device is registered under the Act. A registration holder is either the manufacturer or authorised representative of the medical device.

3.8 reusable surgical instrument

Instrument intended for surgical use by cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or other surgical procedures, without connection to any active medical device and which are intended by the manufacturer to be reused after appropriate procedures for cleaning, disinfection and/or sterilisation have been carried out.

4. General Principles of Grouping

4.1 General medical devices can be grouped into one of the following four categories and can be submitted in one application for medical device registration:

a) SINGLE;
b) SYSTEM;
c) FAMILY;
d) SET

4.2 The three basic rules shall all be fulfilled for the grouping to apply. These are:

a) one proprietary name,
b) one manufacturer; and
c) one common intended purpose.

4.3 Categories

4.3.1 Single

A single medical device is a medical device from a manufacturer identified by a medical device proprietary name with a specific intended purpose. It is sold as a distinct packaged entity, and it may be offered in a range of package sizes, and it does not meet the criteria for family, system or set.

EXAMPLE

a) Medical devices that vary in package sizes are not considered to fall within the medical device family, and one registration application for a SINGLE medical device should be filed for the various package sizes. Condoms that are sold in packages of 3, 12 and 144 can be registered as a SINGLE medical device.

b) A company manufactures a standalone software program that can be used with a number of CT scanners produced by other manufacturers. The standalone software program itself is deemed a medical device, which can be used on different scanners. The software can be registered as a single medical device.

c) A company that assembles and registers a first aid kit as a set has now decided to also supply each of the medical devices in the first aid kit individually. Each medical device supplied individually as a medical device shall be registered separately as a single medical device.

4.3.2 System

4.3.2.1 A medical device SYSTEM comprises of a number of medical devices and accessories and/or constituent- components that are:

a) from the same manufacturer;

b) intended to be used in combination to complete a common intended purpose;

c) compatible when used as a SYSTEM; and

d) sold under a SYSTEM name or the labelling, instruction for use (IFU), brochures or catalogues for each constituent component states that the constituent component is intended for use with the SYSTEM.

4.3.2.2 Constituent-components which consists of components and/or accessories, registered as part of a system shall only be supplied specifically for use with that system. Any constituent-component that is meant for supply for use with multiple systems shall be registered together with each of these other systems. Alternatively, these constituent-component(s) may be registered separately where applicable.

4.3.2.3 The accessories or constituent-component(s) that are to be supplied separately by different manufacturers are required to be registered separately. Accessories from different manufacturing site to be supplied together with the medical device in a system carrying one proprietary name be registered together in the same registration application.

4.3.2.4 The decision flowchart for grouping of medical devices as a system can be found in **Annex A.**

EXAMPLES

a) A hip replacement system comprising of femoral and acetabular components can be registered as a system. The components shall be used in combination to achieve a common intended purpose of total hip replacement. The size of the components may vary.

b) An electrosurgical unit and its accessories that consist of forceps, electrodes, electrode holders, leads, plug adaptor, when used together for a common intended purpose, can be registered as a system.

c) Optional accessory such as wireless controller is part of in-the-ear hearing aid can be registered as a system.

4.3.3 FAMILY

4.3.3.1 A medical device FAMILY is a collection of medical devices and each medical device FAMILY member:

a) is from the same manufacturer;

b) is of the same risk classification;

c) has the same medical device proprietary name;

d) has a common intended purpose;

e) has the same design and manufacturing process; and

f) has variations that are within the scope of the permissible variants.

The decision flowchart for grouping of medical devices as a FAMILY can be found in Annex **B.**

4.3.3.2 A characteristic of a medical device may be considered a permissible variant if:

a) the physical design and construction of the medical devices are the same, or very similar;

b) the manufacturing processes for the medical devices are the same, or very similar;

c) the intended purpose of the medical devices is the same; and

d) the risk profile of the medical devices, taking into account the above factors, is the same.

See **Annex C** for a list of permissible variants in a FAMILY.

