



MDS — G28



Guidance on Bundling Criteria for Medical
Devices within a Single MDMA Application

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Introduction

Purpose

The purpose of this document is to specify criteria for bundling/grouping medical devices within a single medical devices marketing authorization (MDMA) application, as mentioned in the “Requirements for Medical Devices Marketing Authorization ([MDS – REQ1](#))”.

Scope

This document is applicable to manufacturers or their authorized representatives who wish to bundle/group more than one type of medical device, including in-vitro medical devices (IVDs), within a single MDMA application.

Background

SFDA has issued this document in reference to:

- Articles (1), (3) and (8) of the "Medical Devices Law" issued by the Royal Decree No. (M/54) dated 6/7/1442 H.
- Articles (3.1), (10/7) and (10/8) of the "[Implementing Regulation of Medical Devices Law](#)" issued by Saudi Food and Drug Authority Board of Directors decree No. (3-29-1443) dated 19/2/1443H.
- Article (4) of the “Requirements for Medical Devices Marketing Authorization ([MDS – REQ1](#))” related to bundling.



Bundling Criteria

1. Medical Device Family

Medical devices may be bundled/grouped as a family within a single MDMA application only if they meet the following criteria:

- A. Have the same legal manufacturer.
- B. Have the same intended use/purpose.
- C. Have the same risk class.
- D. Have the same GMDN code definition (if available).
- E. Have a common physical design, construction material and manufacturing process.
- F. The application includes a maximum of (5) Technical Files (TFs).
- G. The total number of medical devices does not exceed (50) items.

Examples:

- A catheter with multi lengths and brand names. Can be bundled because they have same intended purposes and performances.
- Steerable guide wires that are available in various lengths and possess various tip shapes and tip flexibilities. Can be bundled because they have same intended purposes and performances.
- Hearing aids that are intended to amplify sound and transmit sound to the ear for adults at different amplitudes for different frequencies to enhance hearing, and only differ in colour
- Bone plates that have the same intended use and indications for use, but vary in shape and size
- A single model of intra ocular lenses (IOLs) that have the same optical design, intended use and indications for use, and only differ in diopter
- Dual-chamber implantable cardioverter defibrillators and single-chamber implantable cardioverter defibrillators that have the same intended use and the same base software. In such cases, the dual-chamber device includes all functionality available in the single-chamber device and differs only in the number of cardiac leads. In this case, the specific indication for use for the single-chamber and dual-chamber devices may be different.

Notes:

1. It is not allowed to bundle a standalone product with a set/kit within a single application even if that product is a component of the set/kit.
2. If the component/accessory is a medical device in its own right and is labelled for use with a specific device, then the device and its components/accessories are not considered a single medical device. Refer to the bundling criteria for a medical device system.



1.1 Medical Device Family – Special for Surgical Instruments

Surgical instruments may be bundled/grouped as a family within a single MDMA application only if they meet the following criteria:

- A. Have the same legal manufacturer.
- B. Have the same risk class.
- C. Have a common construction material and manufacturing process.
- D. The application includes a maximum of (5) Technical Files (TFs).
- E. The total number of medical devices does not exceed (50) items.
- F. Have same functions. The functions listed below are provided as examples only and not as an exhaustive list:

Function	Examples
Cut or incise	Scissors, knives, saws and blades, dental Scissors
Retractor	Traction and bone hooks
Grasp, hold or occlude	Tissue and bone holding forceps, also needle holders
Dilate or probe	Punch
Cannulate or drain	Catheters or any instrument used for drain
Aspirate, inject or infuse	Instrument to remove unwanted fluids as we as to inject fluids such strings or some needles
Suture or ligate	Sutures clips as well as suture needle and ligating blade



1.2 Medical Device Family – Special for Dental Instruments

Dental instruments may be bundled/grouped as a family within a single MDMA application only if they meet the following criteria:

- A. Have the same legal manufacturer.
- B. Have the same intended use/purpose.
- C. Have the same risk class.
- D. The application includes a maximum of (5) Technical Files (TFs).
- E. The total number of medical devices does not exceed (50) items.
- F. Same specialty: The specialty listed below are provided as examples only and not as an exhaustive list:

