GUIDANCE ON THE PRODUCT GROUPING

DRAFT

MEDICAL DEVICE GUIDANCE DOCUMENT

MEDICAL DEVICE CONTROL DIVISION

Ministry of Health Malaysia
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1.0 Introduction
Under the Medical Device Act 20xx, the manufacturer or the Local 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, IVD TEST KIT, SYSTEM, and SET. Each of the categories mentioned can be submitted in the medical device registration application.

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

3.0 Scope
This document applies to all products that fall within the definition of medical device that has been specified in the Guidance Document GD-xx1: The Definition of Medical Device.

4.0 Terms and Definitions
Accessory: for the purposes of this guidance document, an accessory is an article that is intended specifically by its manufacturer to:
• 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 to 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.

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.

Generic 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.
**Intended Purpose:** The use for which the medical device is intended according to the specifications of its manufacturer as stated on any or all of the following:

- the label of the medical device;
- the instructions for use of the medical device;
- the promotional materials in relation to the medical device.

**Local Authorised Representative (LAR):** The applicant who applies to register the device must be a legal person incorporated in Malaysia, or a natural or legal person with business registration in Malaysia who has received a written mandate from the manufacturer to act on his behalf for specified tasks with regard to the latter’s obligations or jurisdiction’s legislation.

**Manufacturer:** means —

(a) any person who is responsible for —

(i) the design, production, fabrication, assembly, processing, packaging and labeling of a medical device whether or not it is the person, or a subcontractor acting on the person’s behalf, who carries out these operations; and

(ii) assigning to the finished medical device under his own name, its intended purpose and for ensuring the finished product meets the regulatory requirement; or

(b) any other person who —

(i) assembles, packages, processes, fully refurbishes, reprocess or labels one or more ready-made medical devices; or

(ii) assigns to them their intended purpose as a medical device under his own name;

but shall not include the following persons:

(a) any person who assembles or adapts the medical device in the market that is intended for an individual patient; and

(b) any person who assembles, packages or adapts the medical device to which the assembling, packaging or adaptation does not change the purpose intended for the medical device.

**Medical Device:** refer to GD-xx1: The Definition of Medical Device.

**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.
5.0 General Principles of Grouping

Medical devices that can be grouped into one of the following five categories can be submitted in one application for product registration and listing in the Malaysia Medical Device Register (MMDR):

- SINGLE,
- FAMILY,
- IVD TEST KIT,
- SYSTEM; and
- SET.

Three basic rules must all be fulfilled for the grouping to apply. These are:

- one generic proprietary name;
- one manufacturer; and
- one common intended purpose.

For the purpose of grouping, the corporate headquarters may be regarded as the manufacturer for its subsidiaries and regional manufacturing sites.

![Diagram of product grouping](image)

**Figure 1: Example of referencing the headquarters as the manufacturer for the purpose of grouping**
For example, TRS MDB ORTHOPAEDIC SYSTEM consists of the following constituent-components (refer to Figure 1):

- Instruments from ABC Bhd (a subsidiary of TRS MDB Malaysia),
- Instruments from XYZ Bhd (a subsidiary of TRS MDB Mexico),
- Plates from TRS MDB Mexico; and
- Screws from TRS MDB China

For the purpose of grouping, the manufacturer of TRS ORTHOPAEDIC SYSTEM will be TRS MDB Malaysia (Headquarters).
6.0 Categories

6.1 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.

Examples:

- **Condoms** that are sold in packages of 3, 12 and 144 can be registered as a SINGLE medical device.
- A company manufactures a **software program** that can be used with a number of CT scanners produced by other manufacturers. Although the software cannot function on its own, it can be used on different scanners. The software can be registered as a SINGLE medical device.
- A company that assembles and registers a **first aid kit** has now decided to also supply each of the medical devices in the first aid kit individually. Each medical device supplied individually must be registered separately as a SINGLE medical device.

6.2 System

A medical device SYSTEM comprises of a number of constituent-components that are:

- from the same manufacturer;
- intended to be used in combination to complete a common intended purpose;
- compatible when used as a SYSTEM; and
- sold under a SYSTEM name or the labeling, 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 must be registered separately.

The decision flowchart for grouping of products as an SYSTEM can be found in Annex 1.
Figure 2: Example on Grouping of Systems as a Family

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.
In addition, if several SYSTEMs fulfill the following conditions to be grouped as a FAMILY, they may be registered as a FAMILY:

- the SYSTEMs are from the same manufacturer;
- the SYSTEMs are of the same risk classification class;
- the SYSTEMs have a common intended purpose;
- the SYSTEMs have the same design and manufacturing process; and
- key constituent-components of the SYSTEMs have variations that are within the scope of the permissible variants.
- has the same generic proprietary name

Individual SYSTEM names may contain additional descriptive phrases.

