



MDS – G7

**Guidance on Medical Devices Bundling/
Grouping Criteria**

SFDA



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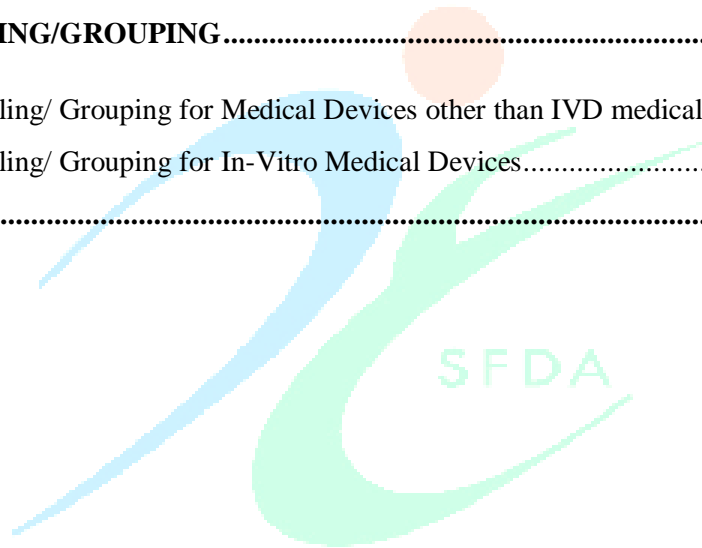
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DEFINITIONS & ABBREVIATIONS

Definitions

<p>Medical Device</p>	<p>means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article:</p> <p>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:</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 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; <p>and</p> <p>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.</p>
<p>In-Vitro Medical Device</p>	<p>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.</p>
<p>Manufacturer</p>	<p>Means any natural or legal person with responsibility for design and manufacture of a medical device with the intention of making it available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person.</p>
<p>Authorized Representative</p>	<p>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.</p>
<p>Global Harmonization Task Force</p>	<p>Countries working to achieve harmonization in medical device regulation among themselves. These countries are Australia, Canada, Japan, the USA and the EU/EFTA.</p>
<p>Generic proprietary name</p>	<p>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.</p>
<p>Component</p>	<p>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.</p>



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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.

Abbreviations

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



INTRODUCTION



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Purpose

The purpose of this document is to **PROVIDE CRITERIA FOR MEDICAL DEVICES BUNDLING/ GROUPING WITHIN A SINGLE MDMA APPLICATION PROCEDURE** that has been introduced by the MDS - G5 Guidance on Marketing Authorization / Points (one and two) of article C ¹.

Scope

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

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

Background

In some cases for applying to MDMA, the applicant's MDMA (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 MDMA is based.

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

¹ C. MDMA's Incorporating More Than One Medical Device Type

1. Where the applicant's MDMA groups more than one medical device type (referred to as 'bundling' in some jurisdictions) within a single application procedure, the grouped medical device types shall all have been authorized for marketing within the GHTF Founding Member jurisdiction, upon which the MDMA is based, on the same basis.
2. Where the MDMA procedure involves medical device types having different purposes, technical performance and classification, the applicant will have to access the MDMA portion of the SFDA's website on multiple occasions to provide the required information. While some of that information will be common, the KSA national provisions will vary with the different medical device types,



CRITERIA OF BUNDLING/GROUPING

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

There is **FOUR TYPES FOR MDMA 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 MDMA 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 MDMA 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 MDMA shall APPLY FOR ANOTHER APPLICATION of MDMA 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”.

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 MDMA can group/ bundle **MORE THAN ONE MEDICAL DEVICE** within a single application of MDMA 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 of MDMA 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 MDMA 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 MDMA shall **APPLY FOR ANOTHER APPLICATION** of MDMA.

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 MDMA 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 MDMA 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 MDMA as a “family of medical devices”																								
4	For SURGICAL INSTRUMENTS can be grouped/bundled within a single application of MDMA as a “family of medical devices” , each group of the following surgical instruments will be grouped/bundled within a single application of MDMA as a “family of medical devices” based on the following FUNCTION : <table border="1" data-bbox="354 961 1216 1572" style="margin: 10px auto;"> <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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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 MDMA can group/ bundle **MORE THAN ONE CONSTITUENT-COMPONENT** to complete a common intended purpose within a single application of MDMA 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 MDMA 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 MDMA 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 MDMA 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 MDMA shall **APPLY FOR ANOTHER APPLICATION** of MDMA.

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 MDMA 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 MDMA as a “medical device system”.

B. MEDICAL DEVICE SYSTEMS GROUP

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

- “Medical devices systems” that are grouped/bundled within a single application of MDMA 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 MDMA can group/ bundle **MORE THAN ONE MEDICAL DEVICE TYPE TO PERFORM A CERTAIN PROCEDURE IN ONE PACKAGE** within a single application of MDMA 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 MDMA:
 - Can be from **DIFFERENT MANUFACTURER**.
 - May have **DIFFERENT DESIGN**.
 - Shall have a **COMMON INTENDED USE/** purpose.



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

NOTES:

- SFDA will assign a “Medical Device **Listing** National Registry Number” on MDMA certificate **FOR EACH MEDICAL DEVICE/ ITEM IN THE PROCEDURE PACK**.
- Where the manufacturer wishes to market any member of procedure pack **SEPARATELY**, applicant’s MDMA shall **APPLY FOR ANOTHER APPLICATION** of MDMA.
- 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** MDMA application.

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

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

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

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

FLOWCHART

