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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); and

b) Medical Device Regulations 2012.

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

— “shall” indicates a requirement;

— “should” indicates a recommendation;

— “may” indicates a permission; and

— “can” indicates a possibility or a capability.

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

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

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

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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.

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 fulfillment 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.

3.3 Component

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.

The Examples:

a) 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 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.

NOTE. Constituent-components 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 should be registered together with each of these other systems. alternatively, these constituent-component(s) that are compatible for use with multiple systems shall be registered separately.

4.3.2.2 The decision flowchart for grouping of medical device 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) In-the-ear hearing aids which are designed in different sizes to be fitted in the ear (i.e. outer ear, middle ear, and inner ear canal), and have been designed using the same main components including the signal processor and compression circuit, microphone, amplifiers, and receiver, can be registered as a FAMILY.

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

g) 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.

4.3.4 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. Refer to Guidance Document on requirement of Labelling on Medical Device (MDA/GD/0026). Individual medical device names may contain additional descriptive phrase.

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 device 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 registered as part of a SET shall have a SINGLE medical device registration before they are sold separately as individual medical devices.

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 product 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 regulatory requirements 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 product owner
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.

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 (viii) Oocyte Transport

No	IVF Media Grouping Category (closed list)	Examples of Media Types (non-exhaustive list)
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
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 Embryo Transfer (Et)

4.3.6 Specific grouping for Hearing aid

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 is apply for hearing aids with of 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 based on design, sound amplification and communication technologies;

Design	Example: Behind-the-ear (BTE) aids, In-the-ear (ITE) aids, In-the-canal (ITC) aids and completely-in-the-canal (CIC) aids
Technology for sound amplification	Example: Analog hearing aids, Digital hearing aids
Communication Technology	Example: Wireless, Non Wireless

The hearing aids should 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 shall not be registered together in the same application even though both devices having similar technology (digital) and communication technology (wireless).

4.3.7 Specific grouping for dental medical devices

Dental Grouping (DG) are collective generic terms used to describe a group of with a common intended purpose.

A grouping of dental medical devices is a collection of dental devices and each individual device:

- is from the same manufacturer ;
- is of the same risk classification and
- intended purpose falls within the description of dental grouping

When dental devices satisfy the above conditions to be grouped in one application, the device name listed on the MEDCAST system upon approval will be based on the dental grouping term used. The description of the dental grouping will be used as intended use MEDCAST system.

The list of dental grouping and respective description is described in **Table 2**:

Table 2: List of dental grouping and respective description

No	Dental Grouping	Description
1.	Adhesive kit for dental composite	A kit/pack that contains a collection of devices intended to be used to bond attachments such as hooks or buttons to the teeth and/or to an orthodontic aligner during dental or orthodontic teeth adjustment.
2.	Cryoanaesthesia device, dental	A dental brace-like device that is chilled to freezing/subfreezing temperatures and then applied to the labial sulci (gums) in a patient's mouth for a period to provide a cold anaesthesia for the underlying nerves. This device may be used as a substitute for hypodermic drug delivery during dental procedures.
3.	Cryogenic spray, dental	A refrigerant use to cool down a tooth by spraying on it, mainly to find out if the pulp is vital. It can also be used as a local anaesthetic when extracting deciduous teeth in children.

