HSA Health Sciences Authority

IMDRF International Medical Device Regulators Forum

SFDA الهيئة العامة للغذاء والدواء Saudi Food & Drug Authority

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Regulatory Updates
(Saudi Food & Drug Authority)

Abdullah Alghuraibi

Executive Director of Medical Devices Evaluation

Saudi Food and Drug Authority

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SFDA 4th STRATEGIC PLAN (2023 - 2027)

VISION
To be a leading international science-based regulator to protect and Promote public health.

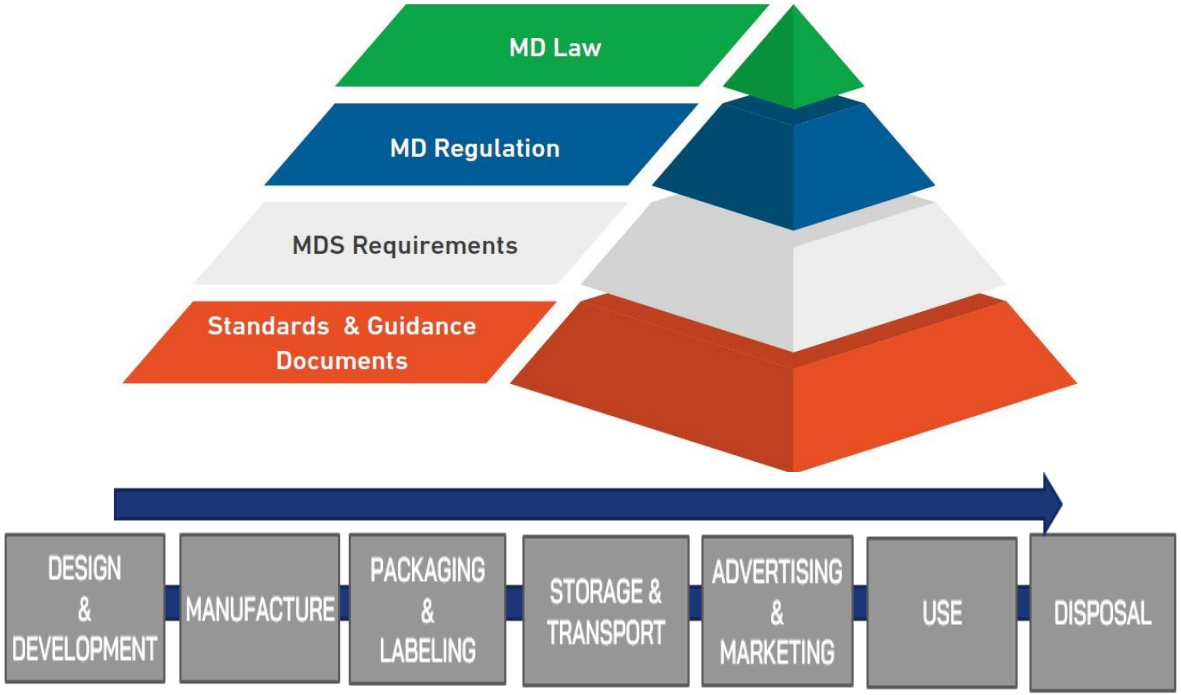
MISSION
Protecting the community through regulations and effective controls to ensure the safety of food, drugs, medical devices, cosmetics, pesticides and feed.

Themes → **Product Safety** | **Local and International Partnerships** | **Operational Excellence**

STRATEGIC OBJECTIVES

Beneficiaries	Developing the Regulatory System	Improving Communication and Awareness	Enhancing Products Availability	Enhancing International Leadership
Financial Sustainability	Diversification of Revenue Resources			
Internal Processes	Developing Regulations and controls of new technology and bio-tech products	Support Research and Innovation	Enable Investors	
SFDA Capabilities	Human capital Development	Increase The Use of Advanced Digital Technology		

SFDA Medical Devices Regulation Framework



- ✓ **Support innovation** and medical devices technology development.
- ✓ **Enhance the Kingdom's leading role** internationally in the medical devices field.
- ✓ **Protect the public health &** patient's safety in KSA.
- ✓ **Support investments** & encourages manufactures to launch branches in the Kingdom.
- ✓ **Effective economic impact** for the Saudi market.

