Sultanate of Oman

Ministry of Health

Directorate of the General Pharmaceutical affair and Drugs control

Medical Device Control Department

Guidance Document GD 14:
Medical Devices Bundling/ Grouping Criteria

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1 Introduction

Under the Omani Medical Device bylaw, 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 Omani 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, Procedure Pack, and IVD. Each of the categories mentioned can be submitted in the medical device registration application.

2 Scope

The purpose of this document is to provide criteria for medical devices bundling/ grouping within a single medical device registration application. This document is applicable to any Medical Devices:

- Local Manufactures.
- Overseas Manufacturers.
- Authorized Representatives.

3 Definition

Medical Device	Means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article. (A). Intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of: - Diagnosis, prevention, monitoring, treatment or alleviation of disease. - Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap. - Investigation, replacement, modification, or support of the anatomy or of a physiological process. - Supporting or sustaining life. - Control of conception. - Disinfection of medical devices. - Providing information for

	medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and (B). Which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.
In-Vitro Medical Device	Means a medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes. This includes reagents, calibrators, control materials, specimen receptacles, software and related instruments or apparatus or other articles. Manufacturer Means any natural or legal person with responsibility for design.
Authorized Representative	Means any natural or legal person established within the KSA who has received a written mandate from the manufacturer to act on his behalf for specified tasks including the obligation to represent the manufacturer in its dealings with the SFDA.
Global Harmonization Task Force	Countries working to achieve harmonization in medical device regulation among themselves. These countries are Australia, Canada, Japan, the USA and the EU/EFTA.
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.
Accessory	Means a product intended specifically by its manufacturer to be used together with a medical device to enable that medical device to achieve its intended purpose.

Surgical instruments	Instruments intended for surgical use by cutting, drilling, sawing, scratching, scraping, clamping, retracing, clipping or other surgical procedure without connection to any other medical device.

4 Abbreviations

SFDA	Saudi Food and Drug Authority.
AR	Authorized Representative.
MDMA	Medical Devices Marketing Authorization.
GHTF	Global Harmonization Task Force.

5 Criteria of Bundling/Grouping

5.1 Criteria of Bundling/ Grouping for Medical Devices other than IVD medical devices:

There are four types of application submission for medical devices other than IVD medical devices as follow:

1. Single medical device.

2. Family of medical devices.

3. System:

    A. Medical device system.

    B. Medical device systems group.

4. Procedure pack of medical devices.

The four types for application submission are discussed below:

5.1.1 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 sizes, quantity and color. Each "single medical device" shall be registered alone within a single application as a "single medical device".

EXAMPLES	
1.	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".
2.	A manufacturer has a "first aid kit" registered as a "procedure pack", where the manufacturer wishes to market any member/ item of the first aid kit separately, applicant shall apply as a "single medical device".
3.	Gloves that are sold in packages of 25, 50 and 100 pieces can be registered as a "single medical device".

5.1.2 Family

"Family of medical devices" is a group of medical devices that are made by the same manufacturer, that differ in only shape and features, that have a similar design and that have the same common intended use. Applicant can group/ bundle more than one medical device within a single application as a "Family of medical devices", when the following criteria are applied. Medical devices that are grouped/bundled within a single application of MDMA shall:

- Be under same manufacturer.
- Have same risk class.
- Have same generic propriety name.
- Have a common intended use/ purpose.
- Have similar design.
- Be within the scope of the permissible variants.

  - For SURGICAL INSTRUMENTS, each group of the following surgical instruments will be grouped/bundled within a single application as a "family of medical devices" based on the following function (see example #4):
    - Cut or incise
    - Retract
    - Grasp, Hold or Occlude
    - Dilate or Probe
    - Cannulate or Drain
    - Aspirate, Inject or Infuse
    - Suture or Ligate
    - Others

NOTES:

- Accessories can be included with its device within the single application at accessories section.
- Accessories included within a single application procedure shall be intended specifically by its manufacturer to be used together with main medical device system to enable that medical device system to achieve its intended purpose.

• Where the manufacturer wishes to market any accessory separately, applicant shall apply for another application.

