



Global Harmonization Working Party

Towards Medical Device Harmonization

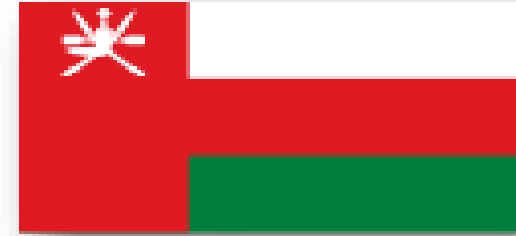
Medical Device regulation updates in Oman

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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.

Development of the regulatory framework for regulating medical Device



بدء الانراج على الأجهزة والترازم الطبية
Start of listing for medical devices

بدء الانراج على الأجهزة والترازم الطبية
Start of import control for medical devices

بدء أعمال اللجنة الفنية لتسجيل الأجهزة والمستلزمات الطبية
Starting Medical device registration committee

إصدار تعليم البدء لتسجيل الأجهزة عالية المخاطرة
Issuing the Registration Circular for High risk MD

2015

2019

2020

2021

2022

2023

2024

2025

مرسوم ملكي 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

قرار وزاري رقم 2020/113 بإصدار اللائحة التنفيذية لقانون تنظيم مزاولة مهنة الصيدلة والمؤسسات 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

البدء بالتقييم الفني للأجهزة الطبية
Starting assessment of medical devices

تفعيل بعض الخدمات الإلكترونية
Activate some Electronic service

تنظيم إجراءات المراقبة على أنشطة بيع الأجهزة
Regulation of approval procedures for medical device sale activities for local

Medical Device Regulation Drug Safety Center

وزارة الصحة
Ministry of Health



Establishment List

Listing of medical device establishments is now complete and started licensing process.

Mfr & Products

Manufacturers and products have been successfully listed



High-Risk Reg

Registration open for highest risk devices and IVD's

Mfr Audits

Audits of device manufacturers have started and continue.



Post Market Watch

Building a database for post-market reports and activated focal points.

Safety Alerts

Safety alerts Circulation and incident investigations





Global Harmonization Working Party

GHWP Towards Medical Device Harmonization

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

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

Update Medical device Services launched Online through MOH portal : [Drug Safety Center\(DSC\)](#)



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,

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2. Manufacturer and Medical device Registration process

Register Medical Device

The service enables the registration of a medical device.

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Registration of Medical Device Manufacturer

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

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مجلس الصحة
لدول مجلس التعاون
Gulf Health Council





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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/>