DRAFT FOR COMMENT PURPOSES (NOT FOR IMPLEMENTATION)

PROJECT ON GUIDANCE ON
CRITERIA OF MEDICAL DEVICES BUNDLING/GROUPING
WITHIN ONE MDMA APPLICATION
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### DEFINITIONS & ABBREVIATIONS

#### Definitions

<table>
<thead>
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<th>Term</th>
<th>Definition</th>
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</table>
| **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 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. |
| **Generic 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 use/purpose. A component may be known as a part but not a medical device in its own right. |
| **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 use/purpose. |
### Surgical Instruments
Instruments intended for surgical use by cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or other surgical procedure without connection to any other medical device.

### Single Medical Device
A medical device that could have different models.

### 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
Comprises of a number of single medical devices, which can be combined or operated in combination to achieve a common intended use/purpose.

### Medical Devices Procedure Pack
A collection of two or more medical devices, assembled together to perform a certain procedure as one package by a manufacturer.

## Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>SFDA</td>
<td>Saudi Food and Drug Authority</td>
</tr>
<tr>
<td>MDMA</td>
<td>Medical Devices Marketing Authorization</td>
</tr>
<tr>
<td>EU MDD</td>
<td>European Union - Medical Devices Directive</td>
</tr>
</tbody>
</table>
INTRODUCTION

Purpose
The purpose of this guidance is to provide criteria for bundling/grouping medical devices within one MDMA application.

Scope
This guidance is applicable to any MDMA applicant who needs to bundle/group more than one medical device type, including in-vitro medical device, within one MDMA application.

Background
In accordance with “Medical Devices Interim Regulation” issued by the SFDA Board of Directors decree No. (1-8-1429) and dated 29/12/1429 H, stipulating that medical devices may be placed on the market and/or put into service only if they comply with the applicable provisions of the Medical Devices Interim Regulation, as signified by the SFDA issuing the manufacturer with a written marketing authorization (MDMA).

In order to reduce the financial costs and time for MDMA applicants, SFDA/MDS allows bundling/grouping of medical device within one MDMA application according to the criteria specified in this guidance document.
BUNDLING/GROUPING CRITERIA

Medical devices may be bundled/grouped within one MDMA application based on the criteria of each category below:

1. Medical Devices:
   1.1. Single Medical Devices
   1.2. Medical Devices Family
   1.3. Medical Devices System
   1.4. Medical Devices Group of Systems
   1.5. Medical Devices Procedure Pack

2. IVD Medical Devices

Note: If the device has accessories, they may be included with the device within the same MDMA application, unless they are marketed separately.

1. Medical Devices

1.1 Single Medical Device

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Examples</th>
<th>Listing Method in MDMA System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical device that have more than one model may be bundled/grouped within one MDMA application only if they have:</td>
<td>o A catheter with multi lengths.</td>
<td>Applicant may list the device in section 2.1, and its models 2.1.4, if applicable.</td>
</tr>
<tr>
<td>1. same legal manufacturer</td>
<td>o A software program manufactured to 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.</td>
<td>For more clarification, see annex (2).</td>
</tr>
<tr>
<td>2. same intended use/purpose</td>
<td>o “First Aid Kit” authorized for marketing as a “Procedure Pack” and the manufacturer wishes to market one item of the kit separately, MDMA applicant shall apply for another MDMA application for the item.</td>
<td></td>
</tr>
<tr>
<td>3. same generic name</td>
<td>o Gloves that are sold in packages of 25, 50 or 100 or different sizes.</td>
<td></td>
</tr>
<tr>
<td>4. same risk class</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Differences in models may include color, quantity, range of size, number of units….etc.

Note: Medical device that have different features can not be bundled/grouped within one MDMA application as a single medical device. However, they may be bundled/grouped as a medical devices family (see section 1.2 in this document).
## 1.2. Medical Device Family