EXAMPLES

a) Condoms that differ in colour, size and texture but are manufactured from the same material and manufacturing process and share a common intended purpose can be registered as a FAMILY.

b) IV administrative sets that differ in features such as length of tubing, but are manufactured from the same material and manufacturing process and share a common intended purpose can be registered as a family.

c) Steerable guidewires that are available in various lengths and possess various tip shapes and tip flexibilities can be registered as a family if their manufacturing process is the same and they share a common intended purpose.

d) Spherical contact lens with additional features of UV protection can be registered as part of a FAMILY, as this feature does not affect the basic design and manufacturing of the lens.

e) Cardiac catheters that are available in a different number of lumens, lengths and diameters can be registered as a FAMILY.

f) Contact lenses are available as toric lens and spherical lens. These medical devices have different intended purposes and performances. They are designed and manufactured differently. Due to these differences, they shall not be considered as members of a FAMILY.

4.3.3.3 Information on all medical devices within a FAMILY shall be submitted as part of one medical device registration application. Only members of a FAMILY that are eventually listed on the register may be placed in the market. Those that are not listed shall not be placed in the market.

4.3.3.4 The medical device proprietary name shall appear on the label of each of the medical device member in the family if packaged or supplied individually. Individual medical device names may contain additional descriptive phrase.

EXAMPLE Two different materials, such as titanium and stainless steel, shall not be combined with all screw insertion tools used in femur orthopaedic procedures under one FAMILY registration application.
Materials are not regarded as being on the list of permissible variations.

4.3.3.5 In addition, if several SYSTEMs fulfil the following conditions to be grouped as a FAMILY, they may be registered as a FAMILY OF SYSTEMs:

a) the SYSTEMs are from the same manufacturer;

b) the SYSTEMs are of the same risk classification class;

c) the SYSTEMs have a common intended purpose;

d) the SYSTEMs have similar design and manufacturing process;

e) key constituent-components of the SYSTEMs have variations that are within the scope of the permissible variants; and

f) the SYSTEMs have the same generic proprietary name, individual system names may contain additional descriptive phrases.

