IMDRF International Medical Device Regulators Forum

16 September 2025

EDA, Egypt Regulatory Updates 2025

EGYPTIAN DRUG AUTHORITY
EDA
هيئة الدواء المصرية

- *Miriam Boles – Head of the Central Administration of Medical Devices (CAMD)*
- *Sondos Moshtohry – Supervisor of Cooperation with International Organizations – Office of the Chairman (CEO)*

Overview

- Newly issued EDA Guidelines
- Revised EDA Guidelines
- EDA’s Guidelines Currently Under Development
- Training Programs
- EDA’s International Harmonization Efforts
- EDA’s IMDRF Activities - Updates

Newly issued EDA Guidelines

1-Guideline for Preclinical testing and clinical investigation for Medical devices (10/24), which is aligned with the following IMDRF and GHTF documents :

- IMDRF MDCE WG/N57FINAL:2019 Clinical Investigation (formerly GHTF/SG5/N3:2010)
- IMDRF/IVD WG/N64 FINAL:2021 Principles of In Vitro Diagnostic (IVD) Medical Devices Classification
- GHTF code: GHTF/SG5/N6:2012 Clinical Evidence for IVD Medical Devices
- GHTF code: GHTF/SG5/N8:2012 Clinical Performance Studies for IVD Medical Devices

2- Regulatory Guideline for importation of non-commercial samples.

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Revised EDA Guidelines

1- Minimum labelling requirements guideline, *2nd version* (12/2024), which is aligned with the following IMDRF technical document:

- IMDRF/GRRP WG/N52: Principles of Labelling for Medical Devices and IVD Medical Devices

2- IVD regulatory guideline, *2nd version* (02/2025), which is closely aligned with the following IMDRF technical documents :

- IMDRF/RPS WG/N13 FINAL:2019 (Edition 3). In Vitro Diagnostic Medical Device Market Authorization Table of Contents (IVD MA ToC)
- IMDRF/GRRP WG/N47 FINAL:2018 Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices

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EDA Guidelines Currently Under Development

1- Regulatory Guideline for manufacturing of medical devices and IVDs under license.

2-Regulatory Guideline of Registration of Locally Manufactured Medical Devices without International Quality Certificates (***2nd version***)

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Training Programs

EDA operates a Center for Continuing Professional Development (CPD) that is tasked with the ongoing development and execution of training programs for EDA staff and pertinent stakeholders in the industry.

- No. of internal training programs for **regulatory staff** in 2025:**19**
- **Total no. of trainees : more than 400**

- No. of external training programs for **Industry stakeholders** in 2025:**7**
- **Total no. of trainees : more than 250**

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EDA's International Harmonization Efforts

- EDA is the first African NRA to achieve WHO ML3 for both Medicines and Vaccines – Producing, *March 2022, December 2024*.

- Since its formal establishment, EDA, Egypt has prioritized international engagements and is currently an active participant in more than 10 international organizations.

- June 2025, EDA, Egypt hosted the **Global Harmonization Working Party (GHWP) TC leaders meeting** for the **1st time on African lands.**

EDA's International Harmonization Efforts

Regional Contribution

- ***June 2025***, in Cairo, an **eight-party** MoU was signed between African (NRAs) recognized by the WHO as Maturity Level 3 (ML3). The agreement includes Egypt, Nigeria, South Africa, Ghana, Tanzania, Zimbabwe, Rwanda, and Senegal.

- ***April 2025***, EDA, Egypt was elected as the Vice-Chair of the (**AMDF**) under the umbrella of (AUDA-NEPAD), for a term of three years. And, in ***February 2025***, EDA, Egypt was elected as the President of the North African Medicines Regulatory Harmonization Initiative (NA-MRH) for a term of three years.

- ***September 2024***, Egypt was chosen to host the Headquarters of the Arab Drug Agency (**Waad**). And, in ***April 2024***, Egypt attained the Board Membership of the African Medicines Agency (**AMA**).

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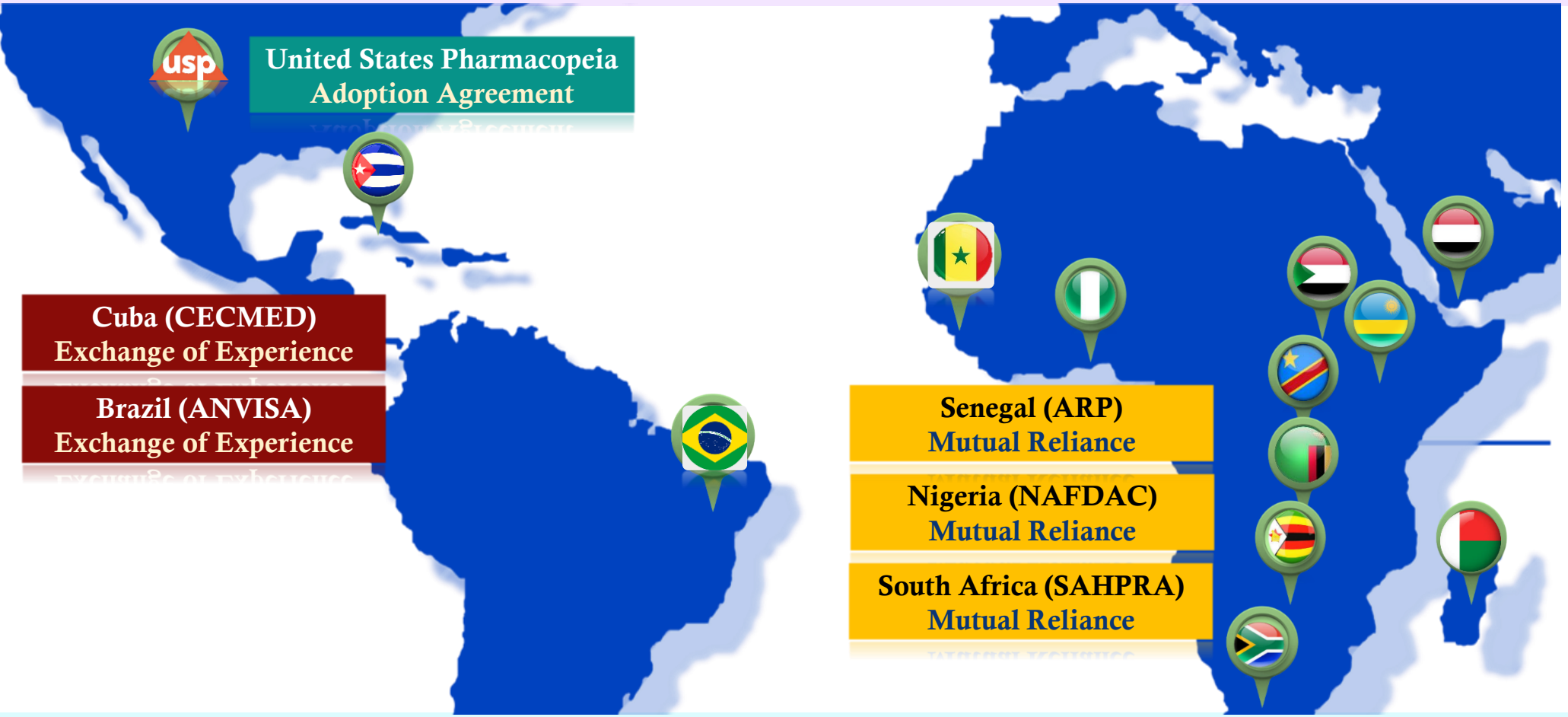
EDA's International Harmonization Efforts

Bilateral Cooperation



- Yemen (Aden) Reliance on EDA, Egypt
- South Sudan Reliance on EDA, Egypt
- Rwanda (RFDA) Reliance on EDA, Egypt
- DRC (ACOREP) Reliance on EDA, Egypt
- Zambia (ZAMRA) Reliance on EDA, Egypt
- Zimbabwe (MCAZ) Reliance on EDA, Egypt
- Madagascar (MSANP) Reliance on EDA, Egypt

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Contribution to Harmonization Efforts in the Scope of Medical Devices

IMDRF

- Jan 24 — Regulated Product Submission (RPS) Working Group (WG)
- Jan 24 — Adverse Event Terminology (AET) WG
- Jun 24 — Clinical Evidence (CE) for IVDs WG

African Medical Devices Forum (AMDF)

- Feb 24 — Pre-Market Sub WG
- Feb 24 — Placing in the Market Sub WG
- Feb 24 — Post-Market Sub WG

Global Harmonization Working Party

GHWP Towards Medical Device Harmonization

- Aug 24 — WG2 Pre-Market: IVDD
- Aug 24 — WG7 Quality Management System

EDA's IMDRF Activities Updates

1- Providing Experts for Drafting and Revising IMDRF Technical Documents

2- Implementation of the IMDRF Technical Documents in a Step-Wise Priority-Based Approach

3- Providing Meaningful Inputs to the Developmental Work of the IMDRF through Regular Surveys

4- Sharing in the Public Consultation Calls of IMDRF Technical Documents & Engaging Stakeholders

EDA's IMDRF Activities Updates

IMDRF Documents Implementation Progress

Implementation Level	June 2024 (n=31)	June 2025 (n=34)
Implemented (IM)	2	7
Partially Implemented (PI)	9	9
Not Implemented (NI)	10	12
Not Applicable (NA)	10	6

