# Guideline on Medical Devices Bundling/ Grouping Criteria

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- Eng. Ghaliya Alqaidi

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## Acronyms:

| | |
|---|---|
| MOH | Ministry of Health |
| DSC | Drug Safety Center |
| MDCD | Medical Device Control Department |
| IVD | In Vitro Diagnostic |
| ISO | International Organization for Standardization |
| QMS: | Quality Management System |
| GMDN | Global Medical Device Nomenclature |
| HS code | Harmonized System |
| AATB certificate | American Association of Tissue Banks Certificate |

## Definitions

| | |
|---|---|
| **Medical Device** | Medical device' 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 medical purpose(s) of:<br>• Diagnosis, prevention, monitoring, treatment or alleviation of disease,<br>• Diagnosis, monitoring, treatment, alleviation of or compensation for an injury,<br>• Investigation, replacement, modification, or support of the anatomy or of a physiological process,<br>• Supporting or sustaining life,<br>•Control of conception,<br>• Disinfection of medical devices,<br>• Providing information by means of in vitro examination of specimens derived from the human body; and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, 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. |
| **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. |

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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.. |
| **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 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(s). |
| **Accessories to a medical device** | means an article intended specifically by its manufacturer to be used together with a particular medical device to enable or assist that device to be used in accordance with its intended use |
| **Verification** | confirmation by examination and provision of objective evidence that the specified requirements have been fulfilled. |
| **Validation** | Validation means confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use can be consistently fulfilled. |
| **Risk** | Combination of the probability of occurrence of harm and the severity of that harm. |

# CHAPTER ONE

## Introduction

Medical devices are required to be registered to cater the regulatory requirements. Regulation is enforced in Oman via ministerial decree 113/2020. This will ensure that products entering the market are safe and efficient.

Under this regulation, manufacturers or the local authorized representatives of foreign manufacturers must register their medical devices prior to importation, exportation, or placement on the Omani market.

Medical devices vary widely, ranging from simple devices to highly complex and sophisticated technologies. They may be supplied as individual components, customized packs, or grouped products, and can be categorized as Single, Family, System, Procedure Pack, or In Vitro Diagnostic (IVD) devices. Each of these categories may be submitted as part of a medical device registration application.

## Purpose

The purpose of this guidance is to describe the criteria, procedures, and general requirements for the bundling or grouping of medical devices.

## 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.

## Structure

This is the first version of this guidance and it consists of several chapters. Chapter one covers a brief introduction to the guideline as well as the purpose, scope and structure. Chapter two explains the procedure of Medical Devices Bundling/ Grouping Criteria. Chapter three covers the required documents and roles and responsibilities in regard to requirements of Medical Devices Bundling/ Grouping Criteria. Chapter four comprises of the annexes section including document history and version control table, references and appendixes which consists of a selection of several templates of creating different policy documents.

# CHAPTER TWO

## Procedure

## General Requirements

Criteria of Bundling/Grouping

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. Medical device system.

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 shall: A maximum of 5 of Medical devices may be bundled/grouped within one application only if they have:

• Be under same legal manufacturer.

• Have same risk class.

• Have same generic propriety name.

• Have a common intended use/ purpose.

• Have similar design, construction material and manufacturing process.

• 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.

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 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 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 as a “family of medical devices”.

4. 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:

| | 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

TOTAL NUMBER of medical device that are grouped/bundled within a single application shall NOT EXCEED 50 items.

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 legal 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 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:

- same legal manufacturer

- same intended use/purpose and under the same specialty

- 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 another 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.

• If the procedure pack includes a drug, applicant shall provide the "Registration Certificate of a Pharmaceutical Product", for the included drug, issued by Drug Control Dept.

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

For IVD Medical Device Type: Grouping is mainly used for:

•Batching together similar IVDs in regulatory processes (e.g., performance evaluation, technical documentation, or vigilance reporting).

•Facilitating conformity assessment by allowing multiple similar devices to be treated as a single "set" where appropriate.

•Eudamed registration (Basic UDI-DI assignment).

**IVD GROUPING TYPES :**

- **IVD Device 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. It may be offered in a range of package sizes.
- **IVD Device Family:** 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 (e.g different assembly format, CASSETTE, MIDSTREAM, STRIP, different combination of testing configurations , size, volume.
- **IVD Device System:** 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 labeling, instruction for use (IFU), brochures or catalogues for each constituent component states that the constituent component is intended for use with the SYSTEM. **EX: Glucose meter Test strips Control solution**
- **IVD Family of Systems:** In addition, if several SYSTEMs fulfil the following conditions to be grouped as a FAMILY, they may be registered as a FAMILY System.
- **IVD Device test Kit:** An IVD TEST KIT is an in vitro diagnostic (IVD) device that consists of reagents or articles that are: a) from the same manufacturer; b) intended to be used in combination to complete a specific intended purpose; c) 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 d) Compatible when used as a TEST

KIT **Ex: A Human Immunodeficiency Virus (HIV) Enzyme Linked ImmunoSorbent Assay (ELISA) TEST KIT may contain controls, calibrators and washing buffers**

- **IVD Device Cluster**: An IVD CLUSTER comprises of a number of in vitro diagnostic reagents or articles that are: a) from the same manufacturer; b) within risk classification A or B; c) of a common test methodology d) Of the same IVD CLUSTER category The IVD CLUSTER may include analyses that are designed for use with the reagents in the IVD CLUSTER. **Ex: Products used for the qualitative/quantitative determination of enzymes in biological samples**
- **IVD Groping/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 : a) a single proprietary SET name; b) a common intended use; c) classification allocated. **EX: Glucose monitor Test strips Lancets**

