وزارة الصحة
Ministry of Health

DSC
مركز سلامة الدواء
Drug Safety Center

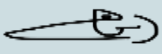
Guideline on Requirements of Medical Device Manufacturer Registration in Sultanate of Oman

Drug Safety Center

2025

First Edition

Document Title	Guideline on Requirements of Medical Device Manufacturer Registration in Sultanate of Oman
Document Type	Guideline
Directorate/Institution	Drug Safety Center
Targeted Group	All Local Medical Device Establishment
Document Author	In Vitro Diagnostic Device Registration Section
Designation	Section Head of In Vitro Diagnostic Device registration
Document Reviewer	Eng. Faiza Alzadjali
Designation	Director of Medical Device Control Department
Release Date	October 2025
Review Frequency	Every 3 years

Validated by		**Approved by**	
Name	**Ph. Safiya Saleh Al Aghbari**	**Name**	**Ph. Ibrahim Nasser Al Rashdi**
Designation	**Head of Quality Assurance & Safety Management Section**	**Designation**	**Directorate General of Drug Safety Center**
Signature		**Signature**	
Date	**26/10/2025**	**Date**	**18/11/2025**

Acknowledgments

The preparation of this guideline was undertaken by the In Vitro Diagnostic Device Registration Section/ Medical Device Control Department. The Drug Safety Center extends its sincere gratitude to all staff members of the medical device control department section for their dedicated efforts. Special acknowledgment is given to the members of the medical device control department section task force for their invaluable contributions

Table of Contents

Acronyms:

MOH	Ministry of Health
DSC	Drug Safety Center
MDCD	Medical Device Control Department
MD	Medical Device
IVD	In Vitro Diagnostic
ISO	International Organization for Standardization
QMS:	Quality Management System
GMDN	Global Medical Device Nomenclature
HS code	Harmonized System

Definitions

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.
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.
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).

CHAPTER ONE

Introduction

Medical devices manufacturers required to be registered to cater for regulatory requirements. Regulation is enforced in Oman via ministerial decree 113/2020. This will ensure that products entering the market are safe and efficient.

This guidance document is meant to assist applicants in the registration of medical device manufacturer in the Ministry of health in 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.

Purpose

The purpose of this guidance is describe the procedures and general requirements for the submission of medical device manufacturers dossier.

Scope

This guidance applies to the following products:

Medical device manufacturers

Structure

This is the first version of this guidance and it consists of several chapters. Chapter one covers a brief introduction to the guideline as well as the purpose, scope and structure. Chapter two explains the general requirements of medical device including IVD manufacturer registration. Chapter three covers the requirements of medical device including IVD manufacturer registration. Chapter four comprises of the document history and version control table, references and Annex.

CHAPTER TWO

General Requirements

1. Registration of medical device including IVD manufacturer requirements shall be presented in a clear, organized, readily, searchable and unambiguous manner.
2. Apply for registration through the online portal.

   https://moh.gov.om/ar/%D8%A7%D9%84%D8%AE%D8%AF%D9%85%D8%A7%D8%AA/?classification=2404&category=9285
3. To fulfil the prerequisite of the MD including IVD manufacturer registration, applicant must complete the manufacturer license (Fees applies) and initial approval for wholesale activity, as well as local medical device establishment approval in case the device will be sold on their behalf
4. Payment of fees should be made.

Note:

- **Drug Safety Center has the right to request more requirements as per product type if needed.**
- **In case of any variation in the manufacturer applicant shall apply through variation services**

Requirements of Medical Device Including IVD Manufacturer Registration:

Section 2: Manufacturer information

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

- **Legal manufacturer**

Legal manufacturer details:

- Legal manufacturer Name
- Legal manufacturer country
- Postal address
- Physical address
- Tel No
- Fax No
- Email
- Quality Management System (QMS) number
- Quality Management System (QMS) Certificate expiry date

Legal manufacturer attachments:

- Quality Management System (QMS) Certificate
- Recent audit report
- Manufacturing/ Production process
- Manufacturer Layout
- Commerce Agency Certificate
- Agreement between Legal manufacturer and sub-contract manufacturer

- **Section 2: Sub-Site / Sub-Contract: (if applicable)**

Sub-Site / Sub-Contract details:

- Sub-Site / Sub-Contract name
- Sub-Site / Sub-Contract country
- Postal address
- Physical address
- Tel No
- Fax No
- Email
- Quality Management System (QMS) Name
- Quality Management System (QMS) Certificate expiry date

2.2 Sub-Site /Sub-Contract Attachments (if applicable:

- Quality Management System (QMS) Certificate
- Recent audit report
- Manufacturing/ Production process
- Manufacturer Layout

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

CHAPTER THREE

Responsibilities:

Department and section staff	Support the review, evaluation, and processing of medical device manufacturer registration applications in accordance with the applicable regulatory requirements.
Department Directors and Section Heads	Supervise and ensure compliance with the registration procedures, approve recommendations, and provide oversight for medical device manufacturer registration activities.
QASM Section	Monitor quality assurance aspects, safety, and post-market surveillance related to registered medical device manufacturer.
DG-DSC	Oversee implementation of the regulatory framework, ensure alignment with national and international standards, and endorse final decisions on medical device manufacturer registrations.

CHAPTER FOUR

Document History and Version Control

Version	Description	Review Date
1	Initial Release	October 2025
2		
3		

References:

- International Medical Device Regulators Forum (IMDRF). (n.d.). *IVD Medical Device Dossier File Sections Requirements (CSDT requirement).*
- International Medical Device Regulators Forum (IMDRF). (n.d.). *IMDRF – International Medical Device Regulators Forum.*
- International Medical Device Regulators Forum (IMDRF). (2016). *Definitions of the Terms Manufacturer, Authorized Representative, Distributor and Importer (IMDRF/GRRP WG/N19:2016).*
- International Medical Device Regulators Forum (IMDRF). (2023). *Labelling for Medical Devices, including In Vitro Diagnostic Medical Devices (IVDs) (IMDRF/GRRP WG/N52:2023).*
- World Health Organization (WHO). (2017). *In Vitro Diagnostic (IVD) Device Definition.* Geneva: World Health Organization.
- Asian Harmonization Working Party (AHWP). (2016). *Guidance for Preparation of a Common Submission Dossier Template (CSDT) Dossier for General Medical Device Product Submission.*

Annex

Appendix 1: Procedure Flowchart