Specialty	Definition/Scope	Examples
General Dentistry	Basic dental care: diagnosis, prevention, and routine treatment.	Dental syringes, general pliers, examination mirrors and probes, matrix holders, simple hand instruments
Restorative Dentistry	Restoration of damaged or decayed teeth using direct or indirect restorative materials.	Amalgam carriers, composite placement instruments, burnishers, excavators, matrix retainers, dental condensers
Oral Surgery	Surgical procedures on teeth, gums, and supporting bone (including extractions and minor oral surgery; not limited to implants).	Extraction forceps, root-tip picks, chisels, needle holders, scalpel handles, hemostats, tissue forceps
Dental Implantology	Preparation of implant sites and placement of dental implants, including bone augmentation procedures.	Bone compactors, bone scrapers, bone thickness gauges, implant drills, osteotomes, sinus lift osteotomes
Orthodontics	Correction of teeth and jaw alignment.	Orthodontic brackets, arch wires, band pushers, bracket tweezers, distal end cutters
Periodontics	Treatment of gums and supporting structures of teeth.	Curettes, scalers, gingival separators, gum scissors, mucotomes, syndesmotomes
Endodontics	Treatment of dental pulp and root canal system.	K-files, spreaders, pluggers, gutta-percha, root canal measurement tools

Prosthodontics	Restoration or replacement of missing or damaged teeth using prostheses.	Retraction cords, crown removers, diamond burs, impression trays
Pediatric Dentistry	Dental care for children using appropriately sized instruments and behavior management techniques.	Small extraction forceps, pediatric syringes, child-sized hand instruments
Preventive Dentistry / Dental Hygiene	Prevention of dental disease and maintenance of oral health.	Scalers, polishing instruments, rubber cups
Dental Laboratory / clinic	Tools and devices used outside the patient's mouth in laboratory or clinical support settings.	Wax carvers, articulators, dental flasks, stainless steel instrument cassettes, polishing devices

Notes:

- Oral Surgery and Implantology overlap in some instruments, but classification depends on the labeled intended use.
- Generic or multi-use surgical instruments can be included under General Dentistry, unless the IFU limits its use to specific dental procedures.
- Lab and auxiliary devices that do not contact patients are not classified as treatment devices.



2. Medical Device System

Medical devices may be bundled/grouped as a system within a single MDMA application only if they meet the following criteria:

- A. Have the same legal manufacturer.
- B. Are intended to be used in combination to complete a common intended use/purpose.
- C. The medical devices system shall be linked in a technical file covering the system components such as (label, IFU, brochures, catalogues, and clinical evaluation files), stating that the components is intended to be used with the system, which lead to the same intended of use/purpose
- D. Only one system per application.
- E. If the items of the system have different risk-classes, the highest risk-class will be considered.
- F. The application includes a maximum of (5) Technical Files (TFs).
- G. The total number of medical devices does not exceed (50) items (including accessories).

Examples:

- A hip replacement medical devices system comprising of femoral and acetabular components. The components must be used in combination to achieve a common intended use/purpose of total hip replacement. The size of the components may vary.
- An electrosurgical unit with forceps, electrodes, electrode holders, leads, plug adaptor, when used together for a common intended use/purpose.
- An endoscopy tower, which consists of endoscopy camera, registered as a main part then the items like screen, scopes and surgical tools attached to the scope registered as accessories.



3. Medical Device Procedure Pack

Medical devices may be bundled/grouped as a procedure pack within a single MDMA application only if they meet the following criteria:

- A. Have the same legal manufacturer. (This applies to the main packs, but not to the components of the pack).
- B. Have the same intended use/purpose and under the same specialty.
- C. Have the same risk class of packs .
- D. The application includes a maximum of (5) Technical Files (TFs).
- E. The total number of medical devices does not exceed (50) items.

Notes:

- 1. The TF documents of the pack and each components shall submitted.
- 2. Provide the labels of each components contents in label section.
- 3. Any submitted approval should be in combination with letter of agreement from each manufacturer of procedure pack components to supply technical documentation to the SFDA upon request. Where the manufacturer wishes to market any component of the procedure pack separately, applicant shall apply for another application. If the procedure pack includes a drug, applicant shall provide the “Marketing Authorization”, for the included drug, issued by SFDA/Drug Sector.
- 4. The following letter shall be submitted:

Name of the pack/kit/set:						
Specialty of the pack/kit/set:						
	Component name	Risk class (based on SFDA classification)	Classification on rational	Dose it has SFDA or other approvals of each components (if applicable) if yes approval number	Intended use OR Brief description	LM name and address
1						
2						
...						