With the issuance of EDA New Guideline for Preclinical testing and Clinical Investigation for Medical devices, and with more internal alignment between the relevant departments,

- **5 previously NI documents were considered (2 NI to IMP, 3 NI to PI).**
- **3 previously PI documents are now fully implemented.**
- **3 New Guidelines not yet implemented (NI).**
- **4 Guidelines were re-considered as applicable (NI).**

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EDA's IMDRF Activities Updates

Providing Inputs to IMDRF Developmental Work & Sharing in Public Consultation Calls

- **Foundational Documents Review**
- **2025 Future Trainings Survey**
- **Strategic Plan 2026-2030 Survey**
- **Regulatory Question Box**
- **Reliance Dataset Review**

- **Public Consultation: IMDRF/SaMD WG/N81 DRAFT: 2024 Medical Device Software: Considerations for Device and Risk Characterization**
- **Public Consultation: IMDRF/GRRP WG/N89 DRAFT:2025 – Playbook for Medical Device Regulatory Reliance Programs**

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IMDRF International Medical Device Regulators Forum

Thank you/Questions

miriam.boles@edaegypt.gov.eg
sondos.moshtohry@edaegypt.gov.eg

IMDRF International Medical Device Regulators Forum

Dirección Nacional de Vigilancia Sanitaria – DINAVISA

DINAVISA

Regulatory Updates – IMDRF Affiliate Member

Q.F. Alison Iglesias
Medical and Dental Devices Directorate – DINAVISA.
Sapporo, September 2025

DINAVISA

The National Directorate of Health Surveillance (DINAVISA) is an entity with legal status under public law, with administrative autonomy, self-governance, and its own assets, as established by Law No. 6788 of August 23, 2021.

The authority responsible for developing appropriate strategies, regulating, controlling, and inspecting health products such as medicines for human use, drugs, chemicals, reagents, medical devices, and any other product used and applied in human medicine, as well as products considered cosmetics, perfumes, household and related products, food, and those products whose regulation and control are assigned to it by law, and may sanction any violations detected.

Regulation of Medical Devices - DINAVISA

Medical Devices it has an **MD INSPECTION DIRECTION**, with two departments:

- Inspection of medical devices,
- Inspection of IVD.

Two Directorates operate with the General Direction of Evaluation of Register:

- **Medical and dental device registration directorate**
- **Directorate of products for IVD**

In addition to other areas with other functions such as **Technovigilance**, etc.

Medical and dental device registration directorate:
1-Department of Dental Devices
2-Low Risk Medical Devices Department
3-Department of Moderate and High Risk Medical Devices

Directorate of products for IVD:
1-In Vitro Product Registration Department
2-Department of Validation of the performance characteristics of the product

Updates to the Medical Device Regulation - DINAVISA

❑ **September 2024 in Seattle, Washington:**
DINAVISA was accepted as an Affiliate Member of the IMDRF.

❑ **January 2024:**
A simplified procedure was established for in vitro diagnostic devices authorized and marketed in countries regulated by PAHO/WHO Reference Regulatory Authorities, the Regulatory Authorities of IMDRF member countries, and Regulatory Authorities with which bilateral agreements exist. This simplified process, under these conditions, applies to all classes of in vitro diagnostic devices. Application approval takes 15 business days.

Updates to the Medical Device Regulation - DINAVISA

❑ September 2024

✓ A simplified process is in place for granting marketing authorizations for Class II, III, and IV medical devices (excluding IVDs) authorized by Strict Regulatory Authorities (ARES) and Reference Regulatory Authorities with the highest level of maturity according to the WHO. In the pre-marketing authorization evaluation process, a minimum number of the required documents are reviewed, as long as the conditions do not differ from those authorized by the aforementioned Regulatory Authorities. These documents are: Letter of Representation, Certificate of Free Sale or Sanitary Registration of the product, Label/Sticker/IFU. The simplified process significantly reduces the time involved in the marketing authorization process for medical devices.

✓ Class I medical devices are issued by Mandatory Health Notification, which is an automatic process and by sworn declaration of the applicant.

Regulatory Convergence:

DINAVISA constantly reviews its standards and other international standards with the goal of adopting them and thereby harmonizing regulatory requirements and approaches across different countries and regions.

This represents an important form of regulatory cooperation that enables enhanced cooperation and collaboration among regulatory authorities.

Regulatory Confidence:

DINAVISA continues to work on the COLLABORATIVE REGULATORY APPROACH, implementing simplified and agile processes by relying on regulatory decisions from other reference authorities to accelerate the marketing authorization of medical devices, improving efficiency and access to medical devices without compromising the rigor of the regulatory process. This also allows it to concentrate its resources on specific activities to strengthen public health systems.

Implementation of IMDRF documents:

As a member of MERCOSUR, DINAVISA actively participates in the technical meetings of the Medical Products Subcommittee (SCOPROME), where MERCOSUR Resolutions are updated and new Resolutions are developed that adopt the concepts and criteria established in the IMDRF working documents.

Implementation of IMDRF documents:

Some of these Resolutions approved and published by MERCOSUR are:

- ***GMC Resolution No. 25/2021 "MERCOSUR TECHNICAL REGULATION FOR THE REGISTRATION OF MEDICAL PRODUCTS (REPEAL OF GMC RESOLUTION No. 40/00)"***

In the development of the aforementioned Resolution, IMDRF documents were used as a reference. Some of these are:

- ✓ IMDRF/SaMD WG/N10FINAL:2013 Title: Software as a Medical Device (SaMD): Key Definitions.
- ✓ IMDRF/SaMD WG/N12FINAL:2014 Title: "Software as a Medical Device": Possible Framework for Risk Categorization and Corresponding Considerations.
- ✓ IMDRF/RPS WG/N19 FINAL:2016 Title: Common Data Elements for Medical Device Identification.

Implementation of IMDRF documents:

Some of these Resolutions approved and published by MERCOSUR are:

- ***GMC Resolution No. 07/24 "MERCOSUR TECHNICAL REGULATION ESSENTIAL REQUIREMENTS FOR SAFETY AND PERFORMANCE OF MEDICAL PRODUCTS AND MEDICAL PRODUCTS FOR IN VITRO DIAGNOSTICS (REPEAL OF GMC RESOLUTION No. 72/98)" which has as Reference the document:***

✓ Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices (IMDRF/GRRP WG/N47FINAL:2018)

Implementation of IMDRF documents:

Draft regulations under development within the scope of MERCOSUR:

- ***Customized Medical Devices.***

This project in development has the following documents as reference:

- ✓ IMDRF/PMD WG/N49 FINAL:2018). Title: Definitions for Personalized Medical Devices
- ✓ (IMDRF/PMD WG/N74 FINAL: 2023). Tittle: Personalized Medical Devices – Production Verification and Validation.

Implementation of IMDRF documents:

Draft regulations under development at DINAVISA, which aims to adopt the concepts and criteria of IMDRF documents:

- Unique Device Identification (UDI)

Benefits of participating as an IMDRF Affiliate Member:

- Regulatory Convergence
- Strengthening the regulatory system
- Facilitation of information exchange between regulatory authorities
- Access to high-level training
- Participation in IMDRF working groups
- Regional Positioning
- Promotion of innovation and patient access to safe and effective devices

Challenges encountered:

- Language
- Active participation in working groups
- Constant technical development

IMDRF International Medical Device Regulators Forum

Thank you

DIRECCION NACIONAL DE VIGILANCIA SANITARIA PARAGUAY

PARAGUÁI TETÃYGUÁRA REKORESÃIRÃ ÑANGAREKOHA MOAKÃHA

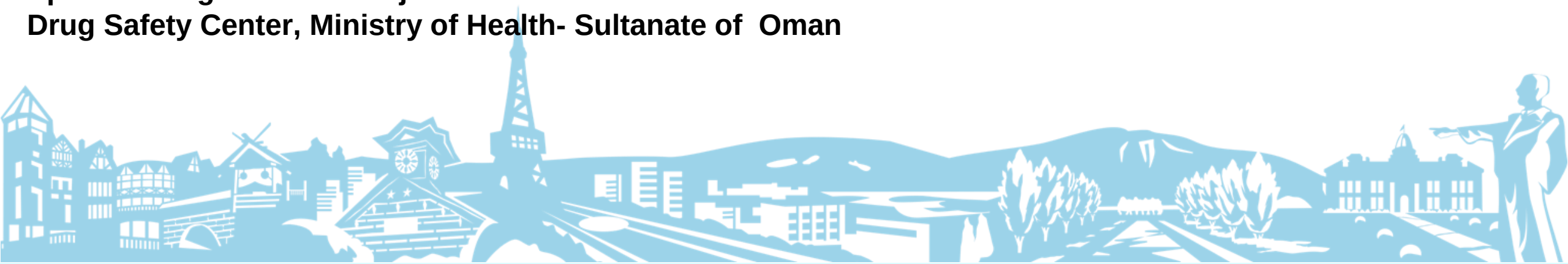
secretariageneral@dinavisa.gov.py

dispositivos.medicos@dinavisa.gov.py

IMDRF International Medical Device Regulators Forum

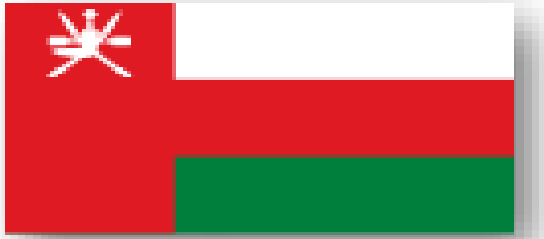
Medical Device regulation updates in Oman

Speaker: Eng. Faiza Al zadjali
Drug Safety Center, Ministry of Health- Sultanate of Oman



IMDRF International Medical Device Regulators Forum

Sultanate of Oman



- Sultanate of Oman country located on the southeastern coast of the Arabian Peninsula.
- Oman has developed a comprehensive and robust healthcare system and aims for large scale strategic development in the healthcare sector with Oman vision 2040.
- The **Ministry of Health (MOH) Drug Safety Center** is the primary body responsible for overseeing medical device regulations. And has been actively involved in following updates in international initiatives and forums of medical device regulation and convergence.