4.3.3.6 A Family of Systems grouping may be applied as per example in Figure 1.

4.3.3.7 The Family of System group is referring to group of devices that have same medical device generic name.

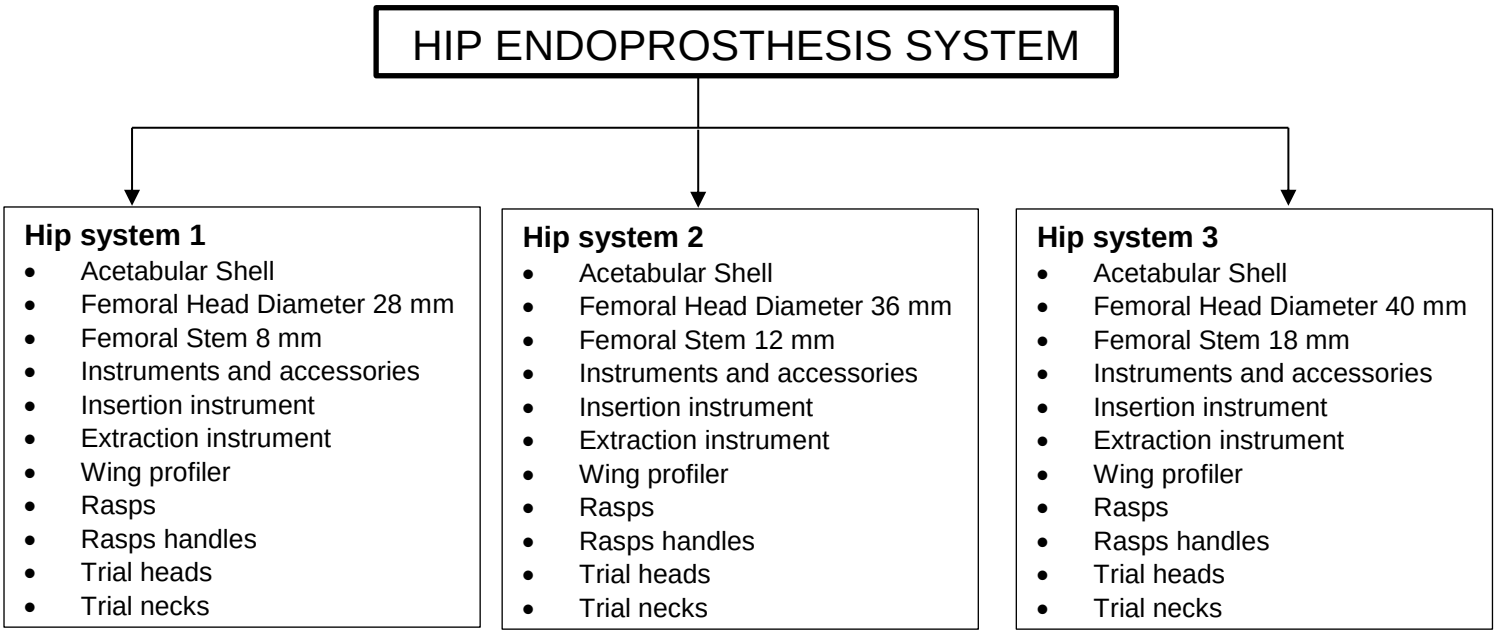


Figure 1 Example of grouping multiple systems as Family of Systems

Hip implant systems that have different components that are available in various lengths can be grouped as a FAMILY of SYSTEMs. The components shall be used in combination with the accessories to achieve a common intended purpose. Length is a permissible variant.

NOTE The key constituent-components, i.e. implantable rods, plates and screws, across the systems are within permissible variants. For example, differences in lengths of the implantable screws are deemed permissible variants.

A constituent component in one system that is supplied for use in several systems must be included in the registration application for every different system.

4.3.3.8 The main implantable devices across the SYSTEMS in the FAMILY of SYSTEMs shall be manufactured from the same material and have common intended use. For example, femoral stem of sizes 28 mm, 36 mm and 40 mm shall be manufactured from the same material.

EXAMPLE Orthopaedic plating and screw system (femur, tibial and knee) with common intended use to assist in bone healing process cannot be grouped together as Family of SYSTEMS due to combination of various bones in lower limb under one common intended use. The bone's location is not one of the permissible variants. The manufacturer of orthopaedic plating systems has to separate their devices into three distinct applications as Family of System (femur, tibial, and knee) based on the three locations of the bones.

4.3.3.9 The accessories that are to be supplied separately by different manufacturers are required to be registered separately. Accessories from different manufacturing sites to be supplied together with the medical device in a system carrying one proprietary name may be registered together in the same declaration application.

For example, **automated blood pressure monitors** with optional features such as memory storage and print capability for various models.

4.3.4 SET

4.3.4.1 A medical device set is a collection of two or more medical devices, assembled together as one package by a manufacturer. The medical device SET has the following:

a) a single proprietary set name;

b) a common intended use;

c) classification allocated to the set is at the level of the highest classified device within the set.

The decision flowchart for grouping of medical devices as a SET can be found in **Annex D.**

4.3.4.2 The collection of medical devices in a SET may differ in number (quantity) and combination (permutation within the list of medical devices in a SET of medical devices) that comprise each SET while maintaining the same proprietary SET name and SET's intended use. When the SET is registered, the manufacturer is able to customize the set for particular hospitals or physicians, while maintaining the same SET name and intended purpose. When the SET is registered, all other combinations in that SET can be supplied on the market.

4.3.4.3 Information on all medical devices within a SET shall be submitted as part of one medical device registration application. Medical devices that are to be supplied separately shall be registered individually.

4.3.4.4 If a medical device in a SET is supplied for use in another SET, such a medical device shall be included in the registration application of that other SET.

4.3.4.5 The SET name indicated for the medical device shall appear in the product label affixed on the external package of the SET. Individual medical devices in the SET do not require to be labelled with that SET name. Individual medical devices in the SET may contain additional descriptive phrases.

4.3.4.6 The label for medical devices in a set shall bear the content list of devices within the package for supply. Some of the medical devices in the SET may be individually packaged and labelled, while others may not have to be packaged and labelled individually. The manufacturer shall account for these during the assembling of the SET and ensure compliance to existing labelling requirements as specified in guidance document MDA/GD/0026 Requirements for Labelling of Medical Devices including traceability of individual devices packaged into the set and record keeping.