Examples:

- Examples on Procedure Packs:
 - ENT procedure pack
 - Ophthalmic procedure pack
 - Urology surgical procedure pack
 - Orthodontic procedure packs
 - Dental kit

- Examples on Specialty:
 - Anesthesiology
 - Cardiovascular
 - Ear, nose, and throat
 - Gastroenterology and urology
 - General and plastic surgery
 - General hospital
 - Neurology
 - Obstetrical and gynecological
 - Ophthalmic
 - Orthopedic
 - Physical medicine
 - Radiology
 - Dental kit

4. IVDs

IVDs may be bundled/grouped within a single MDMA application only if they meet the following criteria:

- A. Have the same legal Manufacturer
 - Having the same name and address.
- B. Have the same risk class.
- C. Have the same intended use/purpose, having the following:
 - The same principle of operation (e.g. agglutination tests, chromatography, flow cytometry, microscopy, nucleic acid based ...etc.)
 - Fall under one of the following groupings specified below:
 - 1) Devices Intended to be Used for Blood Grouping
 - a) Devices intended to be used for blood grouping to ensure the immunological compatibility of blood, blood components, cells, tissue or organs that are intended for transfusion or transplantation or cell administration
 - ABO system [A (ABO1), B (ABO2), AB (ABO3)]
 - Rhesus system [RH1 (D), RHW1, RH2 (C), RH3 (E), RH4 (c), RH5 (e)]
 - Kell system [Kel1 (K)]
 - Kidd system [JK1 (Jka), JK2 (Jkb)]
 - Duffy system [FY1 (Fya), FY2 (Fyb)]
 - b) Other devices intended to be used for blood grouping
 - Other devices intended to be used for blood grouping
 - 2) Devices Intended to be Used for Tissue Typing
 - Devices intended to be used for tissue typing to ensure the immunological compatibility of blood, blood components, cells,

- tissue or organs that are intended for transfusion or transplantation or cell administration (HLA A, B, DR)
- Other devices intended to be used for tissue typing (according to previous point)
 - Other devices intended to be used for tissue typing (except the first point)
- 3) Devices Intended to be Used for Markers of Cancer and Non-Malignant Tumours Except Devices for Human Genetic Testing
- Devices intended to be used in screening, diagnosis, staging or monitoring of cancer
 - Other devices intended to be used for markers of cancer and non-malignant tumours
- 4) Devices Intended to be Used for Human Genetic Testing
- Devices intended to be used in screening / confirmation of congenital / inherited disorders
 - Devices intended to be used to predict genetic disease risk and prognosis
 - Other devices intended to be used for human genetic testing
- 5) Devices Intended to be Used to Determine Markers of Infections/Immune Status (Screening, Confirmation, Identification of Infectious Agents or Determination of Immune Status).
- Devices intended to be used for pre-natal screening of women in order to determine their immune status towards transmissible agents
 - Devices intended to be used to detect the presence of, or exposure to transmissible agents in blood, blood components, cells, tissues or organs, or in any of their derivatives, to assess their suitability for transfusion, transplantation or cell administration
 - Devices intended to be used to detect the presence of, or exposure to an infectious agent including sexually transmitted agents
 - Devices intended to be used to determine the infectious load, to determine infective disease status or immune status and devices used for infectious disease staging
 - Devices intended to be used to grow / isolate / identify and handle infectious agents
 - Other devices intended to be used to determine markers of infections / immune status
- 6) Devices Intended to be Used for Non-Infectious Pathologies, Physiological Markers, and Disorders/Impairments (Except Human Genetic Testing)



- a) Devices intended to be used for a specific disease
 - Devices intended to be used for screening/confirmation of specific disorders/impairments
 - Devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease
 - Devices intended to be used for screening, confirmation/determination, or monitoring of allergies and intolerances
 - Other devices intended to be used for a specific disease
 - b) Devices intended to be used to define or monitor physiological status and therapeutic measures
 - Devices intended to be used for monitoring of levels of medicinal products, substances or biological components
 - Devices intended to be used for non-infectious disease staging
 - Devices intended to be used for detection of pregnancy or fertility testing
 - Devices intended to be used for screening, determination or monitoring of physiological markers
 - Other devices intended to be used to define or monitor physiological status and therapeutic measures
- 7) Devices Which are Controls without a Quantitative or Qualitative Assigned Value
- a) Controls without a quantitative or qualitative assigned value
 - Devices which are controls without a quantitative assigned value
 - Devices which are controls without a qualitative assigned value