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Development of the regulatory framework for regulating medical Device

Pharmaceutical Affairs & Drug Control Regulations

2015

مرسوم سلطاني رقم 2015/35 بإصدار قانون تنظيم مزاولة مهنة الصيدلة وتنظيم المؤسسات الصيدلانية

Royal Decree No. 35/2015
The Law on Regulating the Profession of Pharmacology and Pharmaceutical Establishments

2019

بدء الادراج على الاجهزة واللوازم الطبية
Start o listing for medical devices

2020

قرار وزاري رقم 2020/113
بإصدار اللائحة التنفيذية لقانون تنظيم مزاولة مهنة الصيدلة و المؤسسات الصيدلانية شاملة فصل تنظيم المستلزمات الطبية

Ministerial Decree No. 113/2020
Issuing the Executive Regulation of the Law Governing the Practice of the Pharmacy Profession and Pharmacy Enterprises
Medical device Bylaws establishments

2021

بدء الافراج على الاجهزة واللوازم الطبية
Start of Import control for medical devices

2022

البدء بالتقييم الفني للاجهزة الطبية
Starting assessment of medical devices

2023

بدء اعمال اللجنة الفنية لتسجيل الاجهزة والمستلزمات الطبية
Starting Medical device registration committee

2024

تفعيل بعض الخدمات الالكترونية
Activate some Electronic service

2025

إصدار تعميم لبدء تسجيل الأجهزة عالية الخطورة
Issuing the Registration Circular for High risk MD

تنظيم إجراءات الموافقة على أنشطة بيع الأجهزة الطبية للمنشآت المحليةRegulation of approval procedures for medical device sale activities for local establishments

Medical Device dept Organization Structure

IMDRF International Medical Device Regulators Forum

Responsibilities of Medical Device Control department

Registration Sections

Responsibilities:

1- Listing Medical Device Establishment. Started
2- Listing Medical Device/IVD Manufacturers & Products. started
3- Registration of Medical device establishment. Started for High risk (Class D)
4- Registration of Medical device/IVD Manufacturers & products. Started for High risk (Class D)
6- Medical Device Manufacturer Audits. (started and ongoing)

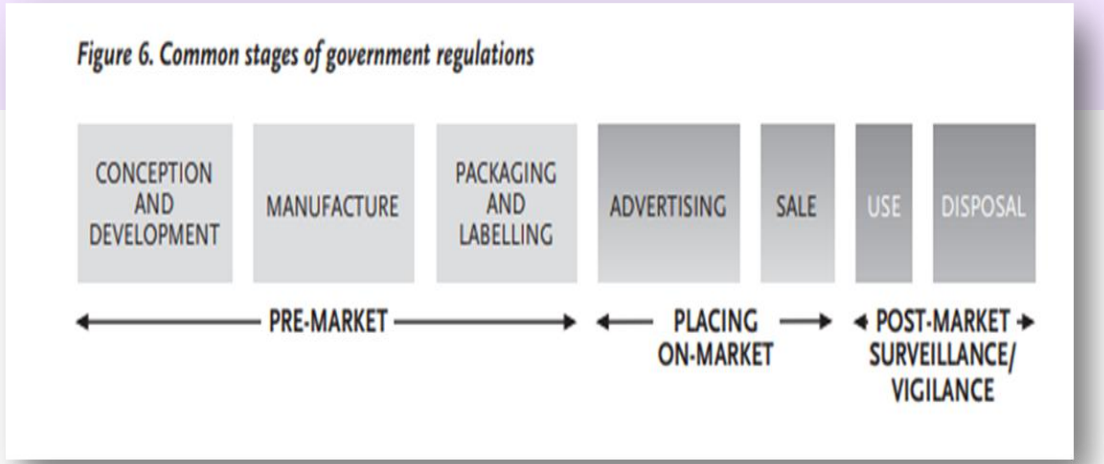
Vigilance Section

Responsibilities:

1. Building a database including all reports related to the Post Market Surveillance. Started
2. Circulation of Medical Device Safety alert. ongoing
3. Evaluation and investigation of adverse, incident events and complaints received. started
4. Activating focal points in different healthcare institutions in Sultanate of Oman. started
5. Exchanging information related to medical device issues with relevant authorities in other countries.

Medical Device regulatory system

WHO Global Benchmarking Tool plus Medical Devices (GBT + Medical devices) for evaluation of National Regulatory system of medical products




Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical Affairs and Drug Control
Muscat

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة والرقابة الدوائية
مسقط

Circular No. 182 / 2021

06 -03-1443 H
13 -10-2021

To All Medical Device Establishments

After Compliments,

Sub: Classification of Medical Devices

As part of the Ministry of Health's endeavor to start registering medical devices and supplies in accordance with the law regulating the practice of the profession of pharmacy and pharmaceutical institutions issued vide Royal Decree No. 35/2015 and the executive regulations issued for the Law as per Ministerial Decision No. 113/2020, this is to inform all concerned that we have classified the medical devices into different category as shown in the table below:

Severity	Class	Risk Level
Low	Class A	Class 1 Devices General IVD (other)/ Exempt IVD
Low- Moderate	Class B	All Class II/ Class IIa Self-test IVD
Moderate-High	Class C	Class IIb/ Class III Annex II List B (IVD)
High	Class D	All other Class III/ Class IV/ AIMD Annex II List A (IVD)

For any queries, please contact the following email: med-device@moh.gov.om

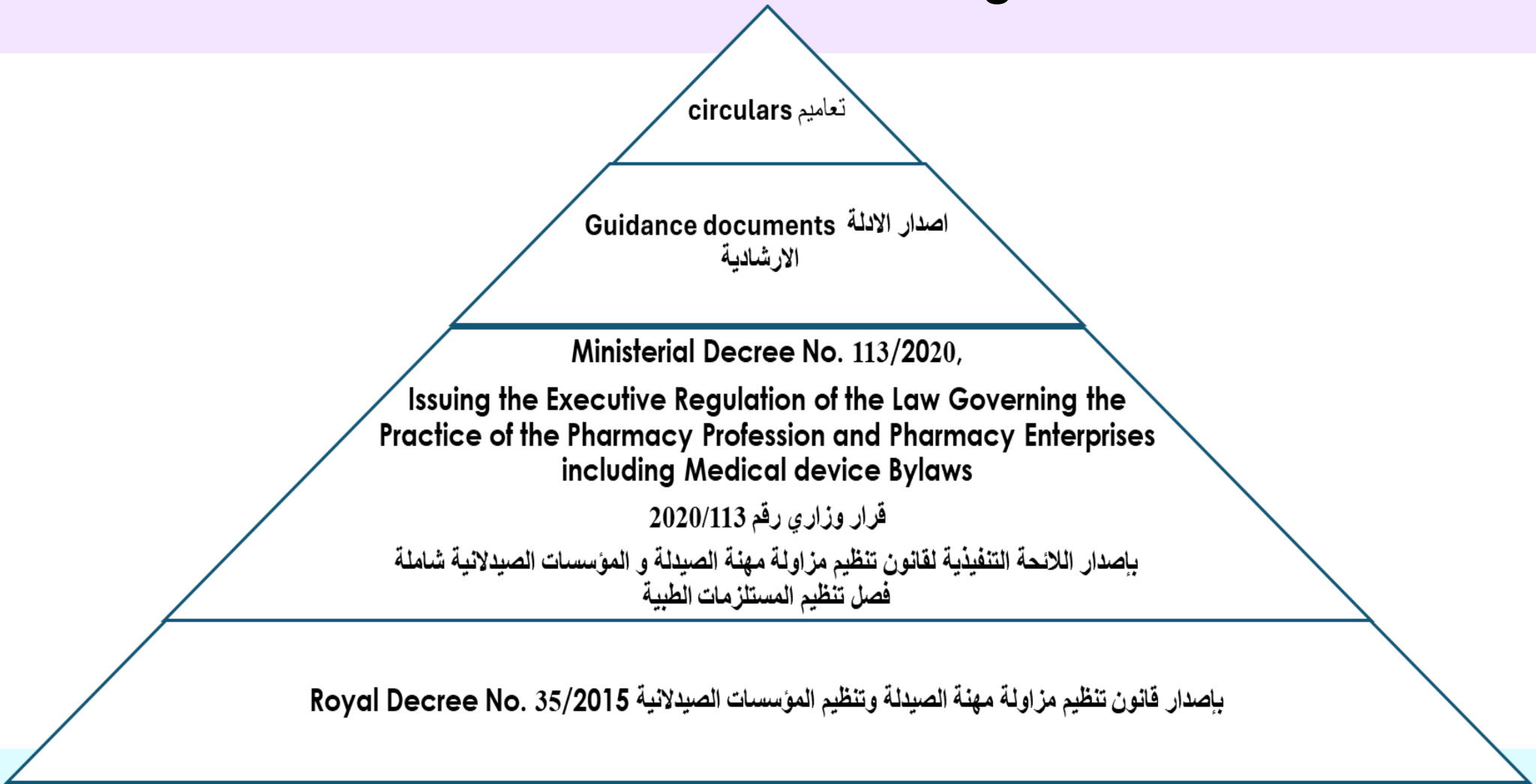
Dr. Mohammed Hamdan Al Rubaie
Director General

