MDS – G7

Guidance on Criteria of Medical Devices Bundling/Grouping within one MDMA Application

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This guidance document has been published after being distributed for public comments dated on 11/9/2017 for 30 days.

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Introduction

Purpose

The purpose of this guidance is to provide criteria for bundling/grouping medical devices within one Medical Devices Marketing Authorization (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

Criteria	Examples	Listing Method in MDMA System
Medical device that have more than one model may be bundled/grouped within one MDMA application only if they have: 1. same legal manufacturer 2. same intended use/purpose 3. same generic name 4. same risk class 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).	○ A catheter with multi lengths. ○ 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. ○ "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. ○ Gloves that are sold in packages of 25, 50 or 100 or different sizes.	Applicant may list the device in section 2.1, and its models 2.1.4, if applicable. For more clarification, see annex (2).

1.2. Medical Device Family

<table>
<tr><th>Criteria</th><th>Examples</th><th>Listing Method in MDMA System</th></tr>
<tr>
<td>Medical devices that have different features may be bundled/grouped within one MDMA application only if they have:
1. same legal manufacturer
2. same intended use/purpose
3. same risk class

Differences in features 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.

Surgical instruments may be bundled/grouped within one MDMA application only if they:
1. have same legal manufacturer
2. have same intended use/purpose
3. have same risk class
4. do not exceed 50 items per application if they have different functions

Dental products may be bundled/grouped within one MDMA application only if they have:
1. same legal manufacturer
2. same intended use/purpose
3. same risk class
4. Same specialty.

For more clarification, see annex (4).</td>
<td>Examples on medical device family:
○ X-ray and mobile x-ray
○ Basic bedside monitor, bedside monitor with EEG module and bedside monitor with paper printer

Examples on different functions of surgical instruments:
<table><tr><th>Function</th><th>Examples</th></tr><tr><td>cut or incise</td><td>scissors, knives, saws and blades</td></tr><tr><td>retract</td><td>traction and bone hooks</td></tr><tr><td>grasp, hold or occlude</td><td>tissue and bone holding forceps, also needle holders</td></tr><tr><td>dilate or probe</td><td>punch</td></tr><tr><td>cannulate or drain</td><td>catheters or any instrument used for drain</td></tr><tr><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>suture or ligate</td><td>sutures, clips as well as suture needles and ligating blades</td></tr><tr><td>other special surgical instruments</td><td>……..</td></tr></table>
Examples on same specialty of dental products:
<table><tr><th>Specialty</th><th>Examples</th></tr><tr><td>restorative</td><td>amalgam</td></tr><tr><td>endodontic</td><td>K-file</td></tr><tr><td>oral and maxillofacial surgery and implant</td><td>dental implant, forceps</td></tr><tr><td>orthodontics</td><td>orthodontic brackets, ortho arch wire</td></tr><tr><td>periodontics</td><td>curette</td></tr><tr><td>prosthodontics</td><td>retraction cord</td></tr></table></td>
<td>Applicant may list each included medical device in section 2.1, and its models 2.1.4, if applicable.

For more clarification, see annex (3).</td>
</tr>
</table>

	lab and clinic: porcelain for lab ,dental unit other special dental products: ……	

1.3 Medical Devices System

Criteria	Examples	Listing Method in MDMA System
medical devices with different intended use/purpose may be bundled/grouped within one MDMA application only if they: ○ have same legal manufacturer ○ are intended to be used in combination to complete a common intended use/purpose. ○ are compatible when used as a medical devices system. ○ 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. 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).	○ 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. ○ Optional accessory such as wireless controller is part of In-the-ear hearing aid. ○ 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.	Applicant may list each product included in the system in section 2.1, and its models 2.1.4, if applicable.

1.4 Medical Devices Group of Systems

Criteria	Examples	Listing Method in MDMA System
Medical Devices Group of systems may be bundled/grouped within one MDMA application only if they have: ○ same legal manufacturer ○ same risk class. ○ same common intended use. For more clarification, see annex (5).	○ Total knee replacement system and tools, total hip replacement system and tools, shoulder replacement system. ○ Endoscopy towers with different features.	Applicant may list each product included in the group of system in section 2.1, and its models 2.1.4, if applicable.