No	Dental Grouping	Description
4.	Cusps, dental	A device designed to provide an artificial projection on the chewing surface of the tooth to achieve a proper bite
5.	Dental abrasives	A dental material which can be applied with an appropriate device to the surface of teeth or dental devices for prophylactic and/or treatment applications. This includes removal of plaque and stains, cleaning fissures (above and below the gingiva), the preparation of a tooth surface prior to bonding, the cleaning of orthodontic appliances (bands and brackets), the removal of adhesive residue, and the cleaning of implants prior to loading. It may include accessories required for dental abrasion.
6.	Dental absorbent	Non medicated device intended to be used to absorb fluids during dental procedures.
7.	Dental adhesives/ primers	A material used as a bonding promoting substance between dental materials. It does not include cements.
8.	Dental broach	A device that is designed with an abrasive outer surface to cut, open, enlarge, resurface with precision holes in hard tissues (e.g. bones, root canals), extirpating pulp and/or for exploring the root canal.
9.	Dental burs	A rotary cutting device designed to fit into a dental handpiece and intended to cut hard structures in the mouth, e.g. teeth or bone.
10.	Dental caries detector, electrical impedance	A device designed to measure resistance to the flow of electric current across teeth for the diagnosis of early stage dental caries and/or to monitor the progress of caries (carious areas being less resistant due to higher concentrations of fluid).
11.	Dental caries detector, optical induced fluorescence	A device designed to determine the changes in the fluorescence of teeth enamel and dentine due to mineral loss, mainly for the diagnosis of early stage dental caries and/or to monitor the progress of caries
12.	Dental caries removal solution	A substance used to detect and remove caries from an infected tooth.
13.	Dental casting materials	Compounds associated with the formation of a dental cast, i.e. a positive copy of a part of the oral anatomy made in an impression (mould).
14.	Dental cavity liner	A substance intended to be applied to the interior of a prepared cavity before insertion of restorative material, to protect the pulp of a tooth from chemical irritation.

No	Dental Grouping	Description
15.	Dental cement	Compounds used to bond a dental prosthesis to the anatomy (luting agent), to form an insulating layer under dental restorations. It may include accessories to complete the cementing procedure.
16.	Dental cement kit	A kit/pack that contains a collection of components designed to complete a cementing procedure.
17.	Dental crowns/ bridges	A material used to manufacture partial or full crowns and bridges.
18.	Dental disinfectants	A substance that destroys harmful microorganisms or inhibit their activity on medical devices which are specific for dental purposes or for use in dental procedures. It is not intended for disinfection as end point of processing.
19.	Dental dry field device	A device used in orthodontic and restorative dentistry to maintain a dry oral cavity for treatment procedures. It forms a frame around the oral cavity and provides the operator with easy access to the field of operation by holding the mouth open, displacing the tongue, and removing saliva during various procedures
20.	Dental dry field kit	A kit/pack that contains a collection of devices used in orthodontic and restorative dentistry to maintain a dry oral cavity for treatment procedures. It provides the operator with easy access to the field of operation by holding the mouth open, displacing the tongue, and removing saliva during various procedures.
21.	Dental etching composite	A device used to create a retentive surface for a composite, an adhesive or a pit and fissure sealant.
22.	Dental file	A device that is intended for smoothing, filing or cutting during dental procedure and typically have various forms of fine-ridged cutting surfaces along part or all of their working length. This device may be used to remove gross supragingival calculus, smooth the cementoenamel junction (CEJ), finish the margins of the teeth or other dental restorations or enlarge the root canal.
23.	Dental implant debridement brush	A rotary dental instrument designed for the debridement of a patient's dental implants affected by peri-implantitis.
24.	Dental implant extractor	A device used to retrieve a dental implant from the oral cavity.