PADC

Reliance & recognition

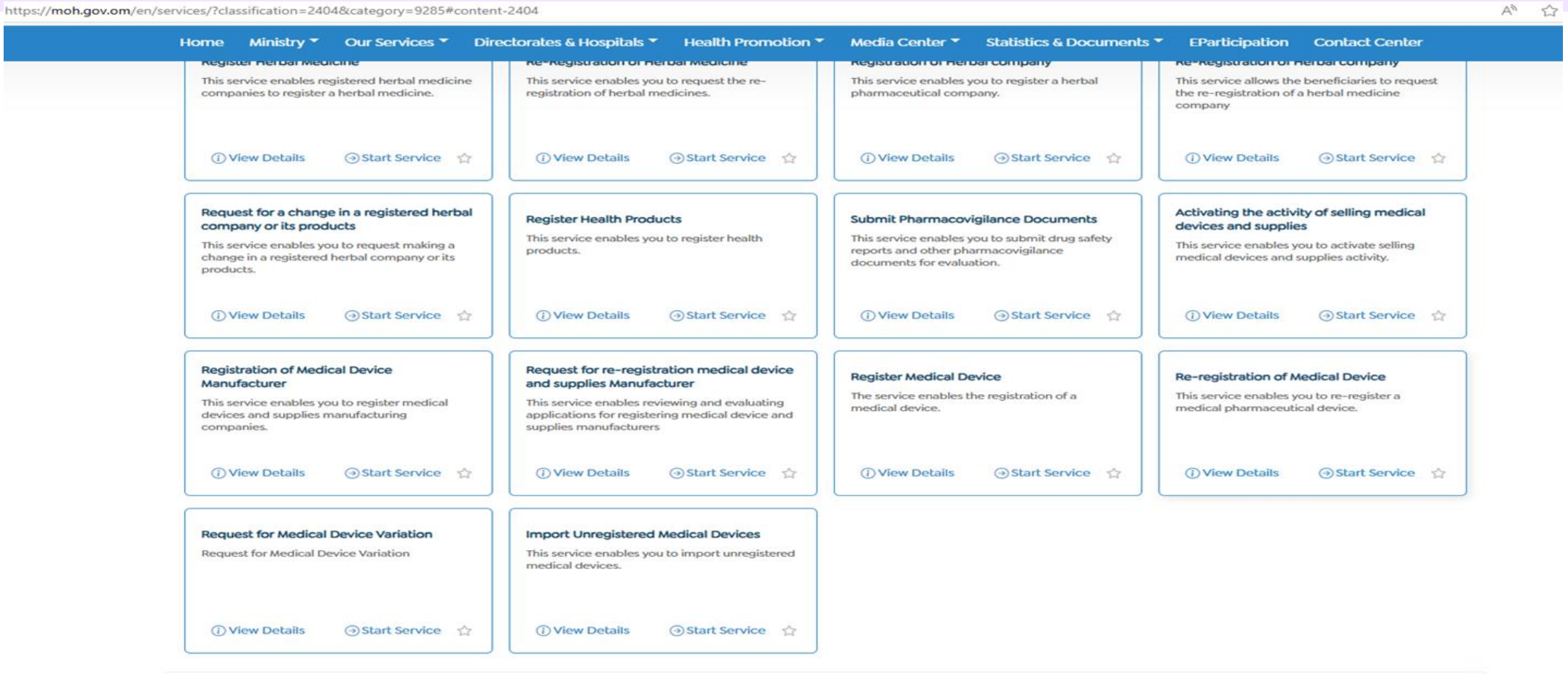
Oman MD regulation has built its system based on WHO recommendations and by adopting its framework , Medical device definitions , Classification (A, B, C and D). And recently in engaging in WHO Global Benchmarking Tool (GBT+MD) self assessment. Also Oman has adopted the existing guidance documents from IMDRF. In addition a Reliance agreement is in the pipeline. Actively participated in activities towards building a convergent medical device regulatory system

Basis of Medical Device Regulation



IMDRF International Medical Device Regulators Forum

Update Medical device Services launched Online through MOH portal



Medical device Online Services through MOH portal

1. Local establishment approval process

Activating the activity of selling medical devices and supplies

This service enables you to activate selling medical devices and supplies activity.

View Details Start Service

Pharmaceutical Facility License & Medical Device Establishments Approval

This service enables you to get a license to open a pharmaceutical facility, including: a public pharmacy, internal pharmacy, drug warehouse, a scientific office, pharmaceutical consulting office, drug analysis laboratories,

View Details Start Service

2. Manufacturer and Medical device Registration process

Registration of Medical Device Manufacturer

This service enables you to register medical devices and supplies manufacturing companies.

View Details Start Service

Register Medical Device

The service enables the registration of a medical device.

View Details Start Service

IMDRF International Medical Device Regulators Forum

Circular No. 182/2021

Risk Classification of Medical Device

Implemented

Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical Affairs and Drug Control
Muscat

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة والرقابة الدوائية
مسقط

Circular No. 182 / 2021

06 -03-1443 H
13 -10-2021

الأفاضل/ مالكي/ مديري الشركات والمؤسسات العاملة في مجال الأجهزة والمستلزمات الطبية

To All Medical Device Establishments

After Compliments,

تحية طيبة وبعد ،،،

Sub: Classification of Medical Devices

الموضوع: تصنيفات الأجهزة الطبية.

As part of the Ministry of Health's endeavor to start registering medical devices and supplies in accordance with the law regulating the practice of the profession of pharmacy and pharmaceutical institutions issued vide Royal Decree No. 35/2015 and the executive regulations issued for the Law as per Ministerial Decision No. 113/2020, this is to inform all concerned that we have classified the medical devices into different category as shown in the table below:

في إطار سعي وزارة الصحة للبدء في تسجيل الأجهزة و المستلزمات الطبية وفقا لما جاء في قانون تنظيم مزاولة مهنة الصيدلة والمؤسسات الصيدلانية الصادر بالمرسوم السلطاني رقم 2015/35 و اللائحة التنفيذية الصادرة بالقرار الوزاري رقم 2020/113، نود الإفادة بأنه سيتم اعتماد تصنيفات الأجهزة الطبية حسب الموضح في الجدول الآتي:

Severity	Class	Risk Level
Low	Class A	Class 1 Devices
		General IVD (other)/ Exempt IVD
Low- Moderate	Class B	All Class II/ Class IIa
		Self-test IVD
Moderate-High	Class C	Class IIb/ Class III
		Annex II List B (IVD)
High	Class D	All other Class III/ Class IV/ AIMD
		Annex II List A (IVD)

في حال وجود أي استفسار ، يرجى التواصل على الايميل التالي:
For any queries, please contact the following email: **med-device@moh.gov.om**

Dr. Mohammed Hamdan Al Rubaie
Director General

PADC

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

IMDRF International Medical Device Regulators Forum

Circular No.161/2025

Commencement of Registration of High Risk Medical device & Supplies Manufacturers & their Products

Started receiving high risk files

Sultanate of Oman
Ministry of Health
Drug Safety Center
Muscat

سلطنة عمان
وزارة الصحة
مركز سلامة الدواء
مسقط

Circular No. 161 / 2025

06-1-1447 H
01-07-2025

الأفاضل/ مالكي/ مديري الشركات والمؤسسات العاملة في مجال الأجهزة والمستلزمات الطبية المحترمين