1.5 Medical Devices Procedure Pack

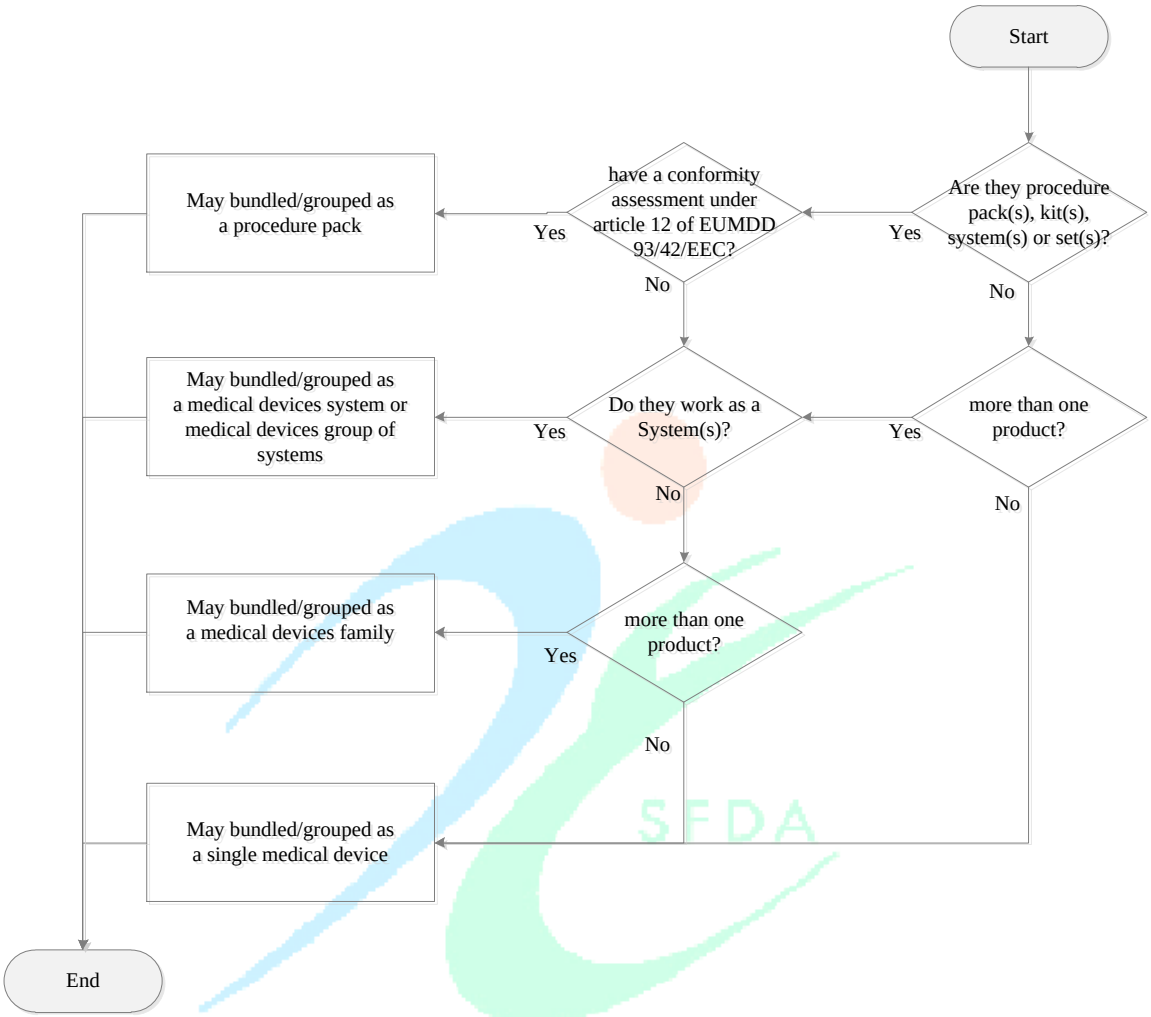
Criteria	Examples	Listing Method in MDMA System
Packs, sets or kits may be bundled/grouped within one MDMA application only if they have conformity assessment under article 12 of EU MDD 93/42/EEC. If packs, sets or kits do not have conformity assessment under article 12 of EU MDD 93/42/EEC, they may be bundled/grouped as single medical device (see section 1.1) or family medical device (see section 1.2), only if they: ○ have same legal manufacturer ○ have a common intended use/ purpose. ○ not exceed 50 items within one MDMA application. ○ 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).	Examples on procedure packs: ○ ENT procedure pack ○ ophthalmic procedure pack ○ urology surgical procedure pack ○ orthodontic procedure packs Examples on specialty: ○ anesthesiology ○ cardiovascular ○ chemistry dental ○ ear, nose, and throat ○ gastroenterology and urology ○ general and plastic surgery ○ general hospital ○ neurology ○ obstetrical and gynecological ○ ophthalmic ○ orthopedic ○ physical medicine ○ radiology	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. Note: "Create PP Application" icon is only for packs, sets or kits that have conformity assessment under article 12 of EU MDD 93/42/EEC.