No	Dental Grouping	Description
25.	Dental implant, accessories	Device designed to provide support and a means of retention for a dental prosthesis during surgical placement of a dental implant into alveolar and/ or basal bone of the mandible or maxilla.
26.	Dental implant, prosthetic teeth bar	A small rod that bears prosthetic teeth and allows them to be attached to the dental implant abutments.
27.	Dental implant, suprastructure	A prefabricated device that is incorporated into, or creates, a suprastructure on dental implants to mimic preparations of natural teeth.
28.	Dental implant/prosthesis, surgical procedure kit	A kit/pack that contains a collection of various dental instruments designed for the surgical placement of dental implants or prostheses. It does not contain pharmaceuticals.
29.	Dental precision attachments	Dental device designed for attaching a fixed or removable prosthesis to the crown of an abutment tooth, dental restoration (including implants), or dental appliance.
30.	Dental procedure console and accessories, hydraulic	An assembly of devices designed to bore/ excavate bones, teeth, and tough tissues during a dental surgical procedure. The system is powered by pressurized water via a connecting hose to the handpiece/motor water-driven turbine.
31.	Dental procedure console and accessories, line-powered	An assembly of devices designed to bore/ excavate bones, teeth, and tough tissues during a dental surgical procedure. This system is electrically-powered and supplies the handpiece/motor with low-voltage electricity through a control unit.
32.	Dental procedure console and accessories, pneumatic	An assembly of devices designed to bore/excavate bones, teeth, and tough tissues during a dental surgical procedure. The system is pneumatically-powered.
33.	Dental procedure handpiece, hydraulic	A hand-held dental device that includes a chuck for attaching dental drills, burs, reamers, and similar rotating instruments used to bore/excavate bones, teeth, and tough tissues in dentistry. The device is driven by a source of pressurized water.
34.	Dental procedure handpiece, line- powered	A hand-held dental device that includes a chuck or collet for attaching a dental drill, bur, reamer, and other similar rotating instruments used to bore/excavate bones, teeth, and tough tissues in dentistry. It is powered by a low- voltage electric micro-motor that is an integral part of the device.

No	Dental Grouping	Description
35.	Dental procedure handpiece, pneumatic	A hand-held dental device that includes a chuck for attaching dental drills, burs, reamers, and similar rotating instruments used to bore/excavate bones, teeth, and tough tissues in dentistry. It is pneumatically-powered.
36.	Dental pulp testing electrode gel	A device intended to be applied to the surface of a tooth before use of a pulp tester to aid conduction of electrical current.
37.	Dental pulp- capping material	A dental compound designed to cover an exposed or nearly-exposed dental pulp (e.g., due to deep cavities) to provide protection against external influences and to promote healing. This compound does not have dental cement or dental cavity liner intended uses.
38.	Dental reamer	A device that is designed with fine-toothed cutting edges to cut, open, enlarge openings in, and/or resurface hard tissues (e.g. bones, root canals) with precision.
39.	Dental reinforcing fibre	A device used in general restorative dentistry and orthodontic treatment as reinforcement of dental materials, used for the construction of dental prostheses. It may also be used for the stabilization of avulsed teeth maintaining diastema closures or split-tooth syndrome.
40.	Dental restorative / cavity varnish	A substance used to cover dental filling material in the initial setting period after application typically to prevent moisture infiltration for the protection of pulpal tissue and to provide a marginal seal to newly placed amalgam restorations.
41.	Dental restorative / repair materials	A substance intended to fill dental cavities, seal pits and fissures, restore damaged dental tissues, or for inlays, onlays and veneering. It may include accessories that are used specifically with the materials. It does not include obturation of root canal.
42.	Dental restorative/ repair kit	A kit/pack that contains a collection of devices designed to fill dental cavities, seal pits and fissures, restore damaged dental tissues, or for inlays, onlays and veneering. It does not include obturation of root canal.
43.	Dental retention pin	A device intended to be placed permanently in the tooth to provide retention and/or stabilization of dental restorations, e.g. fillings or crowns.
44.	Dental retention pin kit	A kit/pack that contains a collection of devices intended for the insertion of permanent pins in healthy dentin to provide retention and/or stabilization of dental restorations, e.g. fillings and crowns.