To All Medical Device Establishments

After Compliments,

تحية طيبة وبعد،

Sub: commencement of Registration of High risk Medical Devices and Supplies Manufacturers and their products.	الموضوع: البدء بتسجيل مصانع الأجهزة والمستلزمات الطبية ومنتجاتها عالية الخطورة
In reference to the Ministerial Decision No. 113/2020 and in accordance with its provisions to regulate the Medical Device and Supplies, would like to notify all medical device establishments to start the registration of Medical Devices and Supplies Manufacturers and their high risk products and Shipment release will not be allowed as of the date 01/07/2026.	استنادا الى القرار الوزاري رقم 2020/113 ووفقا لأحكامه لتنظيم قطاع الأجهزة و المستلزمات الطبية في السلطنة، نود التنويه انه على جميع موردي الأجهزة والمستلزمات الطبية ببدأ تسجيل مصانع الأجهزة والمستلزمات الطبية ومنتجاتها عالية الخطورة، ولن يسمح بالإفراج على الشحنات اعتبارا من تاريخ 01-07-2026
Accordingly, we request all Medical Device Establishments to do the needful for submitting the Technical Files for high risk products through MOH online portal at least two months prior to the arrival of the shipment. The Drug Safety Center is not responsible for any delay in custom clearance unless the registration process is completed.	وعليه نرجو من شركات الأجهزة والمستلزمات الطبية عمل اللازم حول تقديم الملفات الفنية للمنتجات عالية الخطورة عن طريق البوابة الصحية لوزارة الصحة قبل وصول الشحنة بشهرين. وأن مركز سلامة الدواء غير مسؤول عن أي تأخير في الأفراج على الشحنات ما لم يتم الانتهاء من عملية التسجيل.
We would also like to inform you that medical device registration service is active, therefore, those who wish to voluntary register are kindly requested to do so through the Ministry of Health's Portal.	كما نود الإفادة بأن خدمة تسجيل الأجهزة الطبية مفعلة، وعليه يُرجى من الراغبين في التسجيل الطوعي المبادرة بالتسجيل عن طريق البوابة الصحية لوزارة الصحة.
The registration requirements can be found at the following link: https://moh.gov.om/en/hospitals-directorates/directorates-and-centers-at-hq/drug-safety-center/	جميع اشتراطات التسجيل تجدونها على الموقع الالكتروني لوزارة الصحة على الرابط التالي: https://moh.gov.om/ar/المستشفيات-والمديريات/المديريات-والمراكز-بديوان-عام-الوزارة/مركز-سلامة-الدواء/
For any queries, please contact the following email: med-device@moh.gov.om	في حال وجود أي استفسار، يرجى التواصل على البريد التالي: med-device@moh.gov.om

Ph. Ibrahim Nasser Al Rashdi
Director General

DRUG SAFETY CENTER - SULTANATE OF OMAN - MINISTRY OF HEALTH

DSC مركز سلامة الدواء Drug Safety Center | ISO

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
@DSCPHO Email: dscpho@moh.gov.om

IMDRF International Medical Device Regulators Forum

Circular No. 162/2025

Guidelines for the innovative medical device
Guidance for Electronic Instruction for Use

For industry and Public consultation

Sultanate of Oman
Ministry of Health
Drug Safety Center
Muscat

سلطنة عمان
وزارة الصحة
مركز سلامة الدواء
مسقط

Circular No. 162/ 2025

06 -1-1447 H
01 -07-2025

الأفاضل/ مالكي/ مديري الشركات والمؤسسات العاملة في مجال الأجهزة والمستلزمات الطبية المحترمين

To All Medical Device Establishments

After Compliments,

تحية طيبة وبعد ،،

Sub: Guidelines for the Innovative Medical Device Guidance and Guideline for Electronic Instructions for Use .	الموضوع: الأدلة الإرشادية الخاصة للأجهزة الطبية المبتكرة و دليل المستخدم الالكتروني للاجهزة والمستلزمات الطبية .
In reference to the Royal Decree No. 35/2015 which promulgated the law regulating the practice of the profession of pharmacy and pharmaceutical institutions and the Ministerial Decision No. 113/2020 issuing the executive regulations for the law regulating the practice of the profession of pharmacy and pharmaceutical institutions. Towards the enactment of the medical device and equipment regulation in Oman in accordance with the above mentioned Ministerial Decision, we have published draft guidelines about the Innovative Medical Device Guidance and Guideline for Electronic Instructions for Use . The draft guidelines is uploaded in the MOH website and it is available in the link: https://moh.gov.om/en/hospitals-directorates/directorates-and-centers-at-hq/drug-safety-center/#Section1 You can notify your comments, if any, on the draft guideline within a period of two months from the date of this Circular. Comments can be sent to this email: med-device@moh.gov.om Thank you for your understanding and cooperation.	في إطار سعي وزارة الصحة للبدء في تسجيل الأجهزة و المستلزمات الطبية وفقا لما جاء في قانون تنظيم مزاولة مهنة الصيدلة والمؤسسات الصيدلانية الصادر بالمرسوم السلطاني رقم 2015/35 و اللائحة التنفيذية الصادرة بالقرار الوزاري رقم 2020/113، نود الإفادة بأن مركز سلامة الدواء في طور إصدار الأدلة الإرشادية الخاصة للأجهزة الطبية المبتكرة و دليل المستخدم الالكتروني للاجهزة والمستلزمات الطبية. حيث يمكن الإطلاع على مسودات هذه الأدلة من خلال موقع وزارة الصحة الإلكتروني على الرابط أدناه: https://moh.gov.om/ar/-المستشفيات-والمديريات/المديريات-والمراكز-بديوان-عام-الوزارة/مركز-سلامة-الدواء/#Section1 ويمكن للشركات إبداء ملاحظاتها إن وجدت على الأدلة الإرشادية و ذلك خلال فترة شهرين من تاريخ هذا التعميم.حيث يمكن إرسال هذه الملاحظات على الإيميل: med-device@moh.gov.om شاكرين تفهمكم وتعاونكم.

Ph. Ibrahim Nasser Al Rashdi
Director General

DSC مركز سلامة الدواء Drug Safety Center

ISO

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P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
@DSCPHO Email: dscpho@moh.gov.om

IMDRF International Medical Device Regulators Forum

Circular No. 173/2025

Regulation of approval procedures for medical device sale activities for local establishments

Ongoing inspection and compliance for local MD establishment

Sultanate of Oman
Ministry of Health
Drug Safety Center
Muscat

سلطنة عمان
وزارة الصحة
مركز سلامة الدواء
مسقط

Circular No. 173/2025

26-1-1447 H
21-07-2025

الأفاضل/ مالكي/ مديري الشركات والمؤسسات العاملة في مجال الأجهزة والمستلزمات الطبية المحترمين

To All Medical Device Establishments

After Compliments,

تحية طيبة وبعد،،

Sub: Regulation of approval procedures for medical devices sale activities for local establishments.	الموضوع: تنظيم إجراءات الموافقة على أنشطة بيع الأجهزة والمستلزمات الطبية للمنشآت المحلية
In line with the Drug Safety Center's commitment to regulate the procedures for practicing the wholesale and retail sales activities of medical devices and supplies , and in line with the provisions of Ministerial Decision No. 113/2020, and based on the recent applications submitted through the MOH Portal, we would like to inform you of the following: • All approvals for new license applications related to the above-mentioned activities will be suspended. Approvals will be limited to commercial registrations that are 100% owned by Omani nationals. • All establishments that have previously obtained approval to practice the activity and wish to import medical devices must regularize their status in accordance with the Commercial Agencies Law, as it is one of the requirements for registering medical device and supply companies. • Companies that have been practicing the activity previously without adding it in their commercial registration are required apply for the activity approval with the relevant evidence before 01-09-2025. Accordingly, all concerned parties are required to comply with the above, in alignment with the Center's requirements, to ensure the continued practice of such activities in accordance with the applicable regulations. To access the DSC services on Ministry of Health website: https://moh.gov.om/en/hospitals-directorates/directorates-and-centers-at-hq/drug-safety-center/ For any queries, please contact the following email: Med-device@moh.gov.om	في إطار حرص مركز سلامة الدواء على تنظيم إجراءات مزاولة نشاط بيع الأجهزة والمستلزمات الطبية بالجملة والتجزئة، والتزاما بما جاء في القرار الوزاري رقم 2020/113 وما نص عليه، واستنادا إلى الطلبات المقدمة مؤخرا في البوابة الصحية، نود إحاطتكم بما يلي: • سيتم إيقاف منح الموافقات على جميع طلبات تراخيص الأنشطة الجديدة المشار إليها أعلاه، على أن تقتصر الموافقات على السجلات التجارية المملوكة بالكامل للعمانيين بنسبة 100%. • على جميع المنشآت الحاصلة مسبقاً على موافقة مزاولة النشاط والراغبة في استيراد الأجهزة والمستلزمات الطبية، توفيق أوضاعها بما يتناسب مع قانون الوكالات التجارية باعتباره أحد اشتراطات تسجيل شركات الأجهزة والمستلزمات الطبية. • يتوجب على الشركات التي تمارس النشاط مسبقاً دون إدراجه في السجل التجاري، التقدم بطلب الحصول على الموافقة اللازمة مع إرفاق ما يثبت ذلك قبل تاريخ 1 سبتمبر 2025. وعليه، نؤكد على جميع الجهات المعنية ضرورة الالتزام بما ورد أعلاه، بما يتوافق مع متطلبات المركز، لضمان استمرارية مزاولة النشاط وفقاً للأنظمة المعمول بها. للوصول الى خدمات المركز في موقع وزارة الصحة: https://moh.gov.om/ar/المستشفيات-والمديريات/المديريات-والمراكز-بديوان-عام-الوزارة/مركز-سلامة-الدواء/ في حال وجود أي استفسار، يرجى التواصل على الايميل التالي: Med-device@moh.gov.om

Ph. Ibrahim Nasser Al Rashdi
Director General

DSC مركز سلامة الدواء Drug Safety Center

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Thank you/Questions

Thank You

✉ **Email:** med-device@moh.gov.om

🏢 **Drug Safety Centre portal:** https://moh.gov.om/en/hospitals-directorates/directorates-and-centers-at-hq/drug-safety-center/

