IMDRF International Medical Device Regulators Forum

HSA Health Sciences Authority 25 YEARS AND BEYOND

30th IMDRF 2026

Day 2 IMDRF Stakeholder Forum | 15 September 2026

Regulatory Updates
(Saudi Food & Drug Authority)

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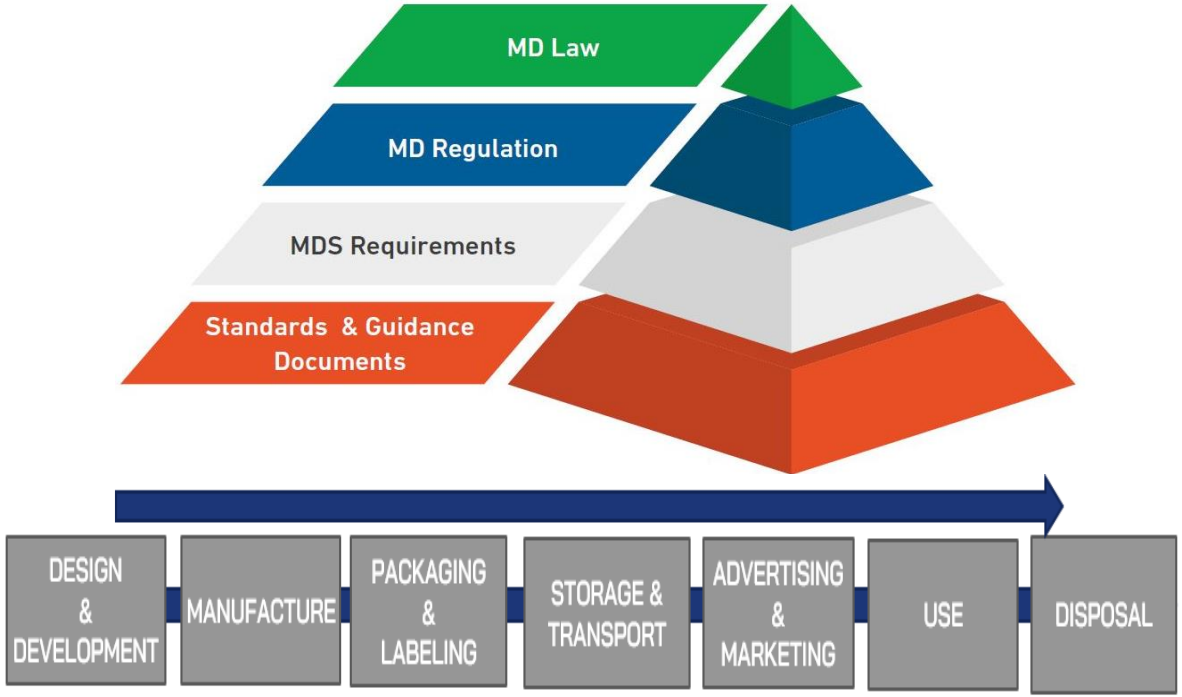
SFDA Medical Devices Regulation Framework



- ✓ **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 safetyin KSA.
- ✓ **Support investments** & encourages manufactures to launch branches in the Kingdom.
- ✓ **Effective economic impact** for the Saudi market.

Medical Device Marketing Authorization Requirements (MDMA)

- Device Description and Specification, Including Variants and Accessories
- Design and Manufacturing Information
- Benefit-Risk Analysis and Risk Management
- Post Market Surveillance Plan
- Information to be Supplied by the Manufacturer
- Essential Principles of Safety and Performance
- Product Verification and Validation
- Periodic Safety Update Report (PSUR) and Post-Market Surveillance Report

SFDA Regulatory Reliance Approach for Medical Devices

Applicable to:

- Manufacturers
- Authorized Representatives (ARs)

Purpose:

Obtain SFDA Medical Device Marketing Authorization (MDMA) through the Reliance Pathway.

Recognized Regulatory Authorities (RRAs):

Country / Jurisdiction	Regulatory Authority
Australia	Therapeutic Goods Administration (TGA)
Canada	Health Canada
European Union (EU)	National competent authorities – European Economic Area (EEA)
Japan	Pharmaceuticals and Medical Devices Agency (PMDA)
United Kingdom (UK)	Medicines and Healthcare products Regulatory Agency (MHRA)
United States of America (USA)	Food and Drug Administration (FDA)

Note: The list of RRA may be updated periodically by the SFDA to include additional jurisdictions, including those of the IMDRF Management Committee (MC) members.