4.3.4.7 A promotional pack or convenience pack without a SET name and without a common medical intended purpose, consisting of different number of medical devices, for example multi-purpose solution, saline solution, and contact lens case, will not require a SET registration. Each medical device in the promotional pack shall require registration as SINGLE medical device.

EXAMPLES of medical devices in a set:

a) A first aid kit consisting of medical devices such as bandages, gauzes, drapes and thermometers, when assembled together as one package by a manufacturer, can be registered as a SET.

b) A dressing tray consisting of a number of medical devices when packaged together for convenience to meet a specific purpose by a manufacturer can be registered as a SET. When the closed list of medical devices in the SET are registered, the manufacturer is able to customize the trays, from the list of devices, for other hospitals, while maintaining the same SET name for the trays and the registered intended purpose.

c) A manufacturer supplies dressing trays customized with different quantity and type of gauze and sutures to different hospitals while maintaining the same SET name and intended purpose.

4.3.5 Special grouping for In Vitro Fertilisation (IVF) Medical Device

In vitro fertilisation (IVF) is a procedure in which eggs (ova) from a woman's ovary are removed. They are fertilised with sperm in a laboratory procedure, and then the fertilised egg (embryo) is returned to the woman's uterus.

IVF is a medical procedure where an egg is fertilised by a sperm outside the body (in vitro). IVF instruments and media are necessary to ensure this medical procedure is performed successfully. IVF media products are used in a wide range of in vitro procedures, involving processing, manipulation and conditioning of sperm, oocytes, blastocysts and embryos. The intended use of IVF media may range from maintenance of the physiological homeostasis required to support and promote fertilisation in vitro, to the maintenance of the physiological homeostasis of the cells during the cryopreservation process and the minimisation of cellular damage during the freezing process. IVF media products may be comprised of a cocktail of physiological inorganic salts, energy sources, amino acids and proteins, and are available in a range of different formulations available.

A device specific grouping of IVF media grouping category comprises of a collection of IVF media that are:
a) from the same manufacturer
b) compatible when used together and intended to be used for an IVF procedure

When IVF media products satisfy the criteria to be grouped into one of the prescribed IVF media grouping categories, they can be grouped together and submitted in one application for registration.

Manufacturers may choose to group these IVF media using the general grouping criteria specified in Clause 4. General Principles of Grouping.

The list of IVF Media grouping categories is a closed and positive list is described as in Table 1.

Table 1: The list of IVF Media grouping categories

No	IVF Media Grouping Category (closed list)	Examples of Media Types (non-exhaustive list)
1	IVF Media for Oocyte Handling	(i) Oocyte Obtaining; (ii) Oocyte Processing; (iii) Oocyte *In Vitro M*aturation; (iv) Oocyte Polar Body Biopsy; (v) Oocyte Cryopreservation; (vi) Oocyte Storage; (vii) Oocyte Thawing; or (viii) Oocyte Transport.
2	IVF Media for Sperm Handling	(i) Semen/Sperm Obtaining (ii) Semen/Sperm Processing (e.g. gradient, swim up, immobilisation, washing) (iii) Semen/Sperm Cryopreservation (iv) Sperm Storage (v) Sperm Thawing (vi) Sperm Transport

No	IVF Media Grouping Category (closed list)	Examples of Media Types (non-exhaustive list)
3	IVF Media for Zygote Handling (processing/media for maintenance of zygotes/etc)	(i) IVF with Insemination (ii) IVF with Intracytoplasmic Sperm Injection (ICSI) (iii) Zygotes Maintenance Zygote Intrafallopian Transfer (ZIFT)
4	IVF Media for *In vitro* Embryo Handling	(i) *In Vitro* Embryo Obtaining (ii) *In Vitro* Embryo Culture and Assessment (iii) *In Vitro* Embryo Biopsy (iv) Assisted Hatching (v) *In Vitro* Embryo Cryopreservation (vi) *In Vitro* Embryo Storage (vii) *In Vitro* Embryo Thawing (viii) *In Vitro* Embryo Transport (ix) Embryo Transfer (Et)

4.3.6 Specific grouping for Hearing aids

Most hearing aids share several similar electronic components, including a microphone that picks up sound; amplifier circuitry that makes the sound louder; a miniature loudspeaker (receiver) that delivers the amplified sound into the ear canal; and batteries that power the electronic parts.

