

Guidance on Medical Devices Bundling / Grouping Criteria

مجلس الصحة
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Gulf Health Council



Guidance on Medical Devices Bundling/ Grouping Criteria



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TABLE OF CONTENT

DEFINITIONS & ABBREVIATIONS	2
Definitions	3,4
Abbreviations	3,4
INTRODUCTION	4
Purpose	5
Scope	5
Background	5
CRITERIA OF BUNDLING/GROUPING	6
I. Criteria of Bundling/ Grouping for Medical Devices other than IVD medical devices ..	6
II. Criteria of Bundling/ Grouping for In-Vitro Medical Devices.....	11
FLOWCHART	12

DEFINITIONS & ABBREVIATIONS

Guidance on Medical Devices Bundling / Grouping Criteria

Definitions

Medical Device	<p>means any instrument, apparatus, implement, machine, appliance, implant, reagent for in-vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:</p> <ul style="list-style-type: none"> - Diagnosis, prevention, monitoring, treatment or alleviation of disease; - Diagnosis, monitoring, treatment, alleviation of or compensation for an injury; - 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 by means of in-vitro examination of specimens derived from the human body and which does not achieve its primary intended action by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.
In-Vitro diagnostic (IVD) Medical Device	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.
Manufacturer	Means any natural or legal person with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under its name; whether or not such a medical device is designed and/or manufactured by that person himself or herself on his or her behalf by another person(s).
Authorized Representative	Any natural or legal person established within the GCC countries who has received a written mandate from the manufacturer to act on his or her behalf for specified tasks, with regards to the latter's obligations under the GCC countries.
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. This has changed now to IMDRF.
International medical device regulators forum	It is a voluntary group of medical device regulators from around the world who have come together to build on the strong foundational work of the Global Harmonization Task Force on Medical Devices (GHTF), and to accelerate international medical device regulatory harmonization and convergence.
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.
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.

Guidance on Medical Devices Bundling / Grouping Criteria

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.
Generic device group	A set of devices having the same or similar intended purposes or commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics.
Intended use / purpose	The objective intent of the manufacturer regarding the use of a product, process or service as reflected in the specifications, instructions and information provided by the manufacturer.

Abbreviations

GCC	Gulf Cooperation Council
GHC	Gulf Health Council
AR	Authorized Representative
GMD application	Gulf Medical Device application
GHTF/IMDRF	Global Harmonization Task Force/ International Medical Device Regulators Forum
IVD	In-vitro diagnostic medical devices



Guidance on Medical Devices Bundling / Grouping Criteria

Purpose

The purpose of this document is to **PROVIDE CRITERIA FOR MEDICAL DEVICES BUNDLING/ GROUPING WITHIN A SINGLE GMD REGISTRATION APPLICATION PROCEDURE.**

Scope

This document is applicable to any **MEDICAL DEVICES:**

- **LOCAL GCC MANUFACTURERS.**
- **OVERSEAS MANUFACTURERS.**
- **ARUTHORIZED REPRESENTATIVES.**

Background

In some cases, for applying to GCC, the applicant's GMD (manufacturer, or where the manufacturer is established overseas, through his authorized representative) needs to group more than one medical device type (referred to as "bundling" in some jurisdictions) within a single application procedure. **THE BUNDLED/GROUPED MEDICAL DEVICE TYPES SHALL HAVE BEEN AUTHORIZED FOR MARKETING WITHIN ONE OR MORE OF THESE COUNTRIES** (Australia, Canada, Japan, USA or the EU), upon which the GMD is based.

Based on GMD bundling criteria, the **APPLICANT'S GMD CAN GROUP MORE THAN ONE MEDICAL DEVICES TYPE WITHIN A SINGLE APPLICATION PROCEDURE.**

Guidance on Medical Devices Bundling / Grouping Criteria

CRITERIA OF BUNDLING/GROUPING

I. Criteria of Bundling/ Grouping for Medical Devices other than IVD medical devices

There are **FOUR TYPES FOR GMD APPLICATION SUBMISSION** for medical devices other than IVD medical devices as the following:

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 GMD application submission are discussed below:

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 of GMD 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’s GMD’s shall APPLY FOR ANOTHER APPLICATION of GMD 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”.

Guidance on Medical Devices Bundling / Grouping Criteria

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’s GMD can group/ bundle **MORE THAN ONE MEDICAL DEVICE** within a single application of GMD as a “Family of medical devices”, when the following **CRITERIA** is applied.

- Medical devices that are grouped/bundled within a single application of GMD shall:
 - Be under **SAME MANUFACTURER**.
 - Have **SAME RISK CLASS**.
 - Have **SAME GENERIC PROPRIETY NAME**.
 - Have a **COMMON INTENDED USE**.
 - 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 of GMD 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 of GMD 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’s GMD shall **APPLY FOR ANOTHER APPLICATION** of GMD.