General Eligibility Criteria & Medical Device Exclusions

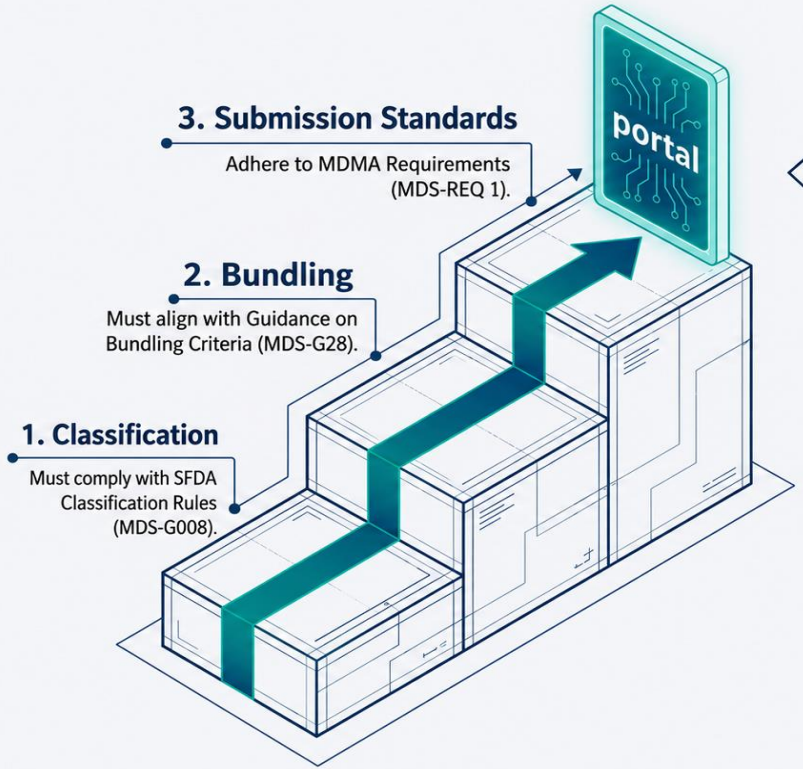
✓ELIGIBLEIF...

- Valid RRA marketing authorization
- Device identical to RRA-authorized version
- Compliant with Saudi national requirements

✗ NOT ELIGIBLE IF...

- Based on self-declaration only
- Relies on predicate equivalence
- Custom-made for individual patients
- Active Post-Market safety concerns or recalls

Finalizing requirements before submission



Quality Management System

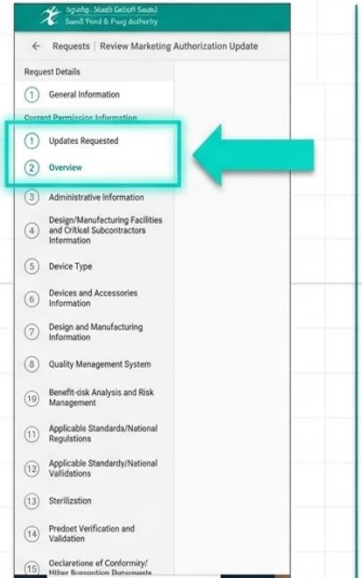
MDSAP

Medical Device Single Audit Program

SFDA accepts MDSAP certificates and reports issued from Auditing Organizations recognized by MDSAP.