No	Dental Grouping	Description
45.	Dental scalers, pneumatic	Scaler tip/inserts which may consist of handpieces that are designed to use compressed air to generate a vibrating action at its point of patient contact for the removal of accretions from tooth surfaces during dental cleaning or periodontal (gum) therapy.
46.	Dental scalers, rotary	Scaler tip/inserts which may consist of handpieces that provides rotation and is used to remove calculus deposits and other accretions from tooth surfaces during dental cleaning and periodontal (gum) therapy.
47.	Dental scalers, ultrasonic	Scaler tip/inserts (which function as part of an ultrasonic scaler system) which may consist of handpieces that together transmit ultrasonic energy from a generator to the oral cavity for the removal of accretions from tooth surfaces during dental cleaning or periodontal (gum) therapy.
48.	Dental scaling system, pneumatic	An assembly of devices designed to use compressed air to generate a vibrating action at its point of patient contact for the removal of accretions from tooth surfaces during dental cleaning or periodontal (gum) therapy. The handpiece may connect to an existing air driven handpiece tubing and the water spray for lavage. This device is used for procedures that may involve the removal of plaque, biofilm, or gross calculus from shallow to deep periodontal pockets. It can be also used for the removal of orthodontic cement.
49.	Dental scaling system, rotary	An assembly of powered dental handpiece that provides rotation and is used to remove calculus deposits and other accretions from tooth surfaces during dental cleaning and periodontal (gum) therapy. This device is used for procedures that may involve the removal of plaque, biofilm, or gross calculus from shallow to deep periodontal pockets. It can be also used for the removal of orthodontic cement.
50.	Dental scaling system, ultrasonic	An assembly of devices that uses ultrasonic energy at its point of patient contact to remove accretions from tooth surfaces during dental cleaning or periodontal (gum) therapy. This device is used for procedures that may involve the removal of plaque, biofilm, or gross calculus from shallow to deep periodontal pockets. It can be also used for the removal of orthodontic cement.
51.	Dental sealants, endodontic	A substance used in endodontics to fill or permanently obturate the root canal of a tooth. The substance may be intended for orthograde use (i.e., a root filling placed from the coronal aspect).
52.	Dental sealants, pit/fissure	A material intended for sealing pits and fissures on teeth. It may include accessories to complete the sealing procedure.

No	Dental Grouping	Description
53.	Dental shaded pontic kit	A kit/pack that contains a collection of devices intended to be used to produce artificial tooth veneers (shaded pontics) typically inside clear plastic custom-made teeth aligners (retainer-style orthodontic appliances). This is used to create the appearance of teeth inside the aligner to cover spaces where teeth may be missing for aesthetic and/or therapeutic purposes during treatment to realign teeth.
54.	Dental solution, scaling	A substance used to soften and partially solubilize a dental calculus (a hard deposit that forms on the teeth) before scaling mechanically so that less force is required, especially when teeth are loose.
55.	Denture base resins	A material used for the fabrication of a denture base or repair of a denture.
56.	Denture clasps	Dental devices designed to retain and stabilize removable partial dentures to stationary teeth.
57.	Denture reliners	A device that is applied as a permanent coating or lining on the base or tissue-contacting surface of a denture to provide a new fitting surface to a denture.
58.	Dental suction system cannula	A component of a dental suction system designed to be inserted into the oral cavity for the aspiration and removal of blood, pus, saliva, debris, and water during a dental procedure.
59.	Facebow	A caliper-like dental instrument used to record the relative position of the maxillary arch to the temporo-mandibular joint (TMJ), or the opening axis of the jaw. It is used to orient dental casts in the same relationship to the opening axis of the articulator.
60.	Fixture/appliance dental drill	A device intended to be used in dental surgery to create channels of appropriate depth and diameter in bone (osteotomy) of the oral cavity to facilitate the implantation of a dental fixture/appliance. It is attached to a motorized handpiece or other power source that provides rotation.
61.	Gingiva bleaching protector	A substance designed to protect a patient's gums from the hydrogen peroxide found in teeth whitening agents used during chairside light-curing bleaching of the teeth.
62.	Gingival retraction cord, non- medicated	A non-medicated device used to temporarily hold off the gingiva during abutment preparation.
63.	Gingival retraction kit	A kit/pack that contains collection of devices used to temporarily hold off the gingiva during abutment preparation.