2. IVD Medical Devices

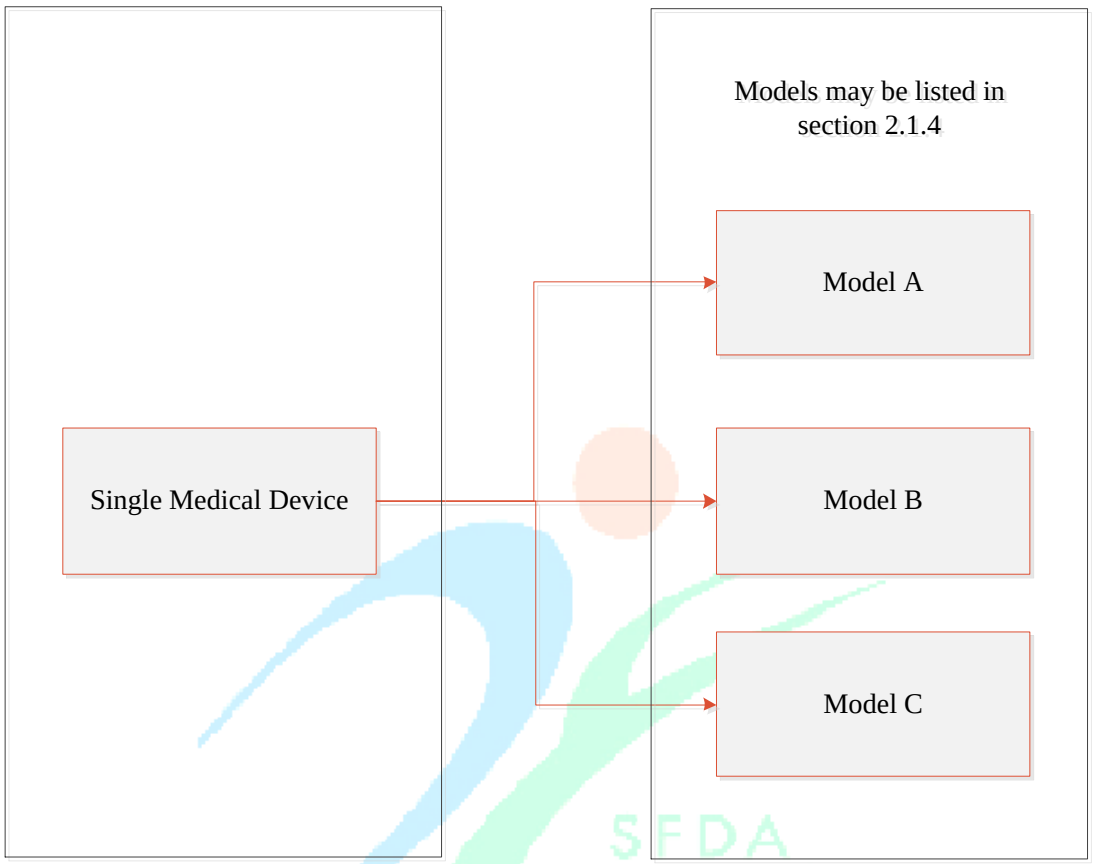
Criteria	Examples	Listing Method in MDMA System
IVD medical devices may be bundled/grouped within one MDMA application only if they: ○ have same legal manufacturer ○ not exceed 50 items within one MDMA application. ○ are from same manufacturer. ○ have same risk class. ○ are in same original approval/ certificate (if applicable) ○ have the same intended use/purpose based on lab specialty. Rapid test with different intended use/purpose and different lab specialty may be bundled/grouped within one MDMA application.	Examples on IVD products with same intended use/purpose: ○ culture media (blood agar and MacConkey agar) ○ susceptibility tests ○ The Enzyme-linked immunosorbent assay "Elisa" kits for infectious disease (e.g. HCV, HIV) ○ hormone measurements kits (e.g. hCG, growth hormone). ○ tissue typing kits ○ blood collection tubes (e.g. EDTA, heparin) Examples on IVD products with different intended use/purpose: ○ blood agar and enzyme tests ○ HIV and ABO grouping ○ pregnancy kit and Hepatitis virus Examples on lab specialty: ○ biochemistry ○ hematology ○ microbiology ○ histology ○ serology	Applicant may list the IVD kit (brand name) in section 2.1, and its models 2.1.4, if applicable. If the applicant wishes to market any item of the kit separately, the applicant may list the item separately in section 2.1, and its models 2.1.4, if applicable.