How to Apply

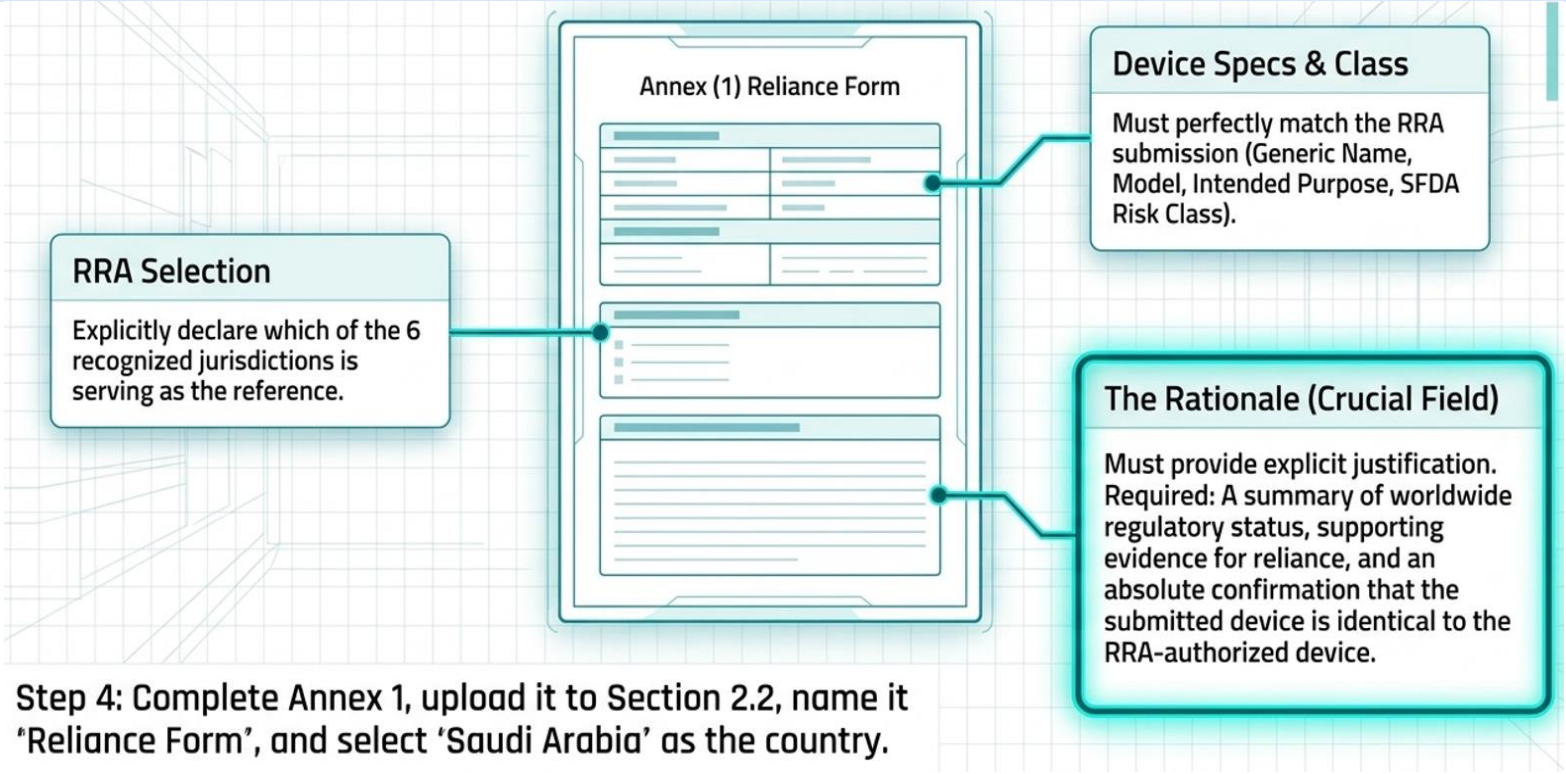
Apply through the GHAD Portal



Enable Reliance Pathway

This selection formally declares the applicant's intent to utilize an RRA marketing authorization as supporting evidence for the SFDA's regulatory assessment.

Reliance Form Submission



Step 4: Complete Annex 1, upload it to Section 2.2, name it 'Reliance Form', and select 'Saudi Arabia' as the country.

