Sultanate of Oman

Ministry of Health

^Directorate General of Pharmaceutical affair and Drugs Control

Medical Device Control Department

Guidance Document GD7: Requirements of Low-Risk In-Vitro Diagnostics Registration in Sultanate of Oman

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Document Title: Requirements of Low-Risk In-Vitro Diagnostics Registration in Sultanate of Oman

Approval Process

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Contents

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 low risk In-vitro diagnostics devices.

This guidance document is meant to assist applicants in the registration of low risk In-Vitro Diagnostic 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 describe for all In-Vitro Diagnostic establishments, and importers of IVD devices the procedures and general requirements for the submission of a product registration for Low Risk IVD devices.

3. Scope

This guidance applies to the following products:

Low Risk In-Vitro Diagnosis Devices.

4. Definition

In Vitro Diagnostic (IVD) Medical Device: In Vitro Diagnostic (IVD) Medical Device 'In Vitro Diagnostic (IVD) 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, including blood and tissue donations, solely or principally to provide information:

- concerning a physiological or pathological state;
- concerning a congenital abnormality;
- concerning the predisposition to a medical condition or a disease;
- To determine the safety and compatibility with potential recipients;
- To predict treatment response or reactions;
- To define or monitor therapeutic measures. This includes kits, reagents, calibrators, control materials, specimen receptacles, software, and related instruments, apparatus, systems or other articles.

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 person 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.

Accessories to an IVD medical device: means an article which, is intended specifically by its manufacturer to:

- Be used together with an IVD medical device to enable that device to be used in accordance with its intended use as an IVD medical device.
- Or to augment or extend the capabilities of that device in fulfilment of its intended use as an IVD medical device.

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.

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.

5. Abbreviations

IVD: In-Vitro Diagnostics
ISO: International Organization for Standardization
QMS: Quality Management System
GMDN: Global Medical Device Nomenclature
HS code: Harmonized System

6. General Requirements

1. In-Vitro Diagnostics 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 In-Vitro Diagnostics 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 the international ISO standard (ISO 13485:2016) or any identical adopted standards for the same issue/version.

3. Registration requirements shall be presented in a clear, organized, readily, searchable and unambiguous manner.

4. Apply for registration through the online portal.

5. 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 product type if needed.**

7. Low risk IVD Dossier File Sections Requirements

7.1 Section 1: Application form

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

7.2 Section 2: Manufacturer information

This section includes the name, physical site, address, details of the legal manufacturer**,** quality management system used and the certificates e.g. (ISO 13485) for the manufacturer.

7.3 Section 3: IVD Device information

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

7.3.1 IVD Device information

7.3.1.1 Trade / Brand name

7.3.1.2 Model name/number
7.3.1.3 Intended Use
7.3.1.4 Description of accessories
7.3.1.5 IVD device classification
7.3.1.6 IVD device category
7.3.1.7 Manufacturer device identification number [1]
7.3.1.8 Format of device identification number that appears in labeling for traceability purpose[2]
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)

[1] Manufacturer device identification number: Code or reference number
[2] Format of device identification number that appear in labeling for traceability purpose: which system used for traceability purpose

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 IVD device grouping/ bundling

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

- IVD single
- IVD family
- IVD system
- IVD kit
- IVD cluster
- Group

7.3.3 Which regulatory jurisdiction the device follows:

- KSA (MDMA)
- USA
- EU
- Canada
- Australia
- Japan
- Others (specify)

7.4 Section 4: Device Labeling

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

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 provides product certificates:

- CE certificate if available.
- Other.

7.6 Section 8: Clinical evidence

This section provides clinical evidence about the products and shall include:

-Clinical evaluation report
- Clinical performance
-Analytical Sensitivity and Specificity.