<table>
<tr><td colspan="2">EXAMPLES</td></tr>
<tr><td>1.</td><td>Steerable guide wires that are available in various lengths and possess various tip shapes and tip flexibilities can be grouped/bundled within a single application as a “family of medical devices” if their variations fall within the scope of permissible variants.</td></tr>
<tr><td>2.</td><td>Cardiac catheters that are available in a different number of lumens, lengths and diameters can be grouped/bundled within a single application as a “family of medical devices”.</td></tr>
<tr><td>3.</td><td>Lung retractor and kidney retractor have the same overall intended purpose as they are both retractors. However, lung forceps and lung retractors don`t have the same overall intended purpose and therefore shall NOT be grouped/bundled within a single application as a “family of medical devices”.</td></tr>
<tr><td>4.</td><td>For surgical instruments can be grouped/bundled within a single application as a “family of medical devices” , each group of the following surgical instruments will be grouped/bundled within a single application as a “family of medical devices” based on the following function:
<table>
<tr><th></th><th>SURGICAL INSTRUMENT NAMES</th><th>DEFINED AS INSTRUMENTS OF</th></tr>
<tr><td>1</td><td>Scissors, Knives, Saws and Blades</td><td>Cut or incise</td></tr>
<tr><td>2</td><td>Traction and bone hooks</td><td>Retract</td></tr>
<tr><td>3</td><td>Tissue and bone holding forceps, also needle holders</td><td>Grasp, Hold or Occlude</td></tr>
<tr><td>4</td><td>Punch</td><td>Dilate or Probe</td></tr>
<tr><td>5</td><td>Catheters or any instrument used for drain.</td><td>Cannulate or Drain</td></tr>
<tr><td>6</td><td>Instrument to remove unwanted fluids as well as to inject fluids such syringes or some needles,</td><td>Aspirate, Inject or Infuse</td></tr>
<tr><td>7</td><td>Sutures, clips as well as suture needles and ligating Blades</td><td>Suture or Ligate</td></tr>
</table></td></tr>
</table>

5.1.3 System

Medical device system:

A "medical device system" comprises of a number of constituent-components to complete a common intended purpose. Applicant can group/ bundle more than one constituent-component to complete a common intended purpose within a single application as a "medical device system", when the following criteria are applied. Members of "medical device system" that are grouped/bundled within a single application shall:

- Have same manufacturer.
- Be intended to be used in combination to complete a common intended purpose.
- Compatible when used as a "medical device system".
- Sold under a "medical device 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 "medical device system".

NOTES:

- Applicant shall select the highest risk-class among the "medical device system" members included in the application.
- Accessories can be included with its device within the single application at accessories section.
- Accessories included within a single application procedure shall be intended specifically by its manufacturer to be used together with main medical device system to enable that medical device system to achieve its intended purpose.
- Where the manufacturer wishes to market any accessory separately, applicant shall apply for another application.

1.	A hip replacement "system" comprising of femoral and acetabular components can be registered as a "medical device 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.
2.	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 grouped/bundled within a single application as a "medical device system".
3.	A glucose monitoring "system" comprising of a glucose meter, test strips, control solutions and linearity solutions can be grouped/bundled within a single application as a "medical device system".

5.1.4 Medical device systems group

Applicant can group/ bundle more than one "medical device system" within a single application as a "grouping medical device systems", when the following criteria are applied:

• "Medical devices systems" that are grouped/bundled within a single application shall:

- Be under same manufacturer.

- Have same risk class.

- Have a common intended use/ purpose.

- Have same design and manufacturing process.

- Have same generic proprietary name.

- Be within the scope of the permissible variants.

• Key constituent-components of "medical devices systems" shall have variations that are within the scope of the permissible variants.

5.1.5 Procedure pack

A "medical device procedure pack" is a collection of two or more medical devices, assembled together to perform a certain procedure as one package by a manufacturer. Applicant can group/ bundle more than one medical device type to perform a certain procedure in one package within a single application as a "procedure pack of medical devices" when the following criteria are applied:

- Members of medical device procedure pack that are grouped/bundled within a single application:

- Can be from different manufacturer.

- May have different design

- The medical device procedure pack shall have a master label showing the content; the label shall be affixed on the external package of the procedure pack.

- The classification of procedure packs shall be grouped/bundled within a single application as a "procedure pack of medical devices" based on specialty as the following:

1. Anesthesiology.
2. Cardiovascular.
3. Chemistry Dental.
4. Ear, Nose, and Throat.
5. Gastroenterology and Urology.
6. General and Plastic Surgery.
7. General Hospital.
8. Neurology.
9. Obstetrical and Gynecological.
10. Ophthalmic.
11. Orthopedic.
12. Physical Medicine.
13. Radiology.

- Total number of medical device that are grouped/bundled within a single application shall not exceed 50 items within a single application.

NOTES:

- Where the manufacturer wishes to market any member of procedure pack separately, applicant shall apply for anther application.

- Where the manufacturer wishes to market any member of procedure pack in another procedure pack, the member of procedure pack shall be included in another procedure pack application.