IMDRF International Medical Device Regulators Forum

Medical Device Authority
Ministry of Health Malaysia

AFFILIATE MEMBER UPDATES: MEDICAL DEVICE AUTHORITY, MALAYSIA

Ms. Aidahwaty binti Ariffin @ M. Olaybal
Senior Director
Pre-market Control Division

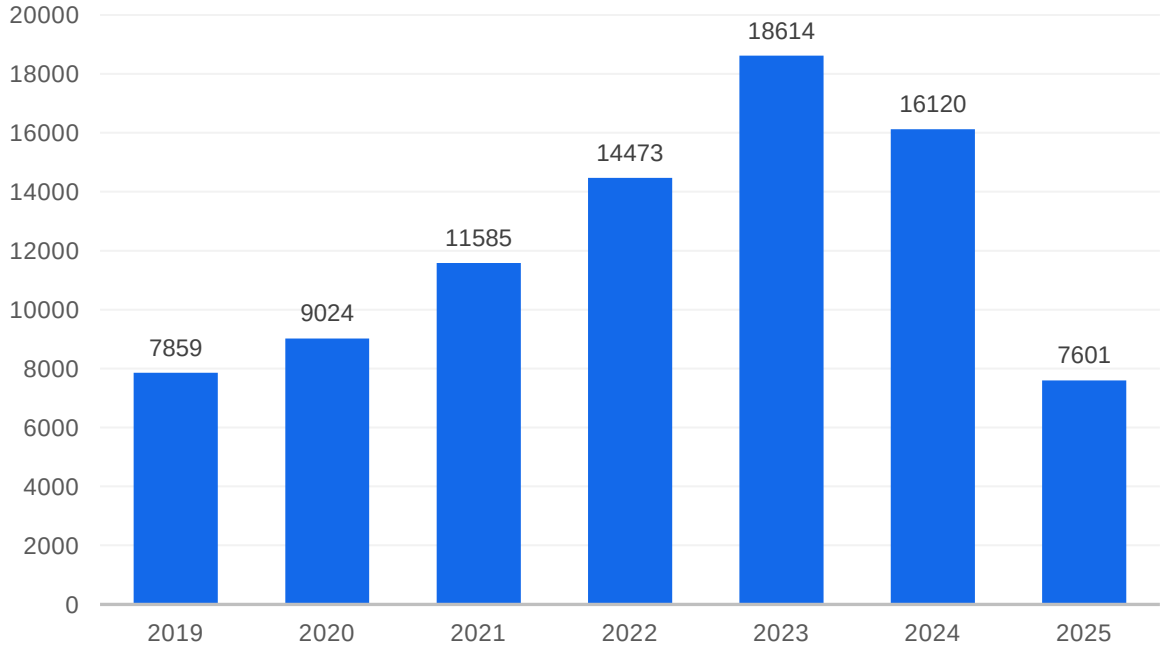
16 September 2025

Presentation Outline

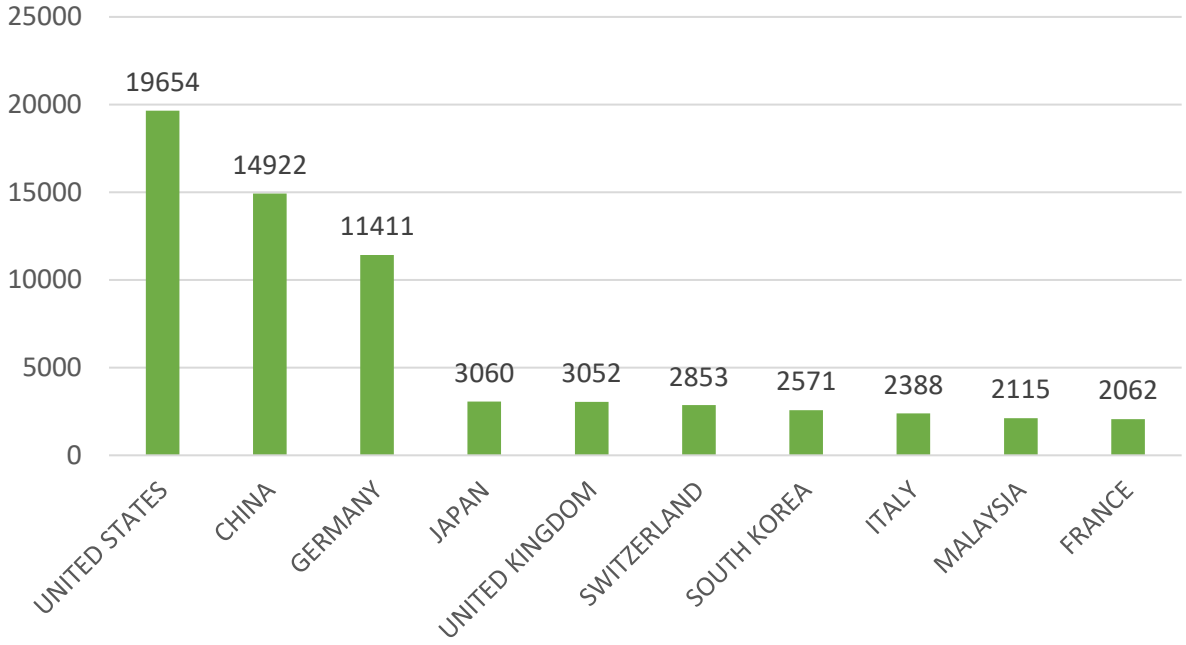
- Landscape Medical Device Registration in Malaysia
- Reliance Initiatives
- New Approach on Change Management

Landscape Medical Device Registration in Malaysia (2019 – 2025)

Total of Application Received by MDA

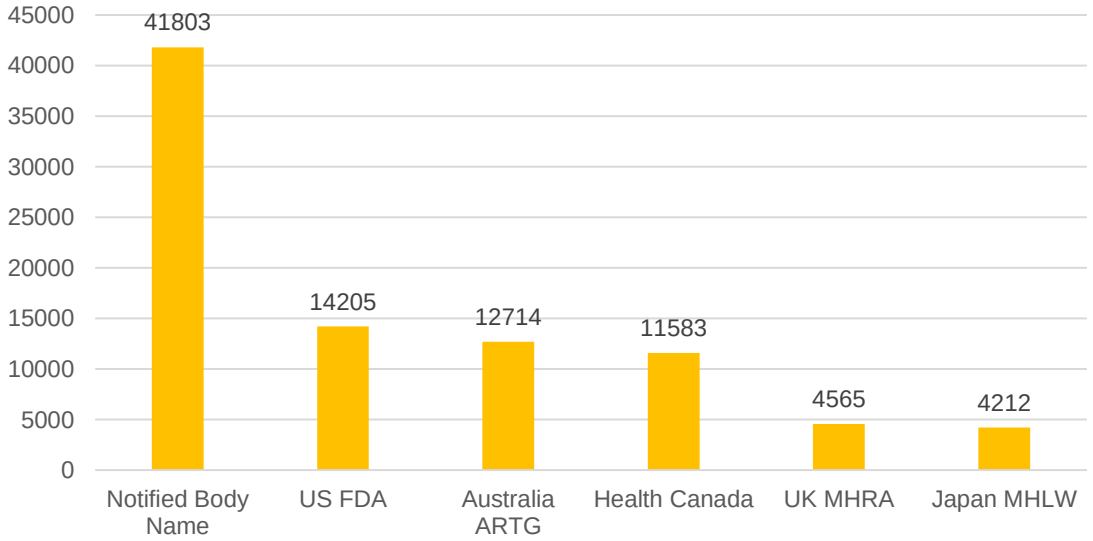


Total of Application Received By Country

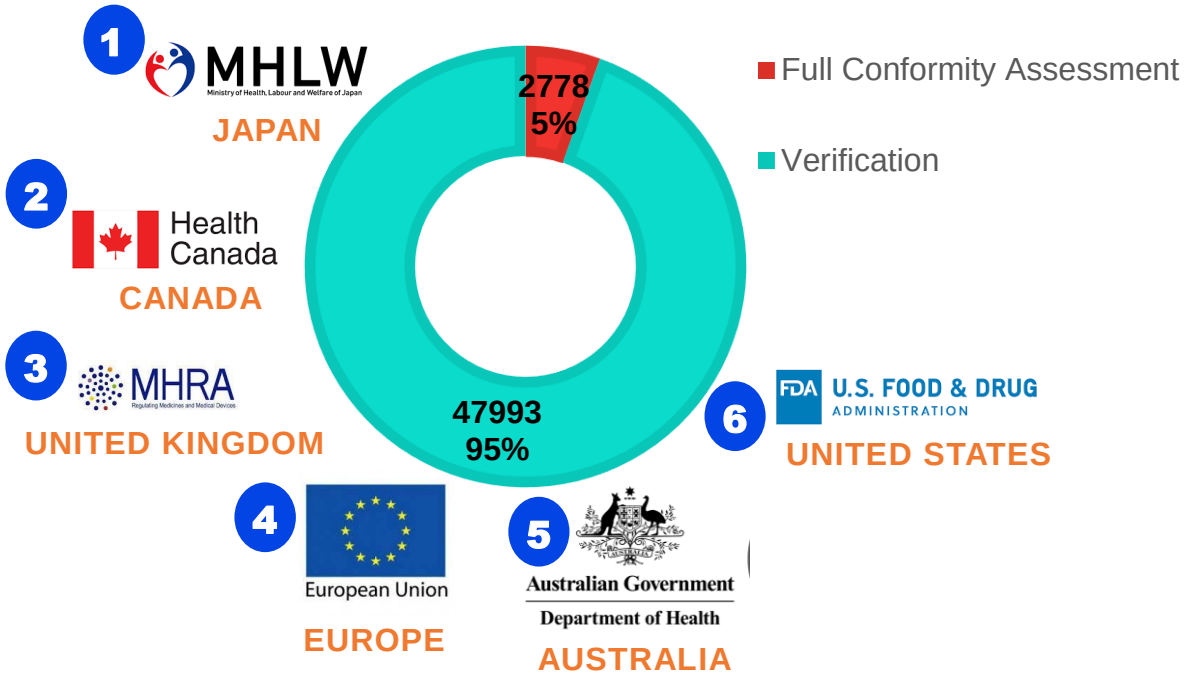


Landscape Medical Device Registration in Malaysia (cont'd)