Annexes

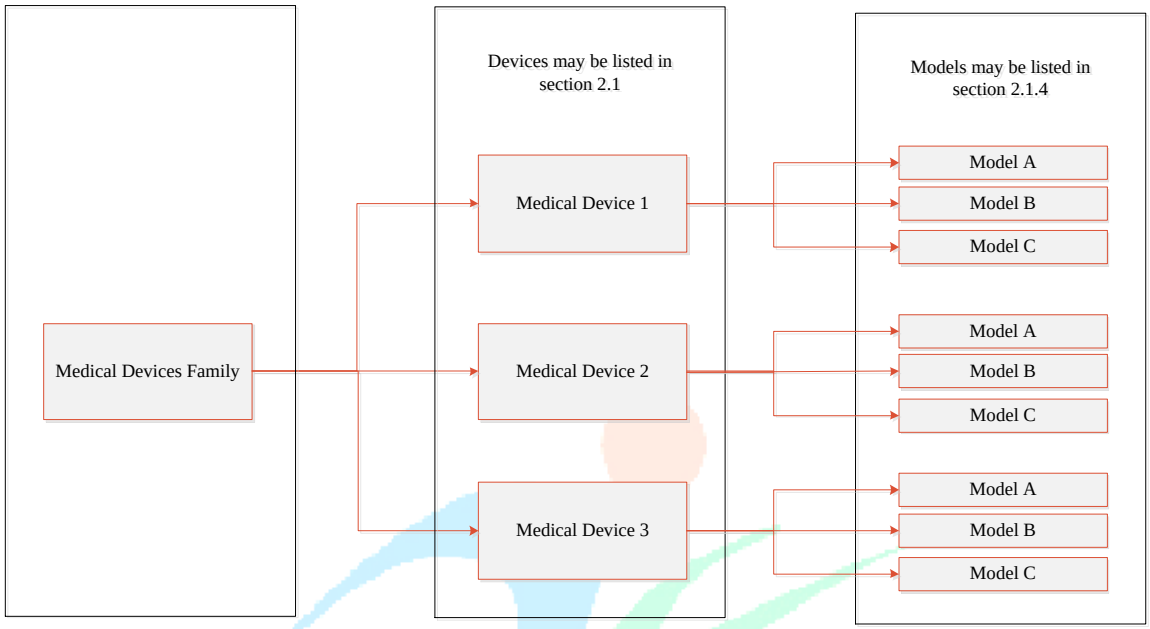
Annex (1): Medical Devices Bundling/Grouping Flowchart