Review Times for Marketing Authorization

Standard Review

35–60

Working Days

Depending on:

- Product type
- Risk classification
- Complexity

Risk Classification & Lead Time

Risk Class	Lead Time
Class A	35 – 60 Working Days
Class B	35 – 60 Working Days
Class C	35 – 60 Working Days
Class D	35 – 60 Working Days

Reliance Pathway

Within the **Reliance Pathway**, review time may be reduced to 35 working days by relying on prior RRA approval instead of a full independent assessment, subject to eligibility and complete documentation

Reliance on Post- Market Surveillance

The SFDA applies reliance principles across several key post-market surveillance activities, including:

Definitions & Terminology	Adverse Event Coding Systems	Adverse event reporting requirements and timelines:	Safety Alert Detection & Information Sharing
• SFDA adopts and utilizes internationally recognized **IMDRF definitions and terminology.** • Supports consistency in regulatory communication and safety information exchange	• SFDA utilizes **IMDRF adverse event terminology and coding systems.** • Supports standardized categorization, identification of potential causes, and analysis of adverse event trends.	• Requirements and timelines are implemented using a **risk-based approach.** • Consider the nature and severity of the event and potential impact on patients, users, and public health.	• SFDA monitors **safety information and regulatory actions**, including recalls , field safety corrective actions, and other relevant safety communications. • Supports signal detection, **risk prioritization, and assessment of further regulatory action** in the Saudi market.

SFDA Published Regulatory Documents in (2026)

#	Document ID &Version No.	Document Title
1	MDS-REQ 3 (Ver. 3)	Requirements for Safe Use of Medical Devices Inside Healthcare Facilities
2	MDS-G028 (Ver. 1)	Guidance on Bundling Criteria for Medical Devices within a Single MDMA Application
3	MDS-G029 (Ver. 1)	Guidance on Risk Communication of Medical Devices

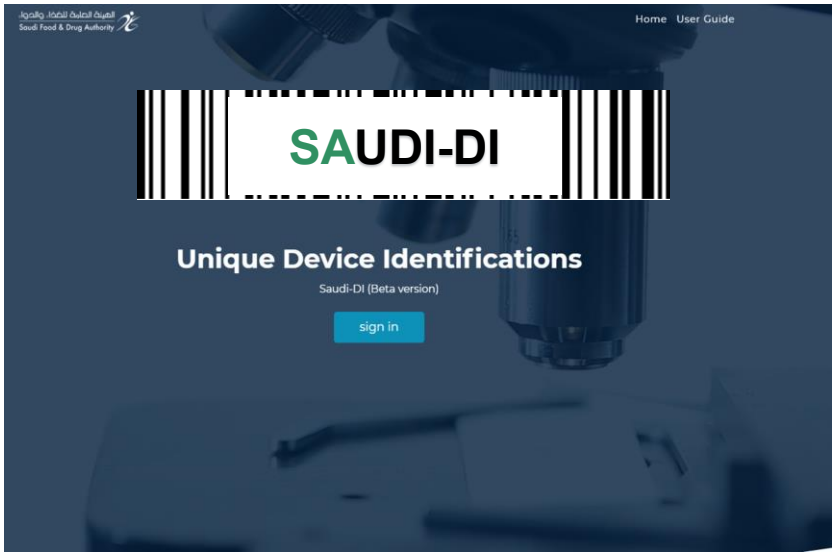
SFDA UnderDevelopment Regulatory Documents in (2026)

IN PROGRESS

#	Document ID &Version No.	Document Title
1	MDS-REQ 1 (Ver. 7)	Requirements for Medical Devices Marketing Authorization
2	MDS-REQ 4 (Ver. 2)	Requirements for the Import and Clearance of Medical Imaging Materials and Particle Accelerators Used in Radioisotopes Formation for Medical Applications
3	MDS-REQ 5 (Ver. 7)	Requirements on Importation and Shipments Clearance of Medical Devices and Supplies
4	MDS-REQ 9 (Ver. 3)	Requirements for Licensing of Medical Devices Establishments
5	MDS-REQ 11 (Ver. 3)	Requirements for Post-Market Surveillance of Medical Devices
6	MDS-G012 (Ver. 2)	Guidance on MDMA –Significant and Non-Significant Changes
7	MDS-G015 (Ver. 3)	Guidance on SFDA Requirements for Quality Assurance Programs for Radiation Emitting and Imaging Devices
8	MDS-G020 (Ver. 4)	Guidance on SFDA Recognized Standards Lists
9	New Document	Guidance on Medical Devices Labeling
10	New Document	Guidance on Biotechnology Based Medical Devices

