Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical affair and Drugs Control

Medical Device Control Department

Guidance on GD 10: Requirements of Fast Track registration for Low Risk Medical Devices in Sultanate of Oman

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1. Introduction

The Directorate General of Pharmaceutical Affairs & Drug Control (DGPA & DC) mutually recognizes other regulatory jurisdictions approvals for medical devices.

This has led to introduction of registration of fast truck low Risk Medical device. This guidance document is meant to assist applicants in the registration of low risk medical devices in Sultanate of Oman.

Applicants are strongly encouraged to familiarize themselves with the criteria and requirements for review processes outlined in this guidance and the other relevant guidance documents before submitting their applications.

Applications with the incorrect risk classification of devices may result in the re-submission of the applications according to the appropriate risk class.

2. Purpose

The purpose of this guidance is to provide guidance on the fast track medical device to correctly register their Low risk medical devices in Sultanate of Oman.

3. Scope

This guidance applies to the following products: -

Low Risk Medical devices which have Market Authorization in Kingdom of Saudi Arabia.

4. Definition

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:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease,
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- 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 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.

Low-Risk Medical device: Low Individual Risk and Low Public Health Risk

Registration: the process by which a party submits information to the Regulatory Authority in a jurisdiction, regarding the identification and establishment location(s) of the manufacturer and other parties, responsible for supplying a medical device(s) to the market in that jurisdiction.

Listing: the process whereby a party submits information to the Regulatory Authority in a jurisdiction, regarding the identification of a medical device(s) that is or will be supplied to the market in that jurisdiction.

Label: means the written, printed or graphic information appearing either on the device itself, or on the packaging of each unit or on the packaging of multiple devices.

Manufacturer: means any natural or legal person2 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: 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.

Accessory 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.

Risk: Combination of the probability of occurrence of harm and the severity of that harm.

Intended use / purpose: the objective intent of the manufacturer regarding the use of a product, process or service as reflected in the specifications, instructions and information provided by the manufacturer.

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

5. Abbreviations

ISO: International Organization for Standards

QMS: Quality Management System

GMDN: Global Medical Device Nomenclature

HS code*:* Harmonized System

6. General Requirements

1. Medical Devices shall not be imported, placed on the market, and/or put into service within Oman unless it is listed in medical device control department database. This can be done through the website: https://www.moh.gov.om/ar/web/dgpadc/-13

2. In case of any variation in the Medical Devices the manufacturer shall: - prepare, hold and update related "Technical Documentation" that confirm to local regulation requirements - establish, document and maintain an effective quality management system (QMS) according to (ISO 13485:2016) or any identical adopted standards for the same issue/version.

3. Fast Track Registration requirements:
    a. Shall be presented in a clear, organized, readily, searchable and unambiguous manner
    b. Apply online through the online portal via the following link:
    c. Choose jurisdiction approval KSA or GHC with valid certificate.
    d. Await certificate validation approval.
    e. If approved, the dossier file section requirements should be filled within 6 months from the first approval.
    f. Payment of fees should be made according to risk classification.

Notes:

- **The applicant is required to submit the requirements in dossier format according to sections as below**
- **DGPA&DC has the right to request more requirements as per the product type if needed.**

7. Low Risk Fast Track Dossier File Sections Requirements:

7.1 Section 1: Application form

This section includes establishment and Authorized contact details which must be filled in the Application form as attached in **Annex (1).**

7.2 Section 2: Manufacturer information

This section includes name, physical site address and details of legal manufacturer, Quality management system used and their certificates, ex: **(ISO 13485) for the manufacturer.**

7.3 Section 3: Medical Device information

- This section defines the device and any accessories information, medical device grouping/bundling and regulatory jurisdiction. The following points shall be documented:

7.3.1 Medical device information.

7.3.1.1 Trade / Brand name.
7.3.1.2 Model name / number.
7.3.1.3 Medical device classification.
7.3.1.4 Intended use.
7.3.1.5 Description of accessories.
7.3.1.6 Medical device category.
7.3.1.7 Manufacturer device identification number.
7.3.1.8 Format of device identification number that appear in labeling for traceability purpose.
7.3.1.9 GMDN.
7.3.1.10 Nomenclature code if different than GMDN
7.3.1.11 HS code.
7.3.1.12 Shelf life (if applicable).
7.3.1.13 Storage condition.
7.3.1.14 Year first sold
7.3.1.15 Warnings
7.3.1.16 Principles of operation/mode of action (how it works/ operates)
7.3.1.17 Picture or drawing of the device which should be details (include sufficient explanation to understand the drawing)
7.3.1.18 Description of any devices required to operate the device (IT infrastructure, laptop, mobile smart phone**)**

7.3.2 Medical device grouping/ bundling.

This section describes which grouping / bundling to be filled as per **Annex (2),** refer to bundling and grouping guidance for more information.

- Single
- Family
- System
- systems
- Procedure pack

7.3.3 Which regulatory jurisdiction the device follows:

- SFDA
- USA
- EU
- Canada
- Australia
- Japan
- Others (specify)

7.4 Section 4: Device Labeling

This section of registration requirements shall include a full set of labels:

1. Labels for the device
2. Packaging which includes the instructions for use (IFU)
3. any promotional material as applicable

7.5 Section 5: Product Verification and Validation

This section includes the product quality assurance certificate.

Product certificates required for Low-Risk:

- CE certificate if available

Notes:

- **If the product is class I non-sterile non-measurable the CE-mark certificate excludes.**
- **The certificate shall be issued by authorized certification body/ accreditation. Including: reference number, scope and expiry date.**

7.6 Section 6: Status of device distribution

In this section, the establishment of medical devices should list the countries where the device is marketed with evidence and submit a free sale certificate or certificate of foreign government CFG if the product from USA.

7.7 Section 7: Declaration of conformity

This section of registration requirements includes a declaration of conformity from the manufacturer and it contains:

- Product Name
- Model number
- Classification
- A statement that the declaration is issued under the sole responsibility of the manufacturer
- Issued/signed stamped from the manufacturer.

Note: All dossier sections requirements should be documented and filled in the online platform.

Annexes

Annex (1) Application form

Form MD1

Establishment registration number (fill by MOH staff)

Application form for the registration of medical device Establishment

This application form to be filled by the applicant ONLY.
All the documents submitted with this application should be either be in English and or Arabic
Arrangement of the documents in the folder should follow the same sequence followed in this form