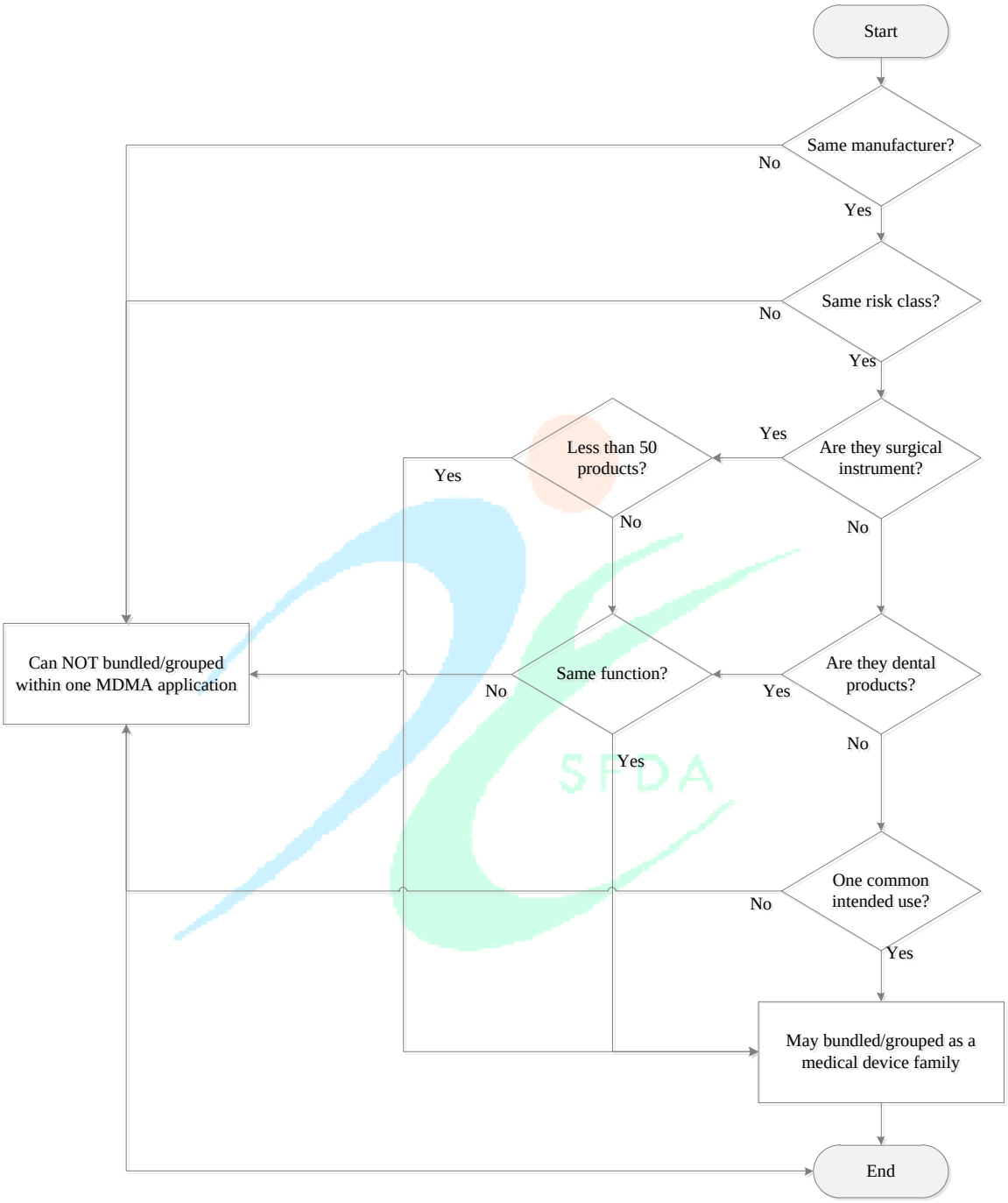
Annex (2): Block Diagram for Single Medical Devices



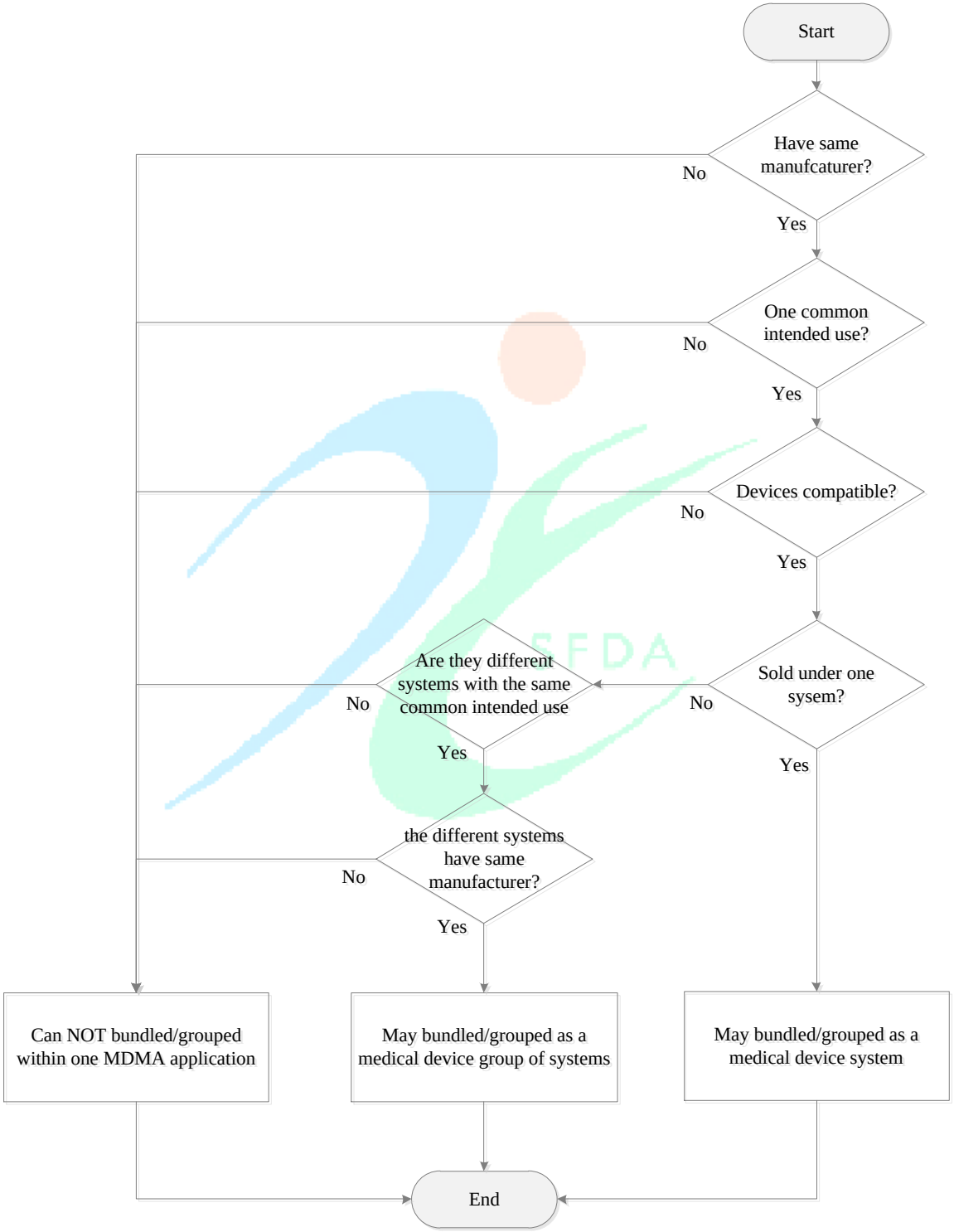
Annex (3): Block Diagram for Medical Devices Family