D. Number of Technical Files (TFs).

1. The application shall not exceed (5) technical files.

Note: A technical file is considered as “one TF” when the same clinical/performance evaluation data (analytical and clinical) are used for all products referenced in the file. For example:

- Population-specific respiratory virus panels (e.g., Flu A/B and RSV) measured simultaneously.
 - Drugs of abuse panels (e.g., cocaine, THC, opiates, methamphetamine, and amphetamine).
 - Assayed controls and/or calibrators bundled with an assay kit
2. The application shall not exceed (50) items in total, including accessories.

Note:

All devices shall be exempted from criteria (C) and (D-1) and may be included within a single application, provided that they fall within one of the following categories and, are classified as class A only, nor considered blood specimen collection devices, laboratory machinery, or automated/powering systems:

- Specimen Container (storage and transport).
- Dye and stains.
- Culture Media and broth.
- Supplement for culture media and broth.
- General purpose reagents include cytological preservatives, decalcifying reagents, fixative and adhesives, tissue processing reagents, isotonic solutions and pH buffers (Formulations, Paraffin, Mounting, Oil Soluble Media, Mounting media, and Water Soluble).
- Tissue processing equipment consists of devices used to prepare human tissue specimens for diagnostic histological examination (e.g. tissue collection container, Embedding, Coverslips, Microscope Slide, Filters, and Tubes).
- Cell and tissue culture supplies and equipment are devices that are used to examine, propagate, nourish, or grow cells and tissue cultures (Dish, Tissue Culture, Flask, Tissue Culture, Apparatus, Roller, Bottle, tube, Spinner, Spinner System, and Cell Culture).



Annexes

Annex (1): Definitions & Abbreviations

KSA	Kingdom of Saudi Arabia
SFDA	Saudi Food and Drug Authority
Law	Law of Medical Devices
Medical Device	Any instrument, apparatus, implement, implant device, in vitro reagent or calibrator, software, or material used for operating medical devices, or any other similar or related article, intended to be used alone or in combination with other devices for diagnosis, prevention, monitoring, controlling, treatment, or alleviation of disease or injury, or for compensation for an injury; investigation, replacement, modification, or support of the anatomy or of a physiological process; supporting or sustaining life; controlling or assisting conception; sterilization of medical devices ; providing information for medical or personal purposes 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, but which may be assisted in its intended function by such means
Medical Supplies	Medical materials and products used in diagnosis, treatment, replacement, modification, disability cases or other medical uses for humans, including medical gases.
Marketing Authorization (MDMA)	A document issued by the SFDA permitting the circulation of a medical device in the market.
Identifying Information (Labeling)	Any statement or information drawn or illustrated / written or printed on the medical device, including: <ul style="list-style-type: none"> - Name of the device; - Code / lot or serial number; - Technical description; - Method of use; and/or - Manner of storage and transportation.
Accessories	Any material or product made to be used with a medical device to enable it to achieve the purpose for which it was manufactured.
Component	one of several possibly unequal subdivisions which together constitute the whole medical device to achieve the latter's intended use/purpose. A component may be known as a part but not a medical device in its own right.
Single Medical Device	is a medical device that may include different models, provided that all such models share the same basic design, intended use, and essential characteristics, and that any differences between them do not affect safety or performance.
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.

Medical Devices Family	a group of single medical devices that are made by the same manufacturer, have the same common intended use/purpose and the same risk classification and differ in only features.
Medical Devices System	A medical device comprising a number of components or parts intended to be used together to fulfil some or all of the device's intended functions, and that is sold under a single name.
Procedure Pack	Collection of medical devices, that may or may not be made by the same manufacturer, such as surgical instruments, dressings or materials, that are packaged together for use in a range of surgical procedures in a particular clinical specialty.



Annex (2): List of Changes on the Previous Version

Number and Date of the Previous Version	Changes Description
0.0	<ul style="list-style-type: none">- New document- Replaces Annex (15) of “Requirements for Medical Devices Marketing Authorization (MDS-REQ1)”