This grouping applies for hearing aids from the same manufacturer that are in the risk-based classification Class B with the same design, sound amplification and communication technologies not including implantable hearing aid devices. The product registration application may contain accessories of a lower risk-based classification if they are specifically intended to be used together with the hearing aids.

Hearing aids shall be grouped separately based on design, sound amplification and communication technologies;

Generally, specific grouping of hearing aids as a FAMILY is a collection of hearing aids that are:

- from the same manufacturer;
- within same risk-based classification Class B;
- have the same design;
- have the same technology for sound amplification (analogue or digital); and
- have the same communication technology (wireless or non-wireless).

Table 2: Examples of hearing aids based on design, sound amplification and communication technology

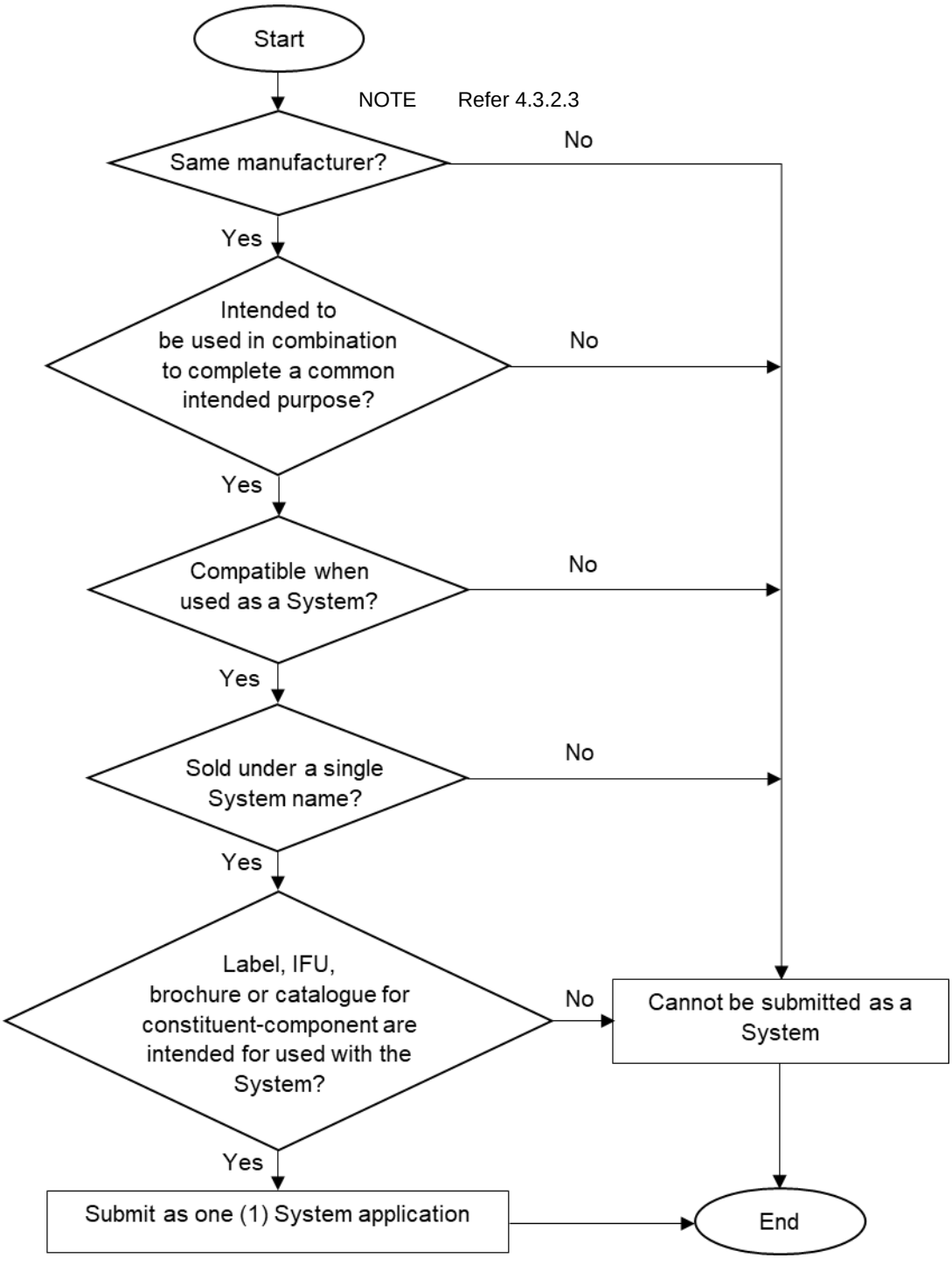
Types	Examples
Design	Behind-the-ear (BTE) aids; or In-the-ear (ITE) aids.
Technology for sound amplification	Analog hearing aids; or Digital hearing aids
Communication Technology	Wireless; or Non-Wireless