Part 1

Is the registrant: Manufacturer ☐ Local Agent ☐ Importer ☐

1.1 Establishment details:

Applicant Name	
CR number	
Email	
Fax	
Telephone number	
Physical location	

1.2 Authorized contact:

Name	
Email	
Contact number	
Qualification	
position	

List name of activities according to CR

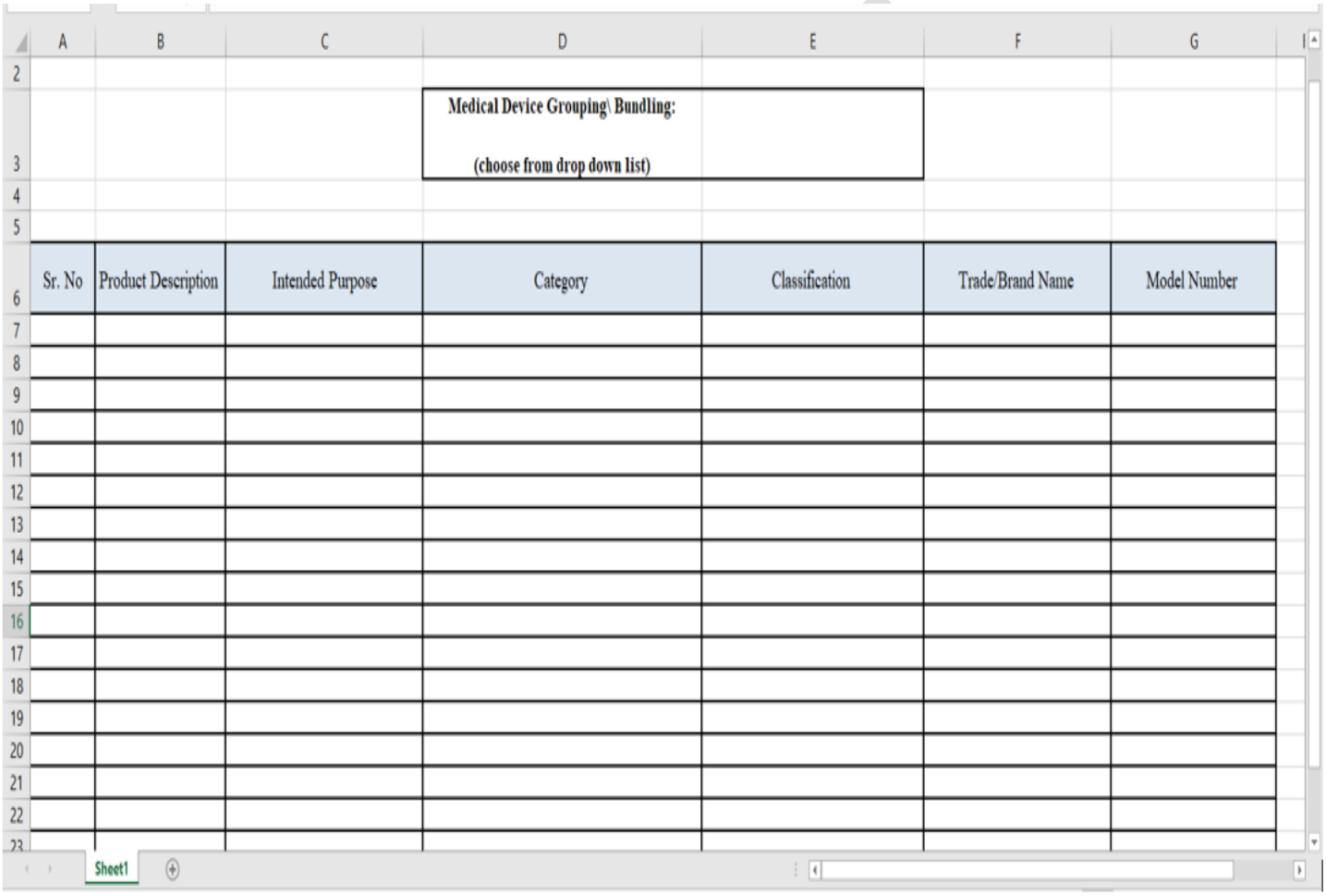
- Availablitiy of store license issued by M.O.H. ☐ available ☐ not available

Name and Signature of authorized person stamp

Date of submission:

Annex (2) Medical Device Grouping /Bundling

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



	A	B	C	D	E	F	G
2							
3				Medical Device Grouping\ Bundling: (choose from drop down list)			
4							
5							
6	Sr. No	Product Description	Intended Purpose	Category	Classification	Trade/Brand Name	Model Number
7							
8							
9							
10							
11							
12							
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16							
17							
18							
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22							
23							

Sheet1

References

List	Links
Low Risk Medical Device Dossier File Sections Requirements **(CSDT requirement)**	http://www.ahwp.info/sites/default/files/AHWP_Common_Submission_Dossier_Template.pdf http://www.ahwp.info/sites/default/files/AHWP-WG1-CSDT%20Guidance_FINAL.pdf
Definitions	https://www.who.int/medical_devices/full_deffinition/en/ http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n065-listing-of-medical-devices-100827.doc http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n065-listing-of-medical-devices-100827.doc http://www.imdrf.org/docs/ghtf/archived/sg1/technical-docs/ghtf-sg1-n70-2011-label-instruction-use-medical-devices-110916.pdf http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n055-definition-terms-090326.doc http://www.imdrf.org/docs/ghtf/final/steering-committee/procedural-docs/ghtf-sc-n4-2012-definitions-of-terms-121109.pdf http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n77-2012-principles-medical-devices-classification-121102.docx http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n77-2012-principles-medical-devices-classification-121102.docx http://www.imdrf.org/docs/ghtf/archived/sg1/technical-docs/ghtf-sg1-n70-2011-label-instruction-use-medical-devices-110916.pdf