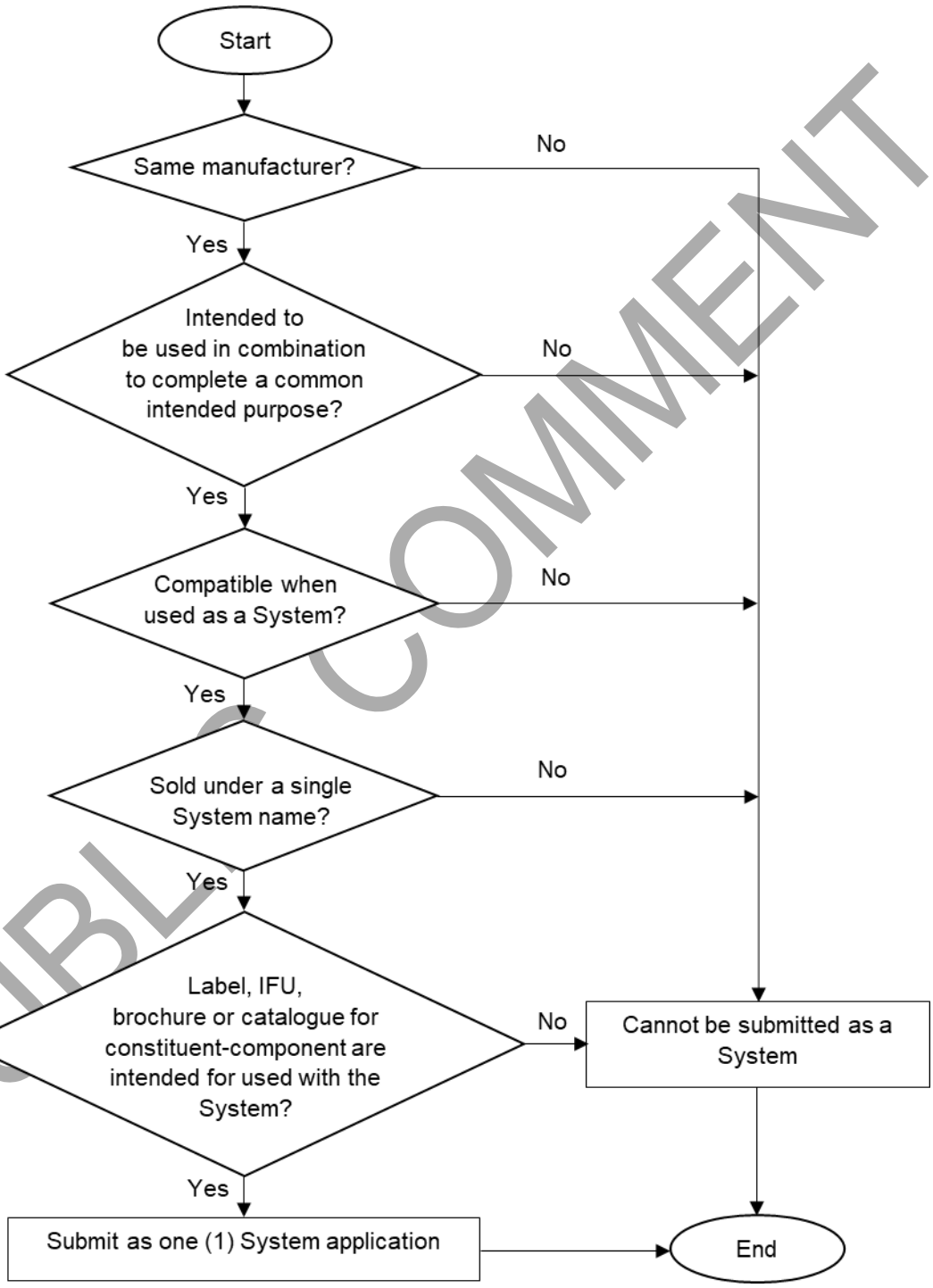
No	Dental Grouping	Description
64.	Gingival retraction solution	A substance used in dentistry to induce gingival retraction by in situ impregnation of a non-medicated gingival retraction cord. It induces contraction of the upper strata of the free gingiva. This device may also induce a local stasis of gingival exudates and gingival haemorrhages.
65.	Non-medicated dental surgical procedure kit,	A kit/pack that contains a collection of dental instruments, dressings and the necessary materials used to perform a dental surgical procedure. It does not contain any pharmaceuticals.
66.	Oral wound dressing	A device intended as a protective cover for the oral mucosa to manage wounds and sores in the mouth. It is used for various types of dental wounds, sores and lesions caused by dental prostheses/orthodontic braces; it may also be used to treat mucosal irritations/inflammation, dryness and gingivitis. This does not include pharmaceuticals.
67.	Orthodontic appliance archwire-cooling device	A device used in orthodontic dentistry to intra-orally chill or cool thermally-activated archwires when placing bends in an orthodontic appliance.
68.	Orthodontic appliances	Dental devices designed to influence the shape and/or function of the stomatognathic system through the application of physical force.
69.	Orthodontic space maintainer	A dental prosthetic replacement for prematurely lost deciduous teeth intended to prevent closure of the space before eruption of the permanent successors.
70.	Periodontal dressing	A material which is placed over the periodontal tissues as a dressing, normally after surgery. This does not include pharmaceuticals.
71.	Root canal filling- removal solution	A substance used in endodontic procedures for the softening and removal of root canal fillings.
72.	Root canal irrigation/ rinsing solution	A substance used to facilitate cleansing/irrigation of the root canal (the canal space) during and/or after endodontic instrumentation for the removal of the smear layer, pulpal tissue, necrotic materials, and bacteria from the instrumented root canal, before placement of the endodontic filling.
73.	Root canal obturation kit	A kit/pack that contains a collection of devices designed to permanently prime, seal, and/or fill a tooth undergoing a root canal procedure.
74.	Root canal post kit	A kit/pack that contains collection of root canal posts and devices used for the insertion of root canal posts.