The hearing aids shall satisfy the basic requirement of the grouping and above conditions shall be considered when registering the devices.

EXAMPLE BTE hearing aid and ITE hearing aid could not be registered together in the same application even though both devices having similar technology (digital) and communication technology (wireless).

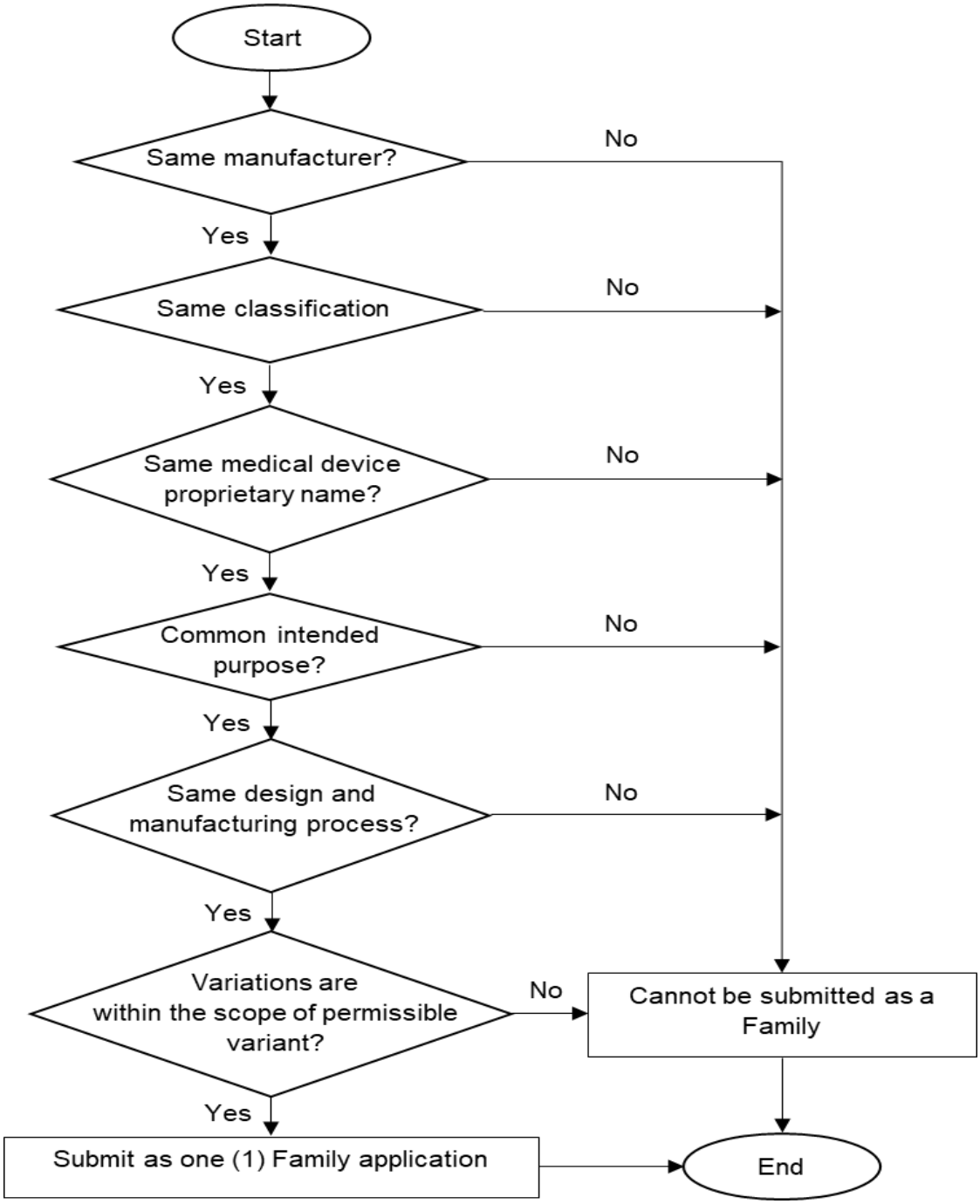
Annex A
(Normative)