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Examples</th>
<th>Listing Method in MDMA System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical devices that have <strong>different features</strong> may be bundled/grouped within one MDMA application <strong>only</strong> if they have:</td>
<td>Examples on medical device family:</td>
<td>Applicant may list each included medical device in section 2.1, and its models 2.1.4, if applicable.</td>
</tr>
<tr>
<td>1. same legal manufacturer</td>
<td>o X-ray and mobile x-ray</td>
<td></td>
</tr>
<tr>
<td>2. same intended use/purpose</td>
<td>o Basic bedside monitor, bedside monitor with EEG module and bedside monitor with paper printer</td>
<td></td>
</tr>
<tr>
<td>3. same risk class</td>
<td></td>
<td>For more clarification, see <strong>annex (3)</strong>.</td>
</tr>
<tr>
<td><strong>Differences in features</strong> may include, material, structural characteristic, design, patient groups, energy source, purpose, brand name, model name or device description, area of application, additional function, additional secondary intended use/purpose.</td>
<td>Examples on different functions of surgical instruments:</td>
<td></td>
</tr>
<tr>
<td>Surgical instruments may be bundled/grouped within one MDMA application <strong>only</strong> if they have:</td>
<td>Function</td>
<td>Examples</td>
</tr>
<tr>
<td>1. have same legal manufacturer</td>
<td>cut or incise</td>
<td>scissors, knives, saws and blades</td>
</tr>
<tr>
<td>2. have same intended use/purpose</td>
<td>retract</td>
<td>traction and bone hooks</td>
</tr>
<tr>
<td>3. have same risk class</td>
<td>grasp, hold or occlude</td>
<td>tissue and bone holding forceps, also needle holders</td>
</tr>
<tr>
<td>4. do not exceed 50 items per application if they have different functions</td>
<td>dilate or probe</td>
<td>punch</td>
</tr>
<tr>
<td>Dental products may be bundled/grouped within one MDMA application <strong>only</strong> if they have:</td>
<td>cannulate or drain</td>
<td>catheters or any instrument used for drain</td>
</tr>
<tr>
<td>1. same legal manufacturer</td>
<td>aspirate, inject or infuse</td>
<td>instrument to remove unwanted fluids as well as to inject fluids such syringes or some needles</td>
</tr>
<tr>
<td>2. same intended use/purpose</td>
<td>suture or ligate</td>
<td>sutures, clips as well as suture needles and ligating blades</td>
</tr>
<tr>
<td>3. same risk class</td>
<td>other special surgical instruments</td>
<td>………….</td>
</tr>
<tr>
<td>4. different functions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>For more clarification, see <strong>annex (4)</strong>.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Function Examples:

- **restorative**: amalgam
- **endodontic**: K-file
- **oral and maxillofacial surgery and implant**: dental implant, forceps
- **orthodontics**: orthodontic brackets, ortho arch wire
- **periodontics**: curette
- **prosthodontics**: retraction cord
### 1.3 Medical Devices System

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Examples</th>
<th>Listing Method in MDMA System</th>
</tr>
</thead>
<tbody>
<tr>
<td>medical devices with different intended use/purpose may be bundled/grouped within one MDMA application only if they:</td>
<td>o 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.</td>
<td>Applicant may list each product included in the system in section 2.1, and its models 2.1.4, if applicable.</td>
</tr>
<tr>
<td>o have same legal manufacturer</td>
<td>o An electrosurgical unit with forceps, electrodes, electrode holders, leads, plug adaptor, when used together for a common intended use/purpose.</td>
<td></td>
</tr>
<tr>
<td>o are intended to be used in combination to complete a common intended use/purpose.</td>
<td>o Optional accessory such as wireless controller is part of In-the-ear hearing aid.</td>
<td></td>
</tr>
<tr>
<td>o are compatible when used as a medical devices system.</td>
<td>o 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.</td>
<td></td>
</tr>
<tr>
<td>o are sold under a medical devices 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/purpose with the system.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If the items of the system have different risk-classes, the **highest risk-class** will be considered.

If the applicant wishes to market any item of the system separately, he shall apply for another MDMA application.

For more clarification, see annex (5).
### 1.4 Medical Devices Group of Systems

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Examples</th>
<th>Listing Method in MDMA System</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Joints replacement systems</strong> may be bundled/grouped within one MDMA application <strong>only</strong> if they have:</td>
<td>-</td>
<td>Applicant may list each product included in the group of system in section 2.1, and its models 2.1.4, if applicable.</td>
</tr>
<tr>
<td>o same legal manufacturer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>o same risk class</td>
<td></td>
<td></td>
</tr>
<tr>
<td>For more clarification, see annex (5).</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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### 1.5 Medical Devices Procedure Pack