The Registrant has to undertake the following post-market duties and obligations for all the constituent-components in the registered SYSTEM, regardless of whether the constituent-components are from the same product owner of the SYSTEM:

- comply with the conditions applicable to the registered medical device and conditions imposed on the Registrant;
- submit applications to the Authority for changes made to the registered medical device;
- maintain records of supply;
- maintain records of complaints;
- report defects and adverse effects to the Authority, and
- notify the Authority concerning field safety corrective action (FSCA), including recall.

An In Vitro Diagnostic (IVD) Medical Device SYSTEM may typically consist of TEST KITs and instruments (e.g. an analyser designed to be used with that TEST KIT).

Examples:

- **A hip replacement SYSTEM** comprising of femoral and acetabular components can be registered as a SYSTEM. The components must be used in combination to achieve a common intended purpose of total hip replacement. The size of the components may vary.
- **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.
- Optional accessory such as wireless controller is part of **In-the-ear hearing aid** can be registered as a SYSTEM.
- **A glucose monitoring SYSTEM** comprising of a glucose meter, test strips, control solutions and linearity solutions can be registered as a SYSTEM.
6.3 Family
A medical device FAMILY is a collection of medical devices and each medical device FAMILY member:

- is from the same manufacturer;
- is of the same risk classification;
- has the same generic proprietary name;
- has a common intended purpose;
- has the same design and manufacturing process; and
- has variations that are within the scope of the permissible variants.

The decision flowchart for grouping of products as an FAMILY can be found in Annex 2.

A characteristic of a medical device may be considered a permissible variant if:
- the physical design and construction of the medical devices are the same, or very similar;
- the manufacturing processes for the medical devices are the same, or very similar;
- the intended purpose of the medical devices is the same; and
- the risk profile of the medical devices, taking into account the above factors, is the same.

See Annex 3 for a list of permissible variants in a FAMILY.

If medical devices satisfy the above conditions to be grouped as a FAMILY, but have different device proprietary names, the products will be listed separately on the Malaysia Medical Device Register (MMDR) based on their proprietary name.

Information on all medical devices within a FAMILY must be submitted as part of one product registration application. Only members of a FAMILY that are eventually listed on the register shall be supplied on the market. Those that are not listed shall not be supplied on the market.

The medical device proprietary name must appear on the label of each of the member medical devices. Individual medical device names may contain additional descriptive phrase.

A special grouping rule is applicable for Class A reusable surgical instruments. See Annex 4 for this grouping rule.
Examples:

- **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.
- **IV administrative sets** that differ in features such as safety wings and 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.
- **Steerable guidewires** that are available in various lengths and possess various tip shapes and tip flexibilities can be registered as a FAMILY if their variations fall within the scope of permissible variants.
- **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.
- **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.
- **Automated blood pressure monitors** with optional features such as memory storage and print capability can be considered as part of a FAMILY.
- **Cardiac catheters** that are available in a different number of lumens, lengths and diameters can be registered as a FAMILY.
- **Contact lenses** are available as toric lens and spherical lens. These products 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.
6.4 SET
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 single proprietary SET name, and
- a common intended purpose
- classification allocated to the set is at the level of the highest classified device within the set.

Each medical device in the SET may have different design and manufactured by different manufacturers.

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.

Information on all medical devices within a SET must be submitted as part of one product registration application. Only medical devices within a SET that are eventually listed on the register shall be supplied on the market. Those that are not listed shall not be supplied on the market. Medical devices that are registered as part of a SET must have a SINGLE medical device registration before they are sold separately as individual medical devices.

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.

The SET name indicated for the medical device must 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.

The Registrant has to undertake the following post-market duties and obligations for all the constituent-components in the registered SET, regardless of whether the constituent-components are from the same manufacturer of the SET:

- comply with the conditions applicable to the registered medical device and conditions imposed on the Registrant;
- submit applications to the Authority for changes made to the registered medical device;
- maintain records of supply;
- maintain records of complaints;
- report defects and adverse effects to the Authority and
- notify the Authority concerning field safety corrective action (FSCA), including recall.
Examples:

- 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.

- 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.