Decision Flowchart for Grouping of Medical Devices as a SYSTEM



Annex B
(Informative)

Decision Flowchart for Grouping of Medical Devices as a FAMILY



Annex C
(Informative)

List of Permissible Variants in a Family

The list of permissible variants is a closed and positive list.

Specific products	Permissible variants
Abutments	Retention (e.g. cement or screw)
Active Implantable Devices	MR conditional and Non- MR Conditional
Biopsy Forceps	Formable or Non-formable
Blood Bags	(i) Anticoagulants with same composition but different concentrations (ii) Additives (different composition and concentrations)
Catheter	(i) Number of lumens in catheter (ii) Curvature (straight or pigtail) (iii) Coating material for lubrication
Condoms	(i) Texture (ii) Flavour
Contact lens	(i) Diopter, (ii) UV protection (iii) Tinting (iv) Colour (v) Wearing schedule (i.e. daily wear, extended wear) (vi) Replacement schedule (i.e. daily, weekly, monthly)
Defibrillators	Automatic or semi-automatic
Dental brackets	Material of bracket
Dental handpieces	(i) Rotational speed (ii) Material of handpiece

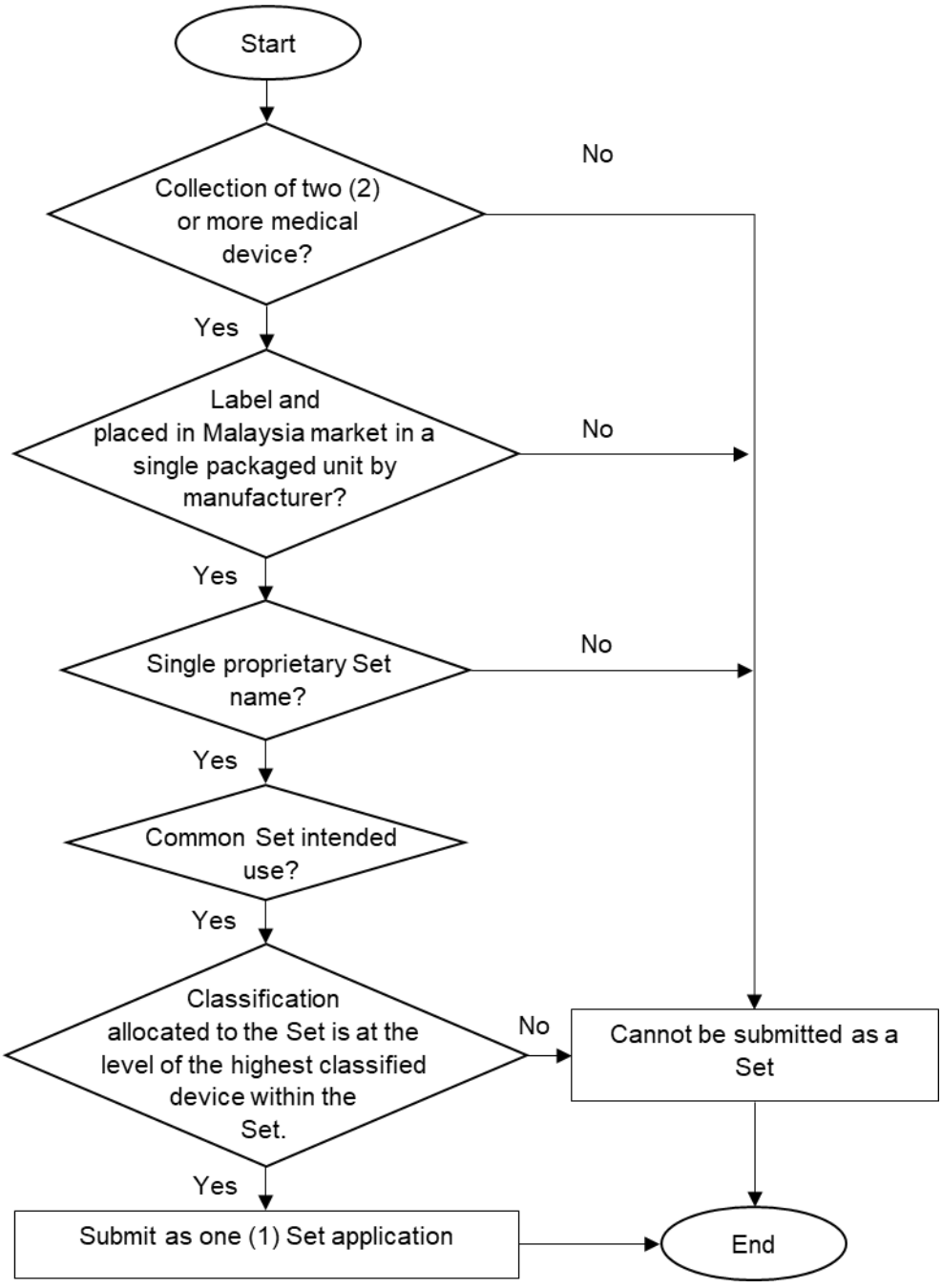
Specific products	Permissible variants
Dermal fillers	Same composition but different concentrations/densities
Diagnostic Radiographic systems	(i) Number of slices (ii) Digital vs Analog (iii) Biplane and Single Plane (iv) Flat Panel vs Cassette (v) PET ring size
Electrophysiological Catheter	(i) Electrode spacing (ii) Number of electrodes
Gloves	Powdered or powder-free
Gamma Camera	Number of detectors
Guide wire	With or without inert coating material
Orthopedic/ Dental Implants	(i) Cemented or non-cemented fixation (ii) Collar