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Examples</th>
<th>Listing Method in MDMA System</th>
</tr>
</thead>
</table>
| Packs, sets or kits may be bundled/grouped within one MDMA application **only** if they have conformity assessment under article 12 of EU MDD 93/42/EEC. | Examples on procedure packs:  
| o first aid kits                                                         | o packs for specific surgical procedure                                  | Applicants may choose the icon "Create PP Application", and then they may list each product included in the procedure pack in section 2.1, and its models 2.1.4, if applicable. |
| o orthodontic procedure packs.                                           | Examples on specialty:  
| o anesthesiology                                                          | o cardiovascular                                                          |                               |
| o chemistry dental                                                       | o ear, nose, and throat                                                   |                               |
| o gastroenterology and urology                                            | o general and plastic surgery                                             |                               |
| o general hospital                                                        | o neurology                                                               |                               |
| o obstetrical and gynecological                                          | o ophthalmic                                                              |                               |
| o orthopedic                                                             | o physical medicine                                                       |                               |
| o radiology                                                               |                                                                          |                               |
| If packs, sets or kits do not have conformity assessment under article 12 of EU MDD 93/42/EEC, they may be bundled/grouped as single medical device (see section 1.1) or family medical device (see section 1.2), **only** if they: |                                                                          |                               |
| o have same legal manufacturer                                           |                                                                          |                               |
| o have a common intended use/purpose.                                    |                                                                          |                               |
| o not exceed 50 items within one MDMA application.                        |                                                                          |                               |
| o grouped/bundled based on specialty.                                     |                                                                          |                               |
| If the procedure pack includes a drug, applicant shall provide the "Marketing Authorization", for the included drug, issued by SFDA/Drug Sector. |                                                                          |                               |
| If the applicant wishes to market any item of the procedure pack **separately**, he shall apply for another MDMA application. |                                                                          |                               |
| For more, see annex (6).                                                 |                                                                          |                               |

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## 2. IVD Medical Devices

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Examples</th>
<th>Listing Method in MDMA System</th>
</tr>
</thead>
<tbody>
<tr>
<td>IVD medical devices may be bundled/grouped within one MDMA application <strong>only</strong> if they:</td>
<td>Examples on IVD products with <strong>same intended use/purpose</strong>:</td>
<td>Applicant may list the IVD kit (brand name) in section 2.1, and its models 2.1.4, if applicable.</td>
</tr>
<tr>
<td>o have same legal manufacturer</td>
<td>o culture media (blood agar and MacConkey agar)</td>
<td></td>
</tr>
<tr>
<td>o not exceed 50 items within one MDMA application.</td>
<td>o susceptibility tests</td>
<td></td>
</tr>
<tr>
<td>o are from same manufacturer.</td>
<td>o The Enzyme-linked immunosorbent assay “Elisa” kits for infectious disease (e.g. HCV, HIV)</td>
<td></td>
</tr>
<tr>
<td>o have same risk class.</td>
<td>o hormone measurements kits (e.g. hCG, growth hormone).</td>
<td></td>
</tr>
<tr>
<td>o are in same original approval/certificate (if applicable)</td>
<td>o tissue typing kits</td>
<td></td>
</tr>
<tr>
<td>o have the <strong>same intended use/purpose based on lab specialty</strong>.</td>
<td>o blood collection tubes (e.g. EDTA, heparin)</td>
<td></td>
</tr>
<tr>
<td><em>Rapid test</em> with different intended use/purpose and different lab specialty may be bundled/grouped within one MDMA application.</td>
<td>Examples on IVD products with <strong>different intended use/purpose</strong>:</td>
<td></td>
</tr>
<tr>
<td>o blood agar and enzyme tests</td>
<td>o HIV and ABO grouping</td>
<td></td>
</tr>
<tr>
<td>o pregnancy kit and Hepatitis virus</td>
<td>Examples on <strong>lab specialty</strong>:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o biochemistry</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o hematology</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o microbiology</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o histology</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o serology</td>
<td></td>
</tr>
</tbody>
</table>
Annex (1) Medical Devices Bundling/Grouping Flowchart

Start

Are they procedure pack(s), kit(s), system(s) or set(s)?

Are they procedure pack(s), kit(s), system(s) or set(s)?

more than one product?

Do they work as System(s)?

Do they work as System(s)?

more than one product?