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

- A promotional pack consisting of different number of medical devices, for example multipurpose solution, saline solution, and contact lens case, will not require a SET registration. Individual medical devices shall require registration as SINGLE medical devices.

6.5 IVD Test Kit

An IVD TEST KIT is an in vitro diagnostic (IVD) device that consists of reagents or articles that are:

- from the same manufacturer;
- intended to be used in combination to complete a specific intended purpose;
- sold under a single TEST KIT name or the labeling, instructions for use (IFU), brochures or catalogues for each reagents or article states that the component is intended for use with the IVD TEST KIT; and
- compatible when used as a TEST KIT.

An IVD TEST KIT does not include the instruments, such as analysers, needed to perform the test.

The decision flowchart for grouping of products as an IVD TEST KIT can be found in Annex 5.

Information on all reagents or articles within an IVD TEST KIT must be submitted as part of one product registration application. Only those reagents or articles within an IVD TEST KIT that are eventually listed on the register shall be supplied on the market. Those that are not listed shall not be supplied on the market.

Individual reagents or articles can be supplied separately as replacement items for the kit. If the reagents or articles in a TEST KIT are supplied for use in more than one TEST KIT, such
reagents or articles shall be included in the product registration application of each of the other TEST KITS.

Reagents or articles from another manufacturer may be registered with the IVD TEST KIT. The Registrant has to undertake the following post-market duties and obligations for all the reagents and articles in the registered IVD TEST KIT, regardless of whether the reagents or articles are from the same manufacturer of the IVD TEST KIT:

• comply with the conditions applicable to the registered medical device and conditions imposed on the Registrant;
• submit applications to the Authority for changes made to the registered medical device;
• maintain records of supply;
• maintain records of complaints;
• report defects and adverse effects to the Authority and
• notify the Authority concerning field safety corrective action (FSCA), including recall.

Examples:
• A Human Immunodeficiency Virus (HIV) Enzyme Linked ImmunoSorbent Assay (ELISA) TEST KIT may contain controls, calibrators and washing buffers. All the reagents and articles are used together to detect HIV and therefore can be registered as a TEST KIT. These reagents and articles can be supplied separately as replacement items for that particular TEST KIT but must be registered as a SINGLE IVD device.
ANNEX 1: Decision Flowchart For Grouping of Products as a System

- Same manufacturer?  
  - Yes  
  - No
- Intended to be used in combination to complete a common intended purpose?  
  - Yes  
  - No
- Compatible when used as a System?  
  - Yes  
  - No
- Sold under a single System name?  
  - Yes  
  - No
- Label, IFU, brochure or catalogue for constituent-component states that the constituent-components are intended for use with the System?  
  - Yes
- Cannot be submitted as a System  
  - No
- Submit as 1 System application
ANNEX 2: Decision Flowchart for Grouping of Medical Devices as a Family

- Same manufacturer? (No -> Yes)
  - Yes
  - Same classification? (No -> Yes)
    - Yes
    - Common intended purpose? (No -> Yes)
      - Yes
      - Same design and manufacturing process? (No -> Yes)
        - Yes
        - Variations are within the scope of permissible variants? (No -> Yes)
          - Yes
          - Same medical device proprietary name? (Yes)
            - Submit as 1 FAMILY application
          - No
        - No
      - No
    - No
  - No
- No

Cannot be submitted as a FAMILY
ANNEX 3: Permissible Variants in a Family

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

<table>
<thead>
<tr>
<th>Specific products</th>
<th>Permissible variants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antibiotic test</td>
<td>(i) Concentrations</td>
</tr>
<tr>
<td>Catheter</td>
<td>(i) Number of lumens in catheter</td>
</tr>
<tr>
<td></td>
<td>(ii) Material of catheter: PVC (polyvinylchloride), PU (polyurethane), nylon and silicone</td>
</tr>
<tr>
<td>IV Cannula</td>
<td>(i) Presence of injection port (ii) Presence of safety wing</td>
</tr>
<tr>
<td>Condoms</td>
<td>(i) Texture</td>
</tr>
<tr>
<td></td>
<td>(ii) Flavour</td>
</tr>
<tr>
<td>Contact lens</td>
<td>(i) Diopter,</td>
</tr>
<tr>
<td></td>
<td>(ii) UV protection</td>
</tr>
<tr>
<td></td>
<td>(iii) Tinting</td>
</tr>
<tr>
<td>Electrophysiological</td>
<td>(i) Electrode spacing</td>
</tr>
<tr>
<td>Catheter</td>
<td>(ii) (ii) Number of electrodes</td>
</tr>
<tr>
<td>Suture</td>
<td>(i) Number of strands</td>
</tr>
<tr>
<td></td>
<td>(ii) Pledgets</td>
</tr>
<tr>
<td>Suture passer</td>
<td>(i) Design of jaw, handle or needle</td>
</tr>
<tr>
<td>Dental handpieces</td>
<td>(i) Rotational speed</td>
</tr>
<tr>
<td></td>
<td>(ii) Material of handpiece</td>
</tr>
<tr>
<td>Dental brackets</td>
<td>(i) Material of bracket</td>
</tr>
<tr>
<td>IVD rapid tests</td>
<td>(i) Different assembly format: cassette, midstream, strip</td>
</tr>
<tr>
<td>IVD urinalysis strips</td>
<td>(i) Different combination of testing configurations</td>
</tr>
</tbody>
</table>
### Other permissible variants in general