No	Dental Grouping	Description
75.	Root canal posts	A device intended to be inserted and cemented into a prepared root canal of a tooth to stabilize and support a restoration.
76.	Root canal preparation kit	A kit/pack that contains a collection of dental devices designed to be used in root canal preparation.
77.	Root surface conditioner	A material used for topical application on exposed/scaled root surfaces for the removal of the smear layer during dental/periodontal surgery. The material is removed after the recommended period to expose the collagenous matrix of dentine surfaces.
78.	Tooth preservation kit	A kit/pack that contains a collection of devices designed to preserve and transport a tooth that has been knocked out (i.e., avulsed) so it can be reimplanted. It is used to avoid tooth cell crushing and/or dehydration by immersing the tooth in a pH balanced solution compatible with periodontal cells, and is used in field emergency situations after traumatic knock out of teeth.
79.	Warm-bonded endodontic obturation system	Devices designed to deliver preheated sealing, filling, and core materials into a root canal for direct warm bonding during an endodontic obturation procedure.

Annex A

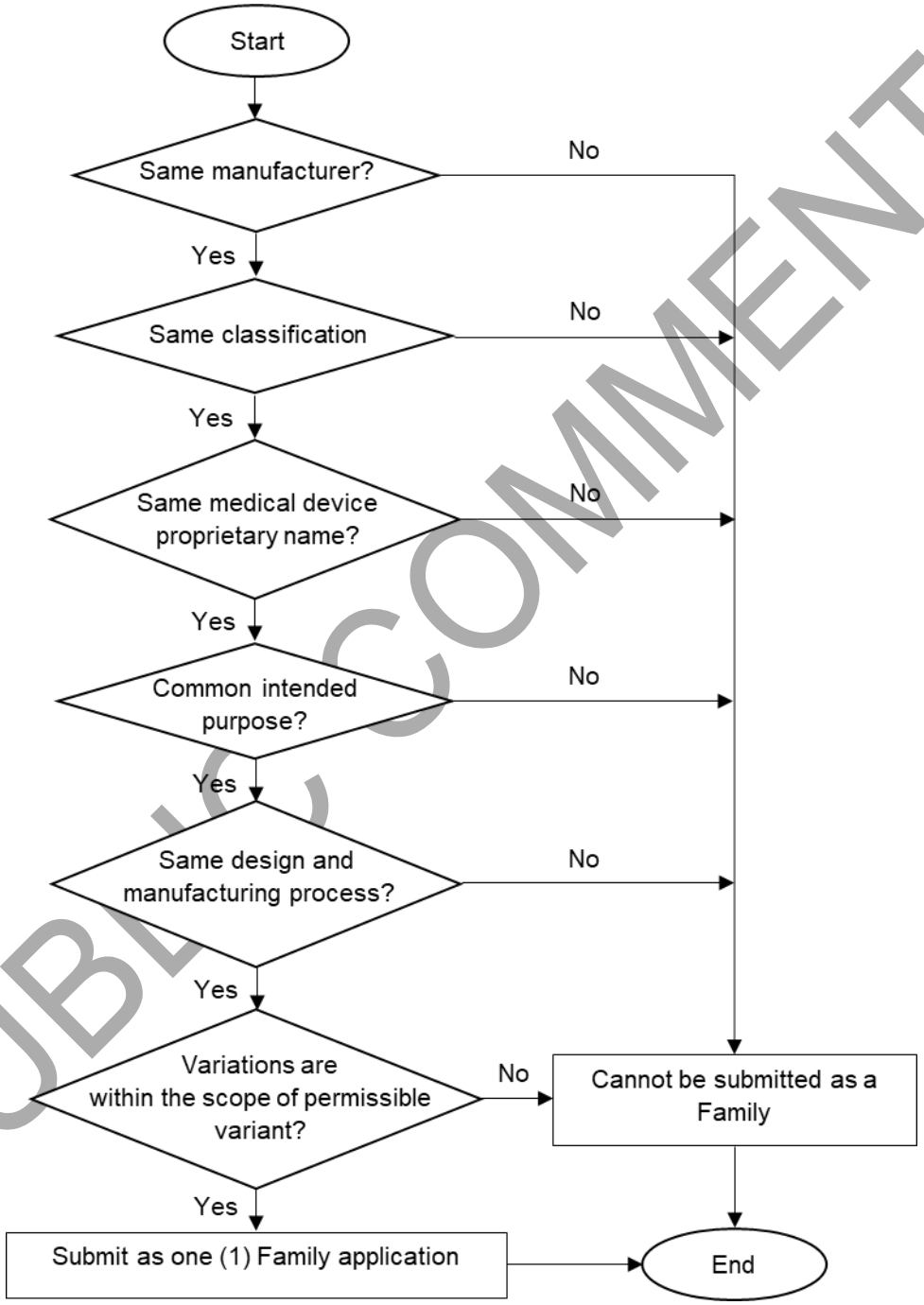
(Informative)