Type of Approval/ Certification Received

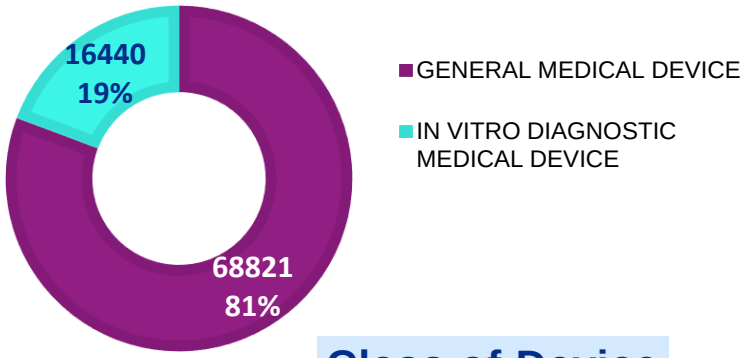


Verification vs Full Conformity Assessment

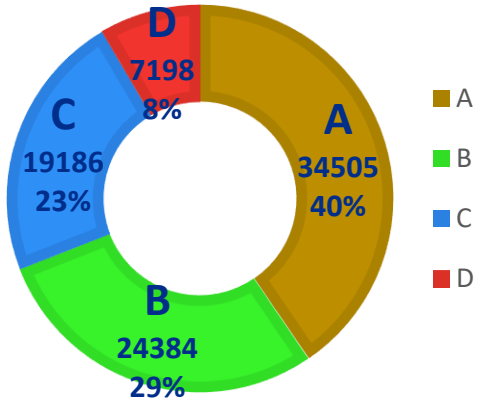


Landscape Medical Device Registration in Malaysia (cont'd)