May bundled/grouped as a procedure pack

May bundled/grouped as a medical devices system or medical devices group of systems

May bundled/grouped as a medical devices family

May bundled/grouped as a single medical device

have a conformity assessment under article 12 of EUMDD 93/42/EEC?

Yes

Yes

Yes

Yes

Yes

Yes

No

No

No

No

No

No

No

No

No

Yes

Yes

Yes

Yes

Yes

Yes

End
Annex (2) Block Diagram for Single Medical Devices

Models may be listed in section 2.1.4

- Model A
- Model B
- Model C
Annex (3) Block Diagram for Medical Devices Family

Medical Devices Family

Medical Device 1

Medical Device 2

Medical Device 3

Devices may be listed in section 2.1

Models may be listed in section 2.1.4

Model A
Model B
Model C

Model A
Model B
Model C

Model A
Model B
Model C
Annex (4) Medical Devices Family Bundling/Grouping Criteria

Start

- Same manufacturer?
  - No
  - Yes
    - Same risk class?
      - No
      - Yes
        - Are they surgical instrument?
          - Yes
          - No
            - Less than 50 products?
              - Yes
              - No
                - Same function?
                  - Yes
                  - No
                    - One common intended use?
                      - Yes
                      - No
                        - May bundled/grouped as a medical device family
                          - End
                        - Can NOT bundled/grouped within one MDMA application
                          - Start
          - No
            - Are they dental products?
              - Yes
              - No
                - Less than 50 products?
                  - Yes
                  - No
                    - Same function?
                      - Yes
                      - No
                        - One common intended use?
                          - Yes
                          - No
                            - May bundled/grouped as a medical device family
                              - End
                          - Can NOT bundled/grouped within one MDMA application
                            - Start
                        - Can NOT bundled/grouped within one MDMA application
                          - Start
                      - No
                        - Same function?
                          - Yes
                          - No
                            - One common intended use?
                              - Yes
                              - No
                                - May bundled/grouped as a medical device family
                                  - End
                                - Can NOT bundled/grouped within one MDMA application
                                  - Start
                      - No
                        - One common intended use?
                          - Yes
                          - No
                            - May bundled/grouped as a medical device family
                              - End
                          - Can NOT bundled/grouped within one MDMA application
                            - Start
                    - No
                      - Same function?
                        - Yes
                        - No
                          - One common intended use?
                            - Yes
                            - No
                              - May bundled/grouped as a medical device family
                                - End
                            - Can NOT bundled/grouped within one MDMA application
                              - Start
                        - No
                          - One common intended use?
                            - Yes
                            - No
                              - May bundled/grouped as a medical device family
                                - End
                          - Can NOT bundled/grouped within one MDMA application
                            - Start
                      - No
                        - One common intended use?
                          - Yes
                          - No
                            - May bundled/grouped as a medical device family
                              - End
                          - Can NOT bundled/grouped within one MDMA application
                            - Start
                  - No
                    - Same function?
                      - Yes
                      - No
                        - One common intended use?
                          - Yes
                          - No
                            - May bundled/grouped as a medical device family
                              - End
                        - Can NOT bundled/grouped within one MDMA application
                          - Start
                    - No
                      - One common intended use?
                        - Yes
                        - No
                          - May bundled/grouped as a medical device family
                            - End
                        - Can NOT bundled/grouped within one MDMA application
                          - Start
Annex (5) Medical Devices System and Medical Devices Group of Systems

Bundling/Grouping Criteria

- Start
- Have same manufacturer?
  - No
  - Yes
    - One common intended use?
      - No
      - Yes
        - Devices compatible?
          - No
          - Yes
            - Sold under one system?
              - No
              - Yes
                - End
  - Yes
    - Are they joint replacement systems?
      - No
      - Yes
        - Are they sold under different systems?
          - No
          - Yes
            - Can NOT bundled/grouped within one MDMA application
  - Yes
    - May bundled/grouped as a medical device group of system

- May bundled/grouped as a medical device system
Annex (6) Medical Devices Procedure Pack Bundling/Grouping Criteria

Start

One common intended use?

Yes

One specialty?

Yes

More than 50 items?

Yes

Can NOT bundled/grouped within one MDMA application

No

No

Can NOT bundled/grouped within one MDMA application

May bundled/grouped as a procedure pack

No

End

May bundled/grouped as a procedure pack