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

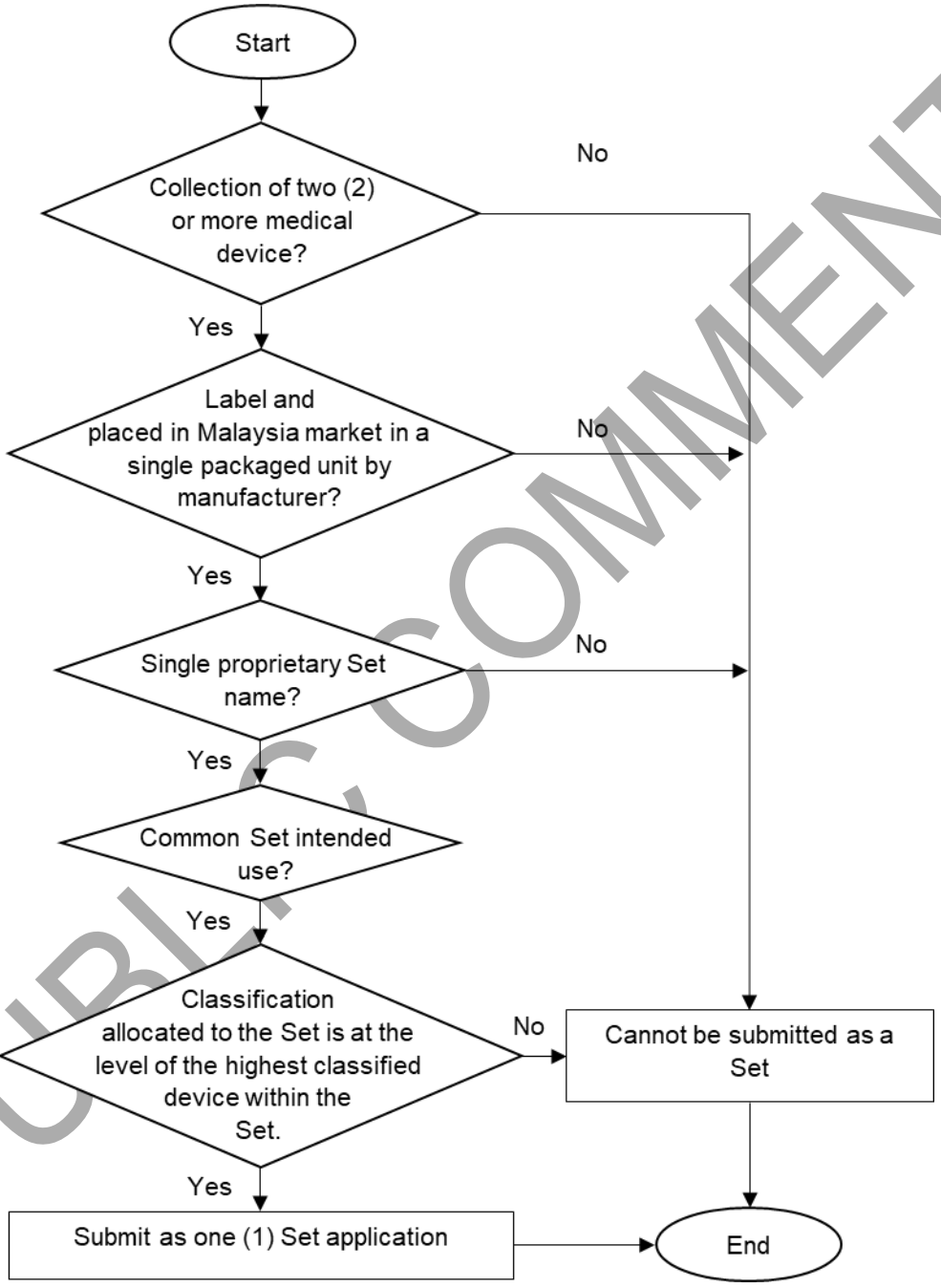
Specific products	Permissible variants
Dermal fillers	Same composition but different concentrations/densities
Diagnostic Radiographic systems	(i) Number of slices (ii) Digital vs Analog (iii) Biplane and Single Plane (iv) Flat Panel vs Cassette (v) PET ring size
Electrophysiological Catheter	(i) Electrode 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 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
Hearing aid	(i) Design a) Behind the ear (BTE) b) In the ear (ITE). ITE devices have all components of the hearing aid contained in a case shell that fits in the ear or canal. (ii) By technology for sound amplification a) Analogue b) Digital (iii) By communication technology a) Wireless b) Non-wireless

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



MEDICAL DEVICE AUTHORITY

MINISTRY OF HEALTH, MALAYSIA

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