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

# CHAPTER THREE

## Responsibilities:

| | |
|---|---|
| **Department and section staff** | Assist in the review, evaluation, and preparation of medical device grouping and bundling submissions, ensuring completeness and compliance with regulatory requirements. |
| **Department Directors and Section Heads** | Supervise and ensure proper implementation of the bundling/grouping procedures, review recommendations from staff, and provide approvals as required. |
| **QASM Section** | Ensure quality assurance and regulatory compliance in the grouping and bundling process, monitor adherence to international standards, and provide guidance on classification of high-risk devices. |
| **DG-DSC** | Oversee the overall process, ensure alignment with national regulations and international best practices, and endorse final decisions regarding the bundling/grouping of high-risk medical devices. |

# CHAPTER FOUR

## Document History and Version Control

| Version | Description | Review Date |
|---|---|---|
| 1 | Initial Release | October 2025 |
| 2 | | |
| 3 | | |

## References:

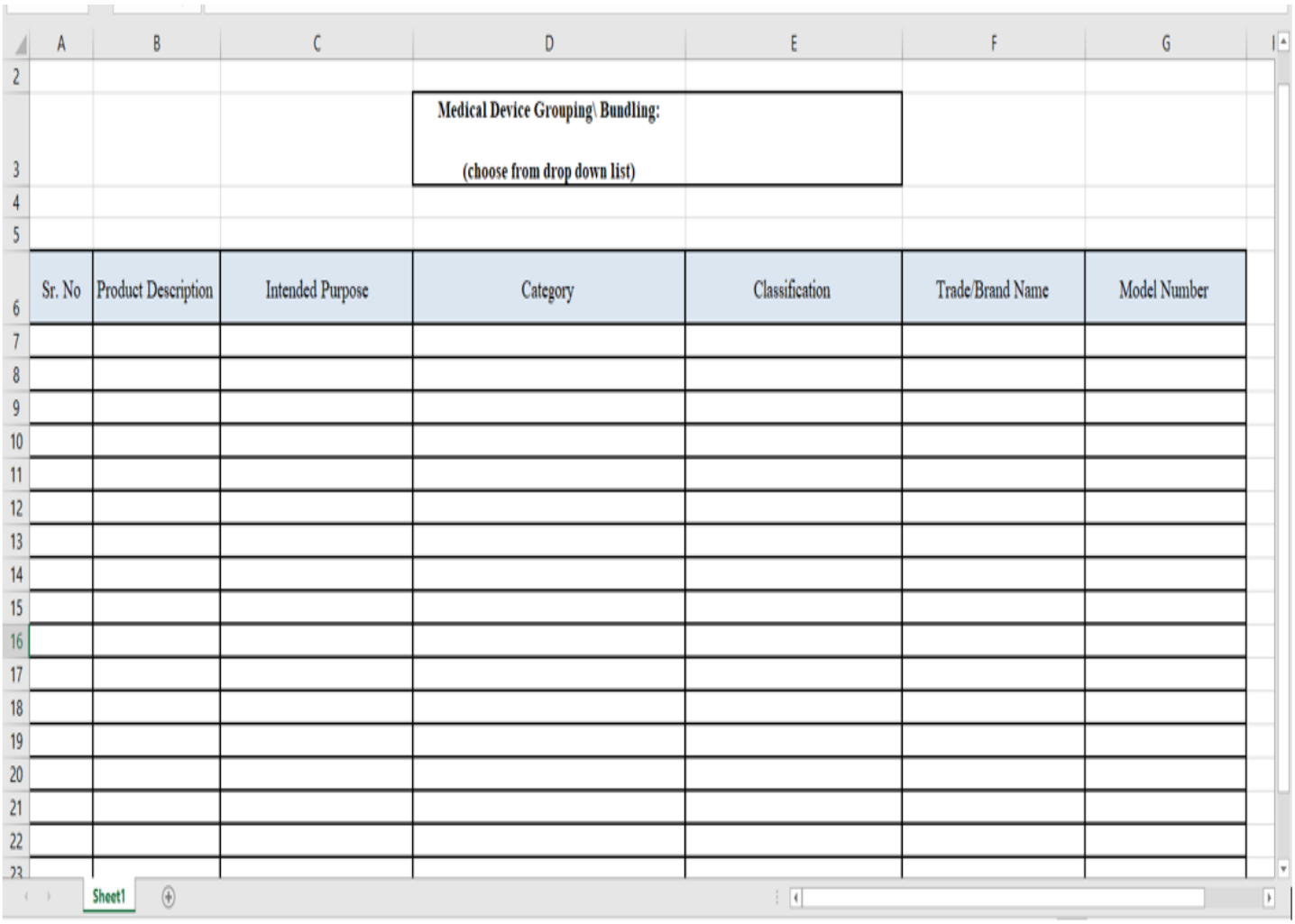
Global Harmonization Task Force (GHTF), 2012. *Principles of Conformity Assessment for Medical Devices (GHTF/SG1/N78:2012).*

Gulf Health Council (GHC), 2022. *Guidance on Grouping and Bundling of Medical Devices*

# Annexes

## Appendix 1: Medical Device Grouping /Bundling

Please refer to the Guidance Document on grouping & bundling for medical devices



Medical Device Grouping\ Bundling:

(choose from drop down list)

| Sr. No | Product Description | Intended Purpose | Category | Classification | Trade/Brand Name | Model Number |
|---|---|---|---|---|---|---|
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Sheet1