مجلس الصحة
لدول مجلس التعاون
Gulf Health Council

Grouping and Bundling Criteria

Medical Devices Central Registration

Gulf Health Council

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

1. Medical Devices:
    1.1. Medical Devices Single
    1.2. Medical Devices Family
    1.3. Medical Devices System
    1.4. Medical Devices Procedure Pack

2. IVD Medical Devices

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

1. Medical Devices
1.1 Medical 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, 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 GMD 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 GMD's shall APPLY FOR ANOTHER APPLICATION of GMD 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"

1. Medical Devices	
1.2 Medical Device Family	
Criteria	Examples
A maximum of 5 TFs of Medical devices may be bundled/grouped within one application only if they have: ▪ same legal manufacturer, ▪ same intended use/purpose, ▪ same risk class, ▪ same Generic-Propriety/GMDN code (optional), and ▪ has a common similar design, construction material and manufacturing process. ▪ Be within the scope of the permissible variants.	▪ A catheter with multi lengths. ▪ Condoms that differ in size and color but are manufactured from the same material and sharing comment intended use ▪ Steerable guide wires that are available in various lengths and possess various tip shapes and tip flexibilities. ▪ Devices that do not share common intended purpose including key indications, medical conditions, and patient populations can not be bundled together. ▪ Lung retractor and kidney retractor have the same overall intended purpose as they

Notes: ▪ Accessories can be included with its device within the single application of GMD 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 GMD shall APPLY FOR ANOTHER APPLICATION of GMD **TOTAL NUMBER** of medical device that are grouped/bundled within a single application shall NOT EXCEED 50 items.	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 GMD as a "family of medical devices" ▪ Devices covered by one technical documentation that covers full set of configurations and marketed with different brand names and different subset configurations. ▪ Contact lenses are available as toric lens and spherical lens. These products have different intended purposes and performances. They are designed and manufactured differently. Due to these differences, they shall <u>not</u> be considered as family. ▪ For SURGICAL INSTRUMENTS can be grouped/bundled within a single application of GMD as a "family of medical devices" , each group of the following surgical instruments will be grouped/bundled within a single application of GMD as a "family of medical devices"

1. Medical Devices	
1.3 Medical Devices System	
Criteria	Examples
Medical devices compromising a system may be bundled/grouped within a maximum of 5 TFs only if they: ▪ have same legal manufacturer; ▪ are intended to be used in combination to complete a common intended use/purpose. ▪ 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. Notes:	– 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. – A glucose monitoring "system" comprising of a glucose meter, test strips,

▪ If the items of the system have different risk-classes, the highest risk-class will be considered. ▪ ACCESSORIES CAN BE INCLUDED with its device within the single application of GMD 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 GMD shall APPLY FOR ANOTHER APPLICATION of GMD **TOTAL NUMBER** of medical device that are grouped/bundled within a single application shall NOT EXCEED 50 items.	control solutions and linearity solutions can be grouped/bundled within a single application of GMD as a "medical device system".

1. Medical Devices

1.4 Medical Devices Procedure Pack

Criteria	Examples
Medical devices compromising a procedure pack may be bundled/grouped within a maximum of 5 TF only if they: ▪ same legal manufacturer ▪ same intended use/purpose and under the same specialty. ▪ May have DIFFERENT DESIGN. ▪ Same risk class. Notes: ▪ For the pack: applicant shall submit TF documents. ▪ For each component: Manufacture shall submit TF for the component. ▪ Any submitted approval should be in combination with letter of agreement from each manufacturer of procedure pack components to supply technical documentation to the GHC upon request.	– 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

▪ 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 "Registration Certificate of a Pharmaceutical Product", for the included drug, issued by GHC/Drug Sector. ▪ GHC will assign a "Medical Device Listing GCC Registry Number" on GMD certificate FOR EACH MEDICAL DEVICE/ ITEM IN THE PROCEDURE PACK ▪ 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 GMD application. TOTAL NUMBER of medical device that are grouped/bundled within a single	

application shall NOT EXCEED 50 items.	

2. IVD Medical Devices	
Criteria	Examples
▪ Maximum of 5 TFs can be submit in one application, must follow these criteria: ▪ Same Risk Classification. ▪ Same legal manufacture. ▪ Same intended use/Same principle of operation ▪ Closely similar design and manufacturing process ▪ Note: TOTAL NUMBER of IVD medical device that are grouped/bundled within a single application shall NOT EXCEED 50 items.	Examples on IVD products with same intended use/purpose: - culture media (blood agar and MacConkey agar) - susceptibility tests - 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 of lab specialty: - biochemistry - hematology - microbiology - histology - serology