New SFDA-MD Guidance

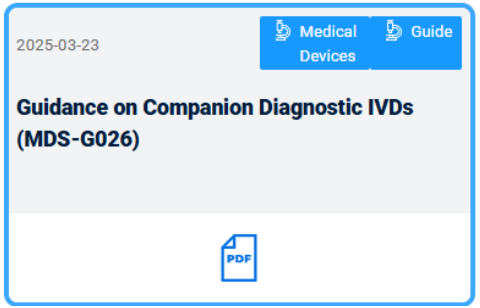
- To **guide MD manufacturers, authorized representatives, importers and distributors** that comply with requirements of ISO 13485:2016, Medical devices — Quality management systems — Requirements for regulatory purposes (ISO 13485) in light of regulatory documents issued by the SFDA medical devices sector (SFDA-MDS).

- It **provides an overview** of the major **categories** within digital health, **outlines** the **regulatory approach** for such technologies, and clarifies the distinction between what qualifies as a regulated medical device and what falls under general wellness products.

Updated SFDA-MD Guidance

- To **specify** the designation **criteria for Innovative** Medical Devices.
- **Outlines** the requirements for applying through the Innovative Medical Devices Pathway, and to **explain** the submission process.
- To **clarify** the manufacturing pathways for medical devices within the KSA (including the transfer and localization of technology) and the associated marketing authorization procedures, as well as **addressing** requirements for circulation, and import for manufacturing purposes, and obtaining a certificate of free sale for export.

Updated SFDA-MD Guidance



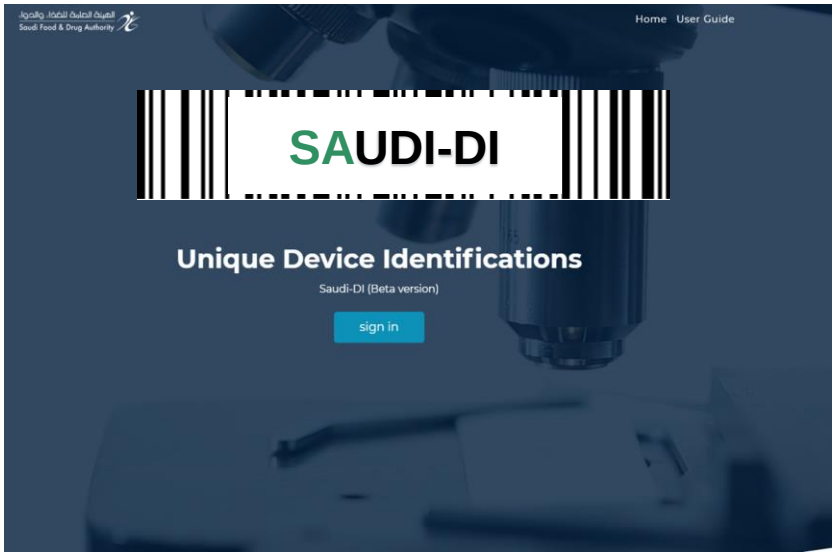
- To **specify** and clarify the **requirements** related to the **inspection and** audit of Quality Management System (**QMS**) conducted by the SFDA on MD manufacturers and establishments, as well as to specify and clarify the inspector's rights and duties.

- To **provide clarification** on Companion Diagnostic (CDx) IVDs, specifically the requirements for development, conducting clinical studies, and **obtaining** Medical Devices Marketing Authorization (MDMA).

SFDA MD-UDI Updates

2025

➢ UDI Compliance



MDS – REQ 7

Requirements for Unique Device Identification (UDI) for Medical Devices

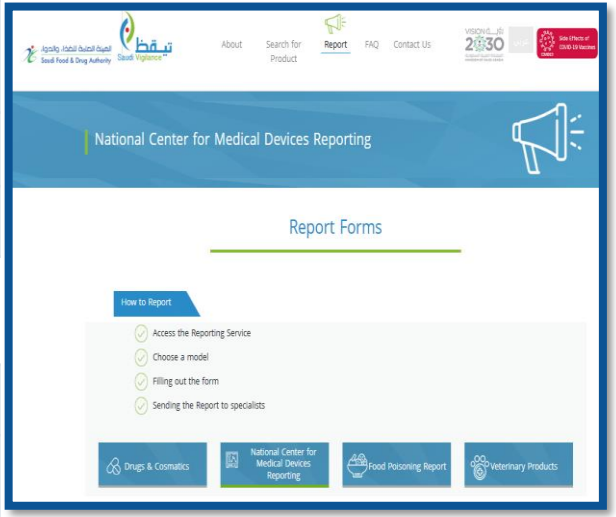
# of Devices	460745
# of Manufacturers	1782

Post-market Surveillance Updates

2025

Safety Alerts

Safety Alerts	478 safety alerts affected the Saudi market out of 2,698 globally detected	
Action Types	Correction 1,363	Removal 1,335
Medical Devices Affected	5,318,321	



Adverse Events & Complaints

Received AE & Complaints reports	183,644		
Type of Reports	Healthcare providers 57,696	Manufacturers & companies 125,662	Public 286