Intra-ocular Lens	(i) Monofocal or Multifocal (ii) Multi-piece or Single-piece (iii) Aspheric or Spheric
Implantable Pulse Generators	Number of Chambers (Cardio)
IV Cannula	(i) Presence of injection port (ii) Presence of safety wing
Polymer products	With or without plasticisers (e.g. DEHP)
Stent	(i) Delivery system, that is over-the-wire or through the scope (ii) Flaps, Flares or sleeves

Specific products	Permissible variants
Suture	(i) Number of strands (ii) Pledgets (iii) Loops (iv) Dyes
Suture passer	Design of jaw, handle or needle
Tracheal Tube *(endotracheal tube, tracheostomy tube)*	With or without cuff
Wound Dressings	Different formats (e.g. solution, creams, gels loaded onto pads, etc)
X-ray detector	Scintillator material
Other permissible variants in general	
Coating material for lubrication only	
Colour	
Diameter, Length, Width, Gauge	
Concentration with same indication and mechanism (same composition different amount of constituent)	
Dimensional design differences due to pediatric versus adult use (The differences due to the different patient population are permissible, e.g. volume and length)	
Flexibility	
Holding force	
Isotope activity level	
Memory storage	
Method of Sterilization (to achieve same sterility outcome)	
Printing capability	
Radiopacity	
Shape, Size, Volume	

Viscosity (The change in viscosity is solely due to changes in the concentration of constituent material)
Type of device mounting (e.g. ceiling mount, wall mount or standing)

Annex D
(informative)

Decision Flowchart for Grouping of Medical Devices as a SET



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