5.2 Criteria of Bundling/ Grouping for In-Vitro Medical Devices

For IVD Medical Device, they may be grouped into one of the following categories:

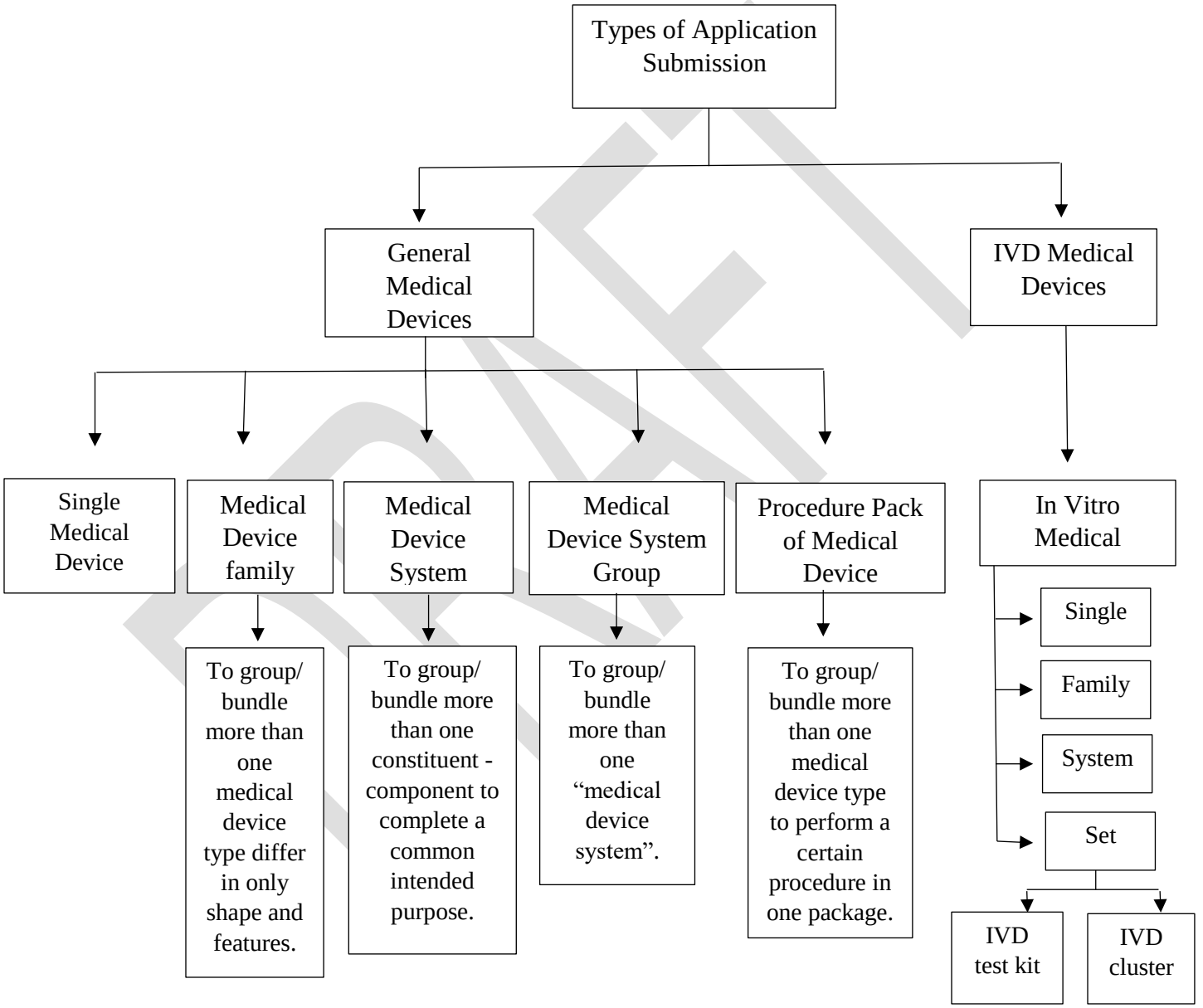
- Single
- Family
- System
- Set:
  - IVD Test Kit
  - IVD cluster

Type of Set group	Criteria	Example
- IVD Test Kit	-Same manufacturer. -Combine to complete a specific intended use. -Compatible. -All reagent in IVD Test Kit must be. -Submitted as part of one product Registration application.	1. Dengue IgM Test Kit. 2. RPR Latex Test Kit.

- IVD cluster	- Same manufacturer. -Within Class A or B. - Common test methodology. -Same IVD Cluster category. (Refer to Guidance documents). -All reagent in IVD Cluster must be. -Submitted as part of one product registration application.	1. Rheumatoid-inflammatory diseases markers.

• Total number of IVD medical device that are grouped/bundled within a single application shall not exceed 50 items within a single application.

6 Flowchart



7 References

Title	Link
Guidance on Medical Devices Bundling/ Grouping Criteria	https://old.sfda.gov.sa/en/medicaldevices/regulations/DocLib/MDS-G7.pdf
MEDICAL DEVICE PRODUCT GROUPING	http://www.ahwp.info/sites/default/files/20191111%20-%2003%20-%20Track104%20-%20Product%20Grouping%20GMD%20and%20IVD.pdf