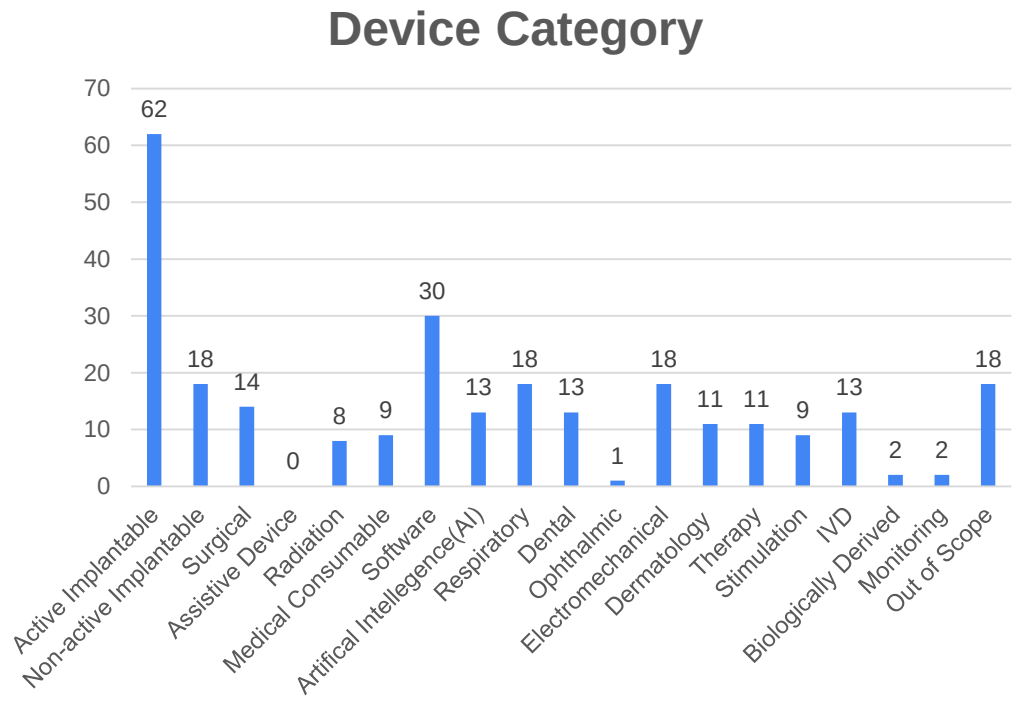
Officers of Healthcare providers:

1,554 Officers

Clinical Trials of Medical Devices Updates

During 2025, a total of 57 applications for medical device clinical trials were received & thoroughly evaluated

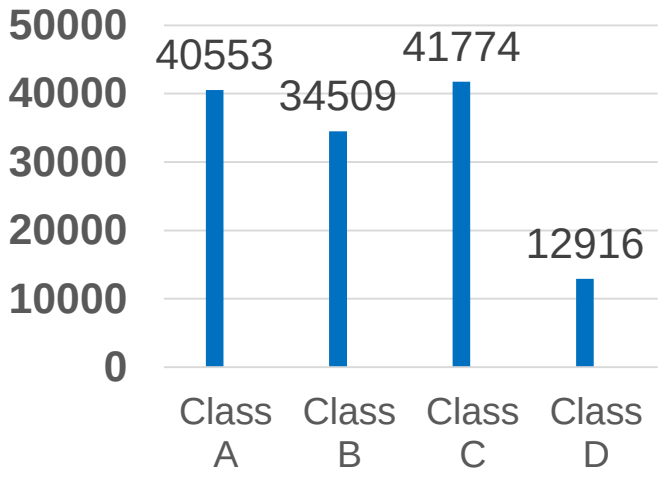
Total of 314 medical device clinical trial applications were submitted and reviewed, as shown in the table



Marketing Authorization Statistics MDMA Updates

Statistics in 2025	
# Request	**14227**
# Products	**129752**

Classification	# Products
A	**40553**
B	**34509**
C	**41774**
D	**12916**



Guidance Under Development

IN PROGRESS

- **Medical Device Cybersecurity Risks**
  Aim to regulate Manufacturers, Importers, & Healthcare Providers that develop software as MD.

- **Risk Communication for Medical Devices**
  All medical device/IVD manufacturers, healthcare providers, and relevant stakeholders involved in the distribution and use of medical devices/IVD's

- **Guidance on Criteria of Medical Devices Bundling**
  Aim to bundle/group more than one type of medical device, including in-vitro medical devices (IVDs), within a single MDMA application.

Thank You!

To access SFDA-MD Regulations and Requirements