<table>
<thead>
<tr>
<th>Feature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colour</td>
</tr>
<tr>
<td>Diameter</td>
</tr>
<tr>
<td>Flexibility</td>
</tr>
<tr>
<td>Gauge</td>
</tr>
<tr>
<td>Holding force</td>
</tr>
<tr>
<td>Isotope activity level</td>
</tr>
<tr>
<td>Length</td>
</tr>
<tr>
<td>Memory storage</td>
</tr>
<tr>
<td>Print capability</td>
</tr>
<tr>
<td>Radiopacity</td>
</tr>
<tr>
<td>Shape</td>
</tr>
<tr>
<td>Size</td>
</tr>
<tr>
<td>Volume</td>
</tr>
<tr>
<td>Width</td>
</tr>
<tr>
<td>Viscosity (The change in viscosity is solely due to changes in the concentration of constituent material)</td>
</tr>
</tbody>
</table>
ANNEX 4: Special Grouping Rule for Class A Reusable Surgical Instruments

A special grouping rule is applicable to Class A reusable surgical instruments. The special grouping rule states that reusable surgical instruments can be grouped together as 1 FAMILY if they satisfy the following conditions:

- are from the same manufacturer
- same overall intended purpose (This refers to the overall intended purpose of the instrument, regardless of location of the body they are used on).

For example, Class A lung retractor and Class A kidney retractor have the same overall intended purpose as they are both retractors. However, lung forceps and lung retractors do not have the same overall intended purpose and therefore cannot be grouped together as a FAMILY.

This special grouping rule is only applicable to Class A reusable surgical instruments. It is not applicable to Class B, C and D reusable surgical instruments.

Example:

<table>
<thead>
<tr>
<th>Instrument name</th>
<th>Description</th>
<th>Intended purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABC Dressing Forceps</td>
<td>Delicate, Serrated Tips, Straight, 4¾&quot;</td>
<td>To pick up or grasp tissue or items in the surgical wound</td>
</tr>
<tr>
<td>DEF Kidney Forceps</td>
<td>Half curved, 222 mm length</td>
<td>To grasp renal polyps</td>
</tr>
<tr>
<td>HIJ Lung Forceps</td>
<td>Triangular jaws, jaw width 11”, length 8”</td>
<td>To grasp lung tissue</td>
</tr>
<tr>
<td>XYZ Uterine Biopsy Forceps</td>
<td>Oblong basket jaw, jaw size 3x10mm, shaft length 10”</td>
<td>To grasp tissue during transvaginal or transrectal tissue biopsy</td>
</tr>
</tbody>
</table>
In the example above, the forceps have the same product owners, but have different proprietary names (ABC, DEF, HIJ and XYZ) and different intended purposes. These forceps are Class A medical devices.

These forceps can be grouped as a FAMLY and registered as part of one application on the basis of the special grouping rule for Class A reusable surgical instrument because:

- they are Class A reusable surgical instruments,
- the product owner is the same for all instruments, and
- they have the same overall intended purpose (i.e. to grasp).
ANNEX 5: Decision Flowchart for Grouping of Products as a IVD Test Kit

- **Same manufacturer?**
  - Yes
  - Intended to be used in combination to complete a common intended purpose?
    - Yes
    - Compatible when used as a System?
      - Yes
      - Sold under a single System name?
        - Yes
        - Label, IFU, brochure or catalogue for constituent-component states that the constituent-components are intended for use with the System?
          - Yes
          - Submit as 1 System application
        - No
      - No
    - No
  - No
  - Cannot be submitted as a System
    - Yes
    - No