7.6 Section 6: Status of device distribution

In this section the establishment of IVD devices should list the countries where the device is marketed with evidence and submit (original) 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 declaration of conformity from manufacturer and it is containing:

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

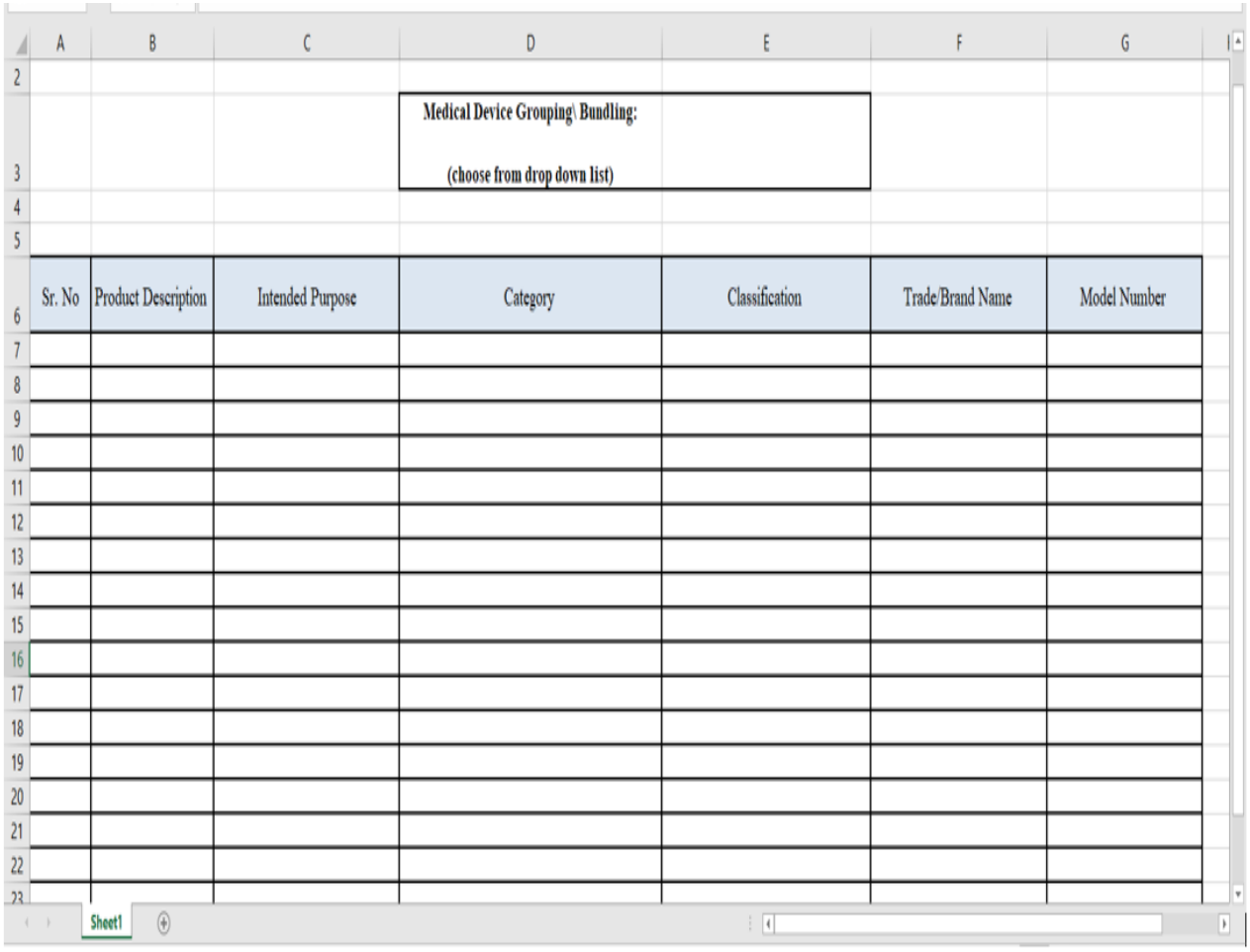
- Availablitiy of store license issued by M.O.H. ☐ available ☐ not available

Name and Signature of authorized person stamp

Date of submission:

Annex (2) IVD 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
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23							

Sheet1

References

List	Links
IVD 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 https://www.fda.gov/media/116573/download