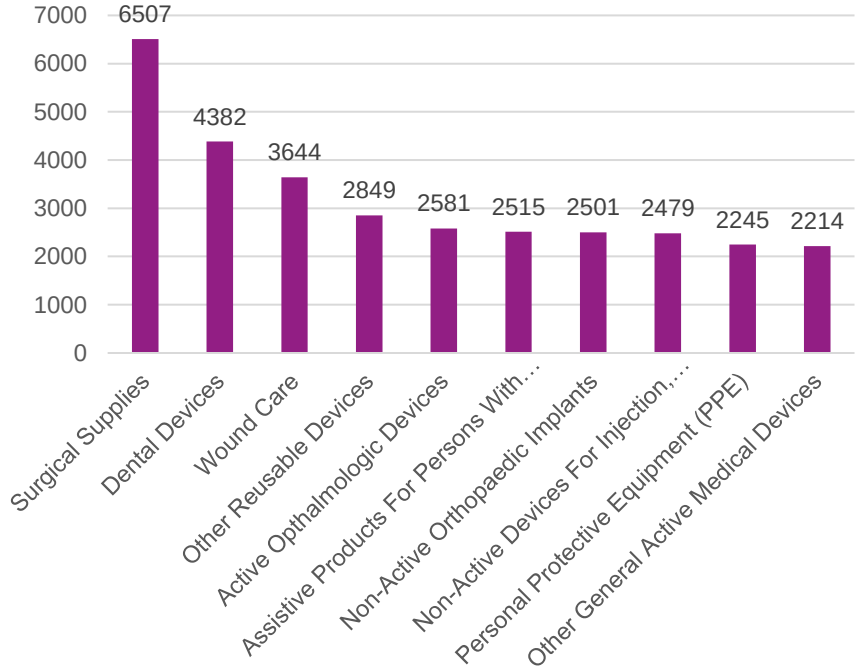
Medical Device Category



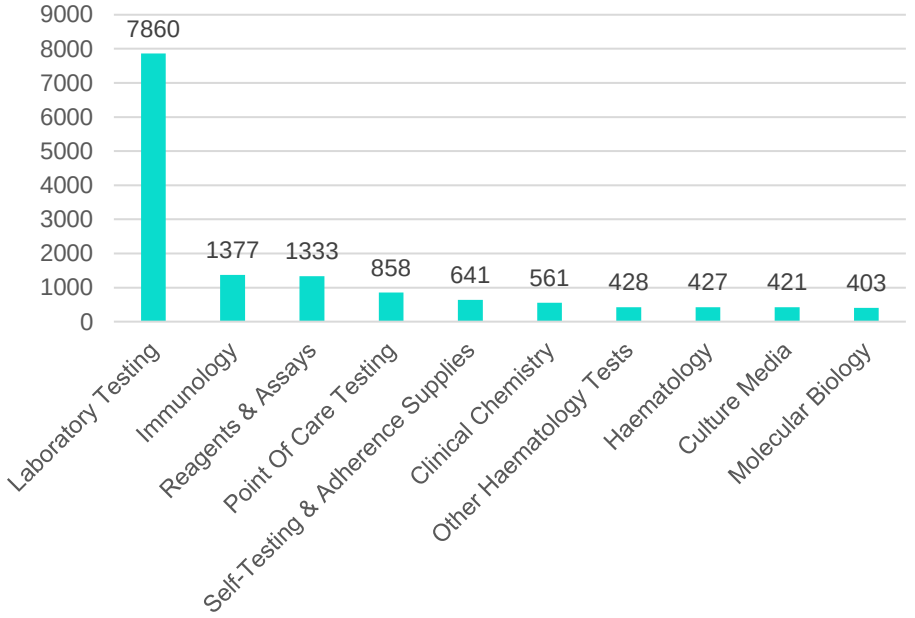
Class of Device



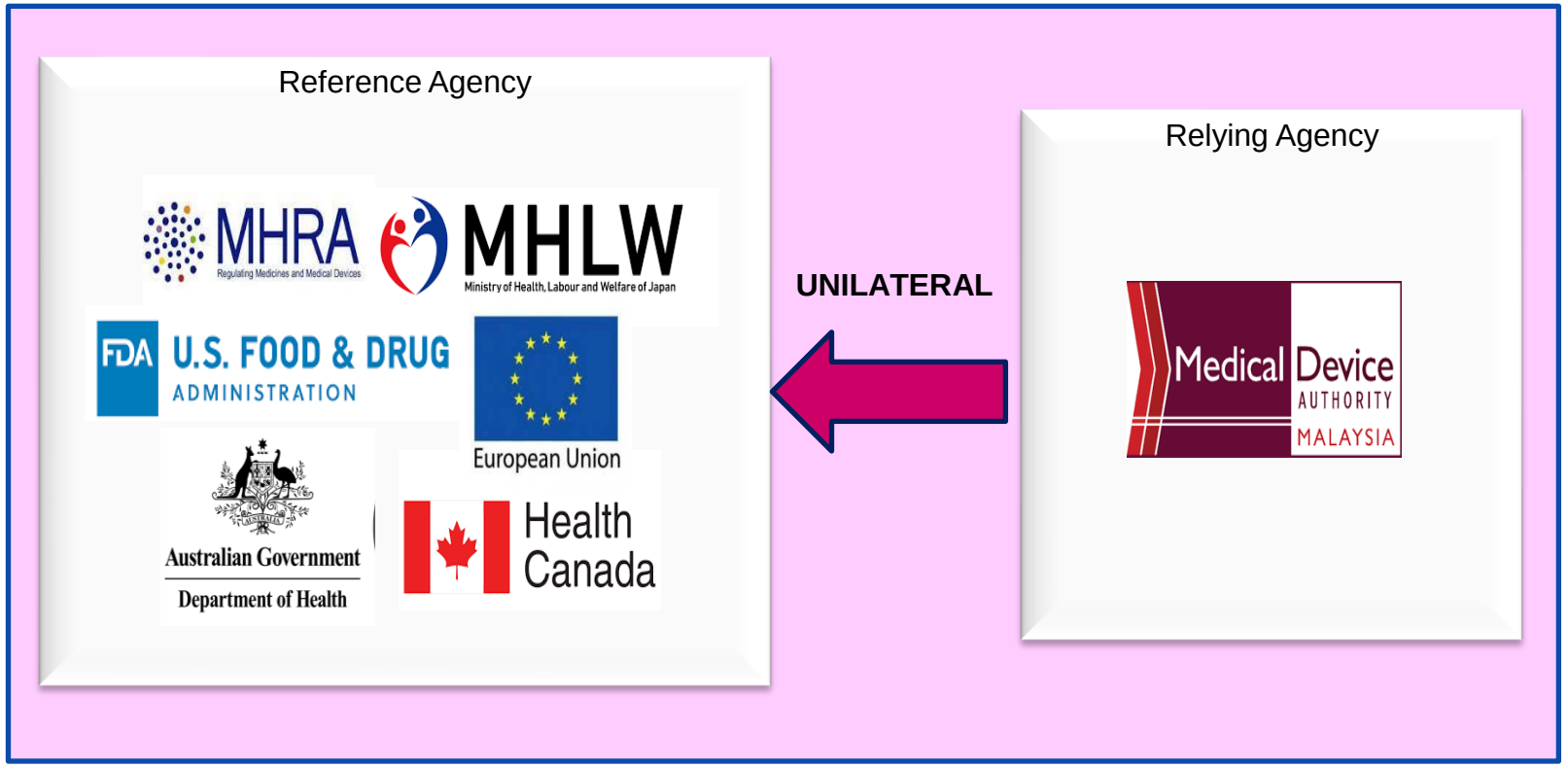
Type of General Medical Device



In Vitro Diagnostic Medical Device

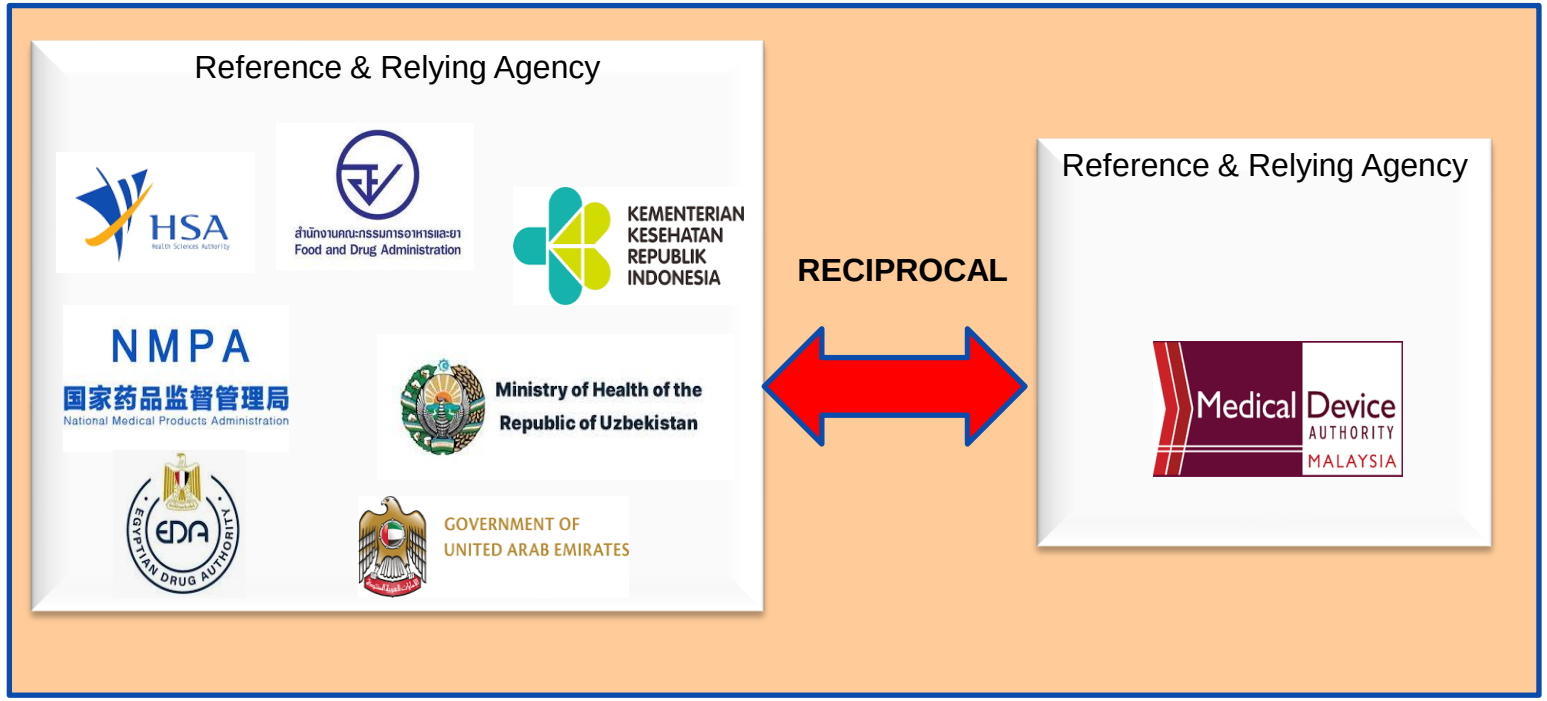


Reliance Initiatives (Current) : Unilateral



Reference:
Circular Letter of MDA No1 Year 2025 – Conformity Assessment Procedures for Medical Device Approved by Recognised Countries

Reliance Initiatives (Current) : Reciprocal



Reference:

1. *Malaysia–China Medical Device Regulatory Reliance Programme (Pilot Phase I)*
2. *Malaysia And Singapore Sign Memorandum Of Understanding And Launch Medical Device Regulatory Reliance Pilot To Fast Track Medical Device Market Access*

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Medical Device Regulatory Reliance Programme in Malaysia (MDSAP)

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Change Management (CM) - Malaysia

- A streamlined regulatory approach that enables faster implementation of changes to registered medical devices—especially pre-approved software updates for Software as a Medical Device (SaMD)—based on the manufacturer's proven quality management systems.
- This new framework allows manufacturers to make certain "pre-specified" changes to SaMD after registration without needing to submit a full change notification each time. Instead, they rely on their robust quality management practices—such as ISO 13485 and IEC 62304 compliance—to ensure safety and effectiveness throughout the product's lifecycle
- The framework draws upon the GHWP Guidance Document on Change Management and has been customized to align with Malaysia's regulatory requirements and implementation context.

Type of Changes

1. Change in Manufacturing Process, Facility, and/or QMS (including QC)
2. Change in Design for GMD and IVD
3. Change in Sterilization Facility and its Process
4. Changes to Software for Medical Device
5. Changes in materials for GMD
6. Changes in materials for IVD
7. Changes to Labelling
8. Changes to registered medical devices registration information
9. Others

Change Management (Improvement from current practice)

No	Area	Current	Future
1	Title	Change Notification	Change Management
2	Classification of Change Category	Three Category: Category 1 – New registration application Category 2 – Major Change Category 3 – Minor Change	Two Category: Significant Change – affect safety and/or performance of MD Non-Significant Change - not affect safety and/or performance of MD **Auto generated by the system based on the changes made to the related section in the form*
3	Reporting of Changes	All category of change shall be reported to MDA	Significant changes – Reported to MDA for review & approval before implementation of change Non-Significant Change – Not reported to MDA. Change to be recorded in QMS / Technical documentation of medical device Non-Significant Change (required notification) – Notification to MDA. Can be implemented immediately upon submission
4	MDA Approval	For all types of change	Only for Significant change
5	Form and Documents	Changes not reflected in the initial registration form Summary table of change - manually upload in the system Change Declaration of Safety and Performance - manually upload in the system	Changes updated in the initial medical device registration form Summary table of change – Info retrieved from the system Change Declaration of Safety and Performance - provided in the system
6	Bundling of Changes -Multiple device ID	Multiple submission id only limited to - Change in manufacturer name and address Change in manufacturing site name and address Change in sterilisation site name and address Change in QMS information	Additional Multiple submission id for: Change in brand / proprietary name Change in labelling- e.g.EU MDR symbol, AR info
7	FSCA Related Changes	Cannot identify FSCA related change application	Can Identify FSCA related change application in system

Positive Impact of the New Approach on CM

- **Reduce in regulatory cost**

MDA will implement new approach for Change Notification Framework that will reduce in the regulatory cost. Changes to registered medical device will be categorised as significant and non-significant change according to the impact on the safety and performance of the medical device. Most of the change notification Category 2 and Category 3 will be categorised under non-significant change and do not required submission to the MDA. This approached will be significantly reduced in the regulatory cost and the changes can be implemented immediately for market access.

- **Patients earlier access to new technologies and treatments**

Structured change management helps companies integrate new technologies and innovations into their product development and manufacturing processes more effectively, driving innovation and keeping them competitive

- **Eliminating or reducing differences between jurisdictions**

Encourage harmonization initiative between the regulatory authorities which in line with GHWP guidance

- **Enhanced Regulatory Compliance**

By managing changes systematically, companies can more easily adapt to new healthcare regulations and keep their products compliant with legal requirements, reducing the risk of non-compliance

- **Increased Establishment Operational Efficiency**

Streamlined processes and the adoption of new technologies like Industry 4.0 can automate tasks, improve workflow, and boost productivity, making operations more cost-effective

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Thank you/Questions

CONTACT US

Medical Device Authority (MDA)

www.mda.gov.my

+603 - 8230 0300

Contact information:

Ms. Aidahwaty M. Olaybal

aidahwaty@mda.gov.my

Ms. Norhafizah Mohd Salleh

norhafizah@mda.gov.my

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Questions?