Guidance on Medical Devices Bundling / Grouping Criteria

EXAMPLES																									
1	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 of GMD as a “family of medical devices” if their variations fall within the scope of permissible variants.																								
2	Cardiac catheters that are available in a different number of lumens, lengths and diameters can be grouped/bundled within a single application of GMD as a “family of medical devices”.																								
3	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 of GMD as a “family of medical devices”																								
4	For SURGICAL INSTRUMENTS can be grouped/bundled within a single application of GMD as a “family of medical devices” , each group of the following surgical instruments will be grouped/bundled within a single application of GMD as a “family of medical devices” based on the following FUNCTION : <table border="1" data-bbox="354 961 1214 1570"> <thead> <tr> <th></th> <th>SURGICAL INSTRUMENT NAMES</th> <th>DEFINED AS INSTRUMENTS OF</th> </tr> </thead> <tbody> <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> </tbody> </table>		SURGICAL INSTRUMENT NAMES	DEFINED AS INSTRUMENTS OF	1	Scissors, Knives, Saws and Blades	Cut or incise	2	Traction and bone hooks	Retract	3	Tissue and bone holding forceps, also needle holders	Grasp, Hold or Occlude	4	Punch	Dilate or Probe	5	Catheters or any instrument used for drain.	Cannulate or Drain	6	Instrument to remove unwanted fluids as well as to inject fluids such syringes or some needles,	Aspirate, Inject or Infuse	7	Sutures, clips as well as suture needles and ligating Blades	Suture or Ligate
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Guidance on Medical Devices Bundling / Grouping Criteria

3. SYSTEM

A. MEDICAL DEVICE SYSTEM:

A “medical device system” **COMPRISES OF A NUMBER OF CONSTITUENT-COMPONENTS TO COMPLETE A COMMON INTENDED PURPOSE.**

Applicant’s GMD can group/ bundle **MORE THAN ONE CONSTITUENT-COMPONENT** to complete a common intended purpose within a single application of GMD as a “medical device system”, when the following **CRITERIA** are applied.

Members of “medical device system” that are grouped/bundled within a single application of GMD 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’s GMD 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 of GMD 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’s GMD shall **APPLY FOR ANOTHER APPLICATION** of GMD.

Guidance on Medical Devices Bundling / Grouping Criteria

EXAMPLES	
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 of GMD 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 of GMD as a “medical device system”.

B. MEDICAL DEVICE SYSTEMS GROUP

Applicant’s GMD can group/ bundle **MORE THAN ONE “MEDICAL DEVICE SYSTEM”** within a single application of GMD as a “grouping medical device systems”, when the following **CRITERIA** are applied:

- “Medical devices systems” that are grouped/bundled within a single application of GMD 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.

4. 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’s GMD can group/ bundle **MORE THAN ONE MEDICAL DEVICE TYPE TO PERFORM A CERTAIN PROCEDURE IN ONE PACKAGE** within a single application of GMD 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 of GMD:
 - Can be from **DIFFERENT MANUFACTURER**.
 - May have **DIFFERENT DESIGN**.
 - Shall have a **COMMON INTENDED USE/ purpose**.

Guidance on Medical Devices Bundling / Grouping Criteria

- 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 of GMD 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 of GMD shall **NOT EXCEED 50** items within a single application of GMD.

NOTES:

- GHC will assign a “Medical Device **Listing** GCC Registry Number” on GMD certificate **FOR EACH MEDICAL DEVICE/ ITEM IN THE PROCEDURE PACK.**
- Where the manufacturer wishes to market any member of procedure pack **SEPARATELY**, applicant’s GMD shall **APPLY FOR ANOTHER APPLICATION** of GMD.
- Where the manufacturer wishes to **MARKET ANY MEMBER OF PROCEDURE PACK IN ANOTHER PROCEDURE PACK**, the member of procedure pack shall be **INCLUDED IN THE ANOTHER PROCEDURE PACK** GMD application.

II. Criteria of Bundling/ Grouping for In-Vitro Medical Devices

Applicant’s GMD can group/ bundle **MORE THAN ONE IVD MEDICAL DEVICE TYPE** within a single application of GMD when the following **CRITERIA** are applied:

- IVD medical devices that are grouped/bundled within a single application of GMD shall:
 - Be under **SAME MANUFACTURER.**

Guidance on Medical Devices Bundling / Grouping Criteria

- Have **SAME RISK CLASS**.
 - Have **SAME INTENDED USE/ purpose**.
 - Be in **SAME ORIGINAL APPROVAL/ CERTIFICATE** (if applicable).
- **TOTAL NUMBER** of IVD medical device that are grouped/bundled within a single application of GMD shall **NOT EXCEED 50** items within a single application of GMD.

FLOWCHART