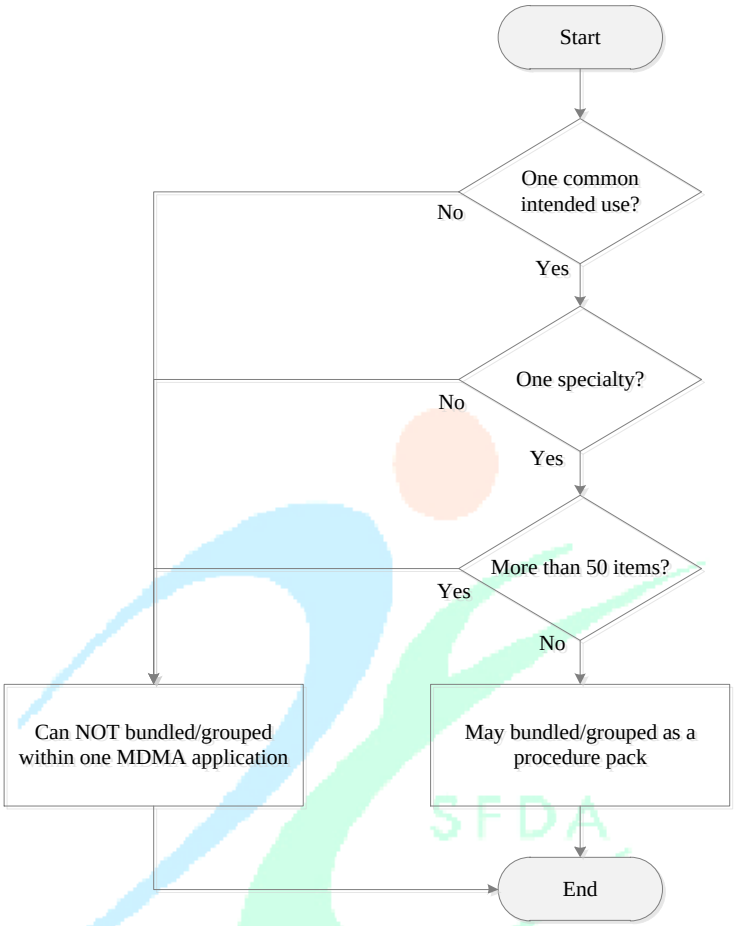
Annex (4): Medical Devices Family Bundling/Grouping Criteria



Annex (5): Medical Devices System and Medical Devices Group of Systems Bundling/Grouping Criteria



Annex (6): Medical Devices Procedure Pack Bundling/Grouping Criteria



Annex (7): Definitions & Abbreviations

SFDA	Saudi Food and Drug Authority
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, retracing, 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.
MDMA	Medical Devices Marketing Authorization
EU MDD	European Union - Medical Devices Directive