SFDA MD-UDI Updates

➢ UDI Compliance



MDS – REQ 7

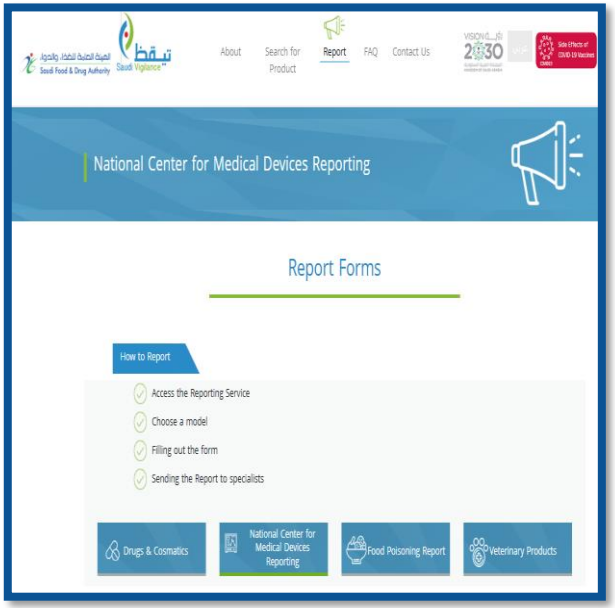
Requirements for Unique Device Identification (UDI) for Medical Devices

# of Devices	+ 500,000
# of Manufacturers	+1950

Post-market Surveillance Updates

Safety Alerts

Safety Alerts	230 safety alerts affected the Saudi market out of 1,028 globally detected	
Action Types	Correction 545	Removal 479
Medical Devices Affected	2,941,538	



Adverse Events & Complaints

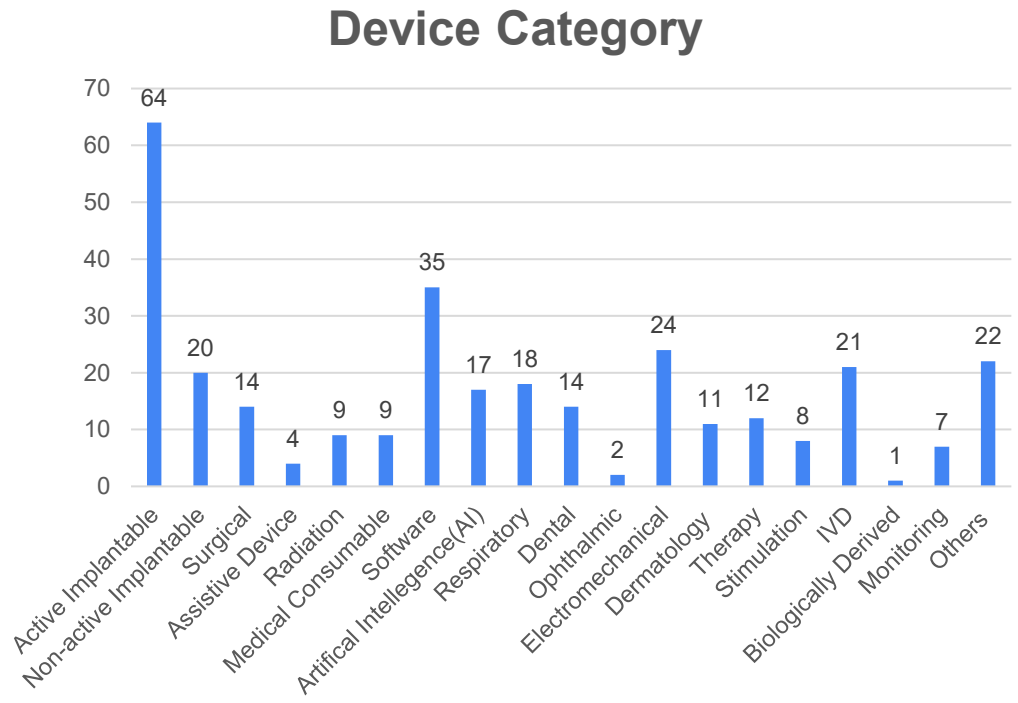
Received AE & Complaints reports	1279		
Type of Reports	Healthcare providers 322	Manufacturers &companies 807	Public 150

Officers of Healthcare providers: 1,724 Officers

Clinical Trials of Medical Devices Updates

During 2026, a total of 47 applications for medical device clinical trials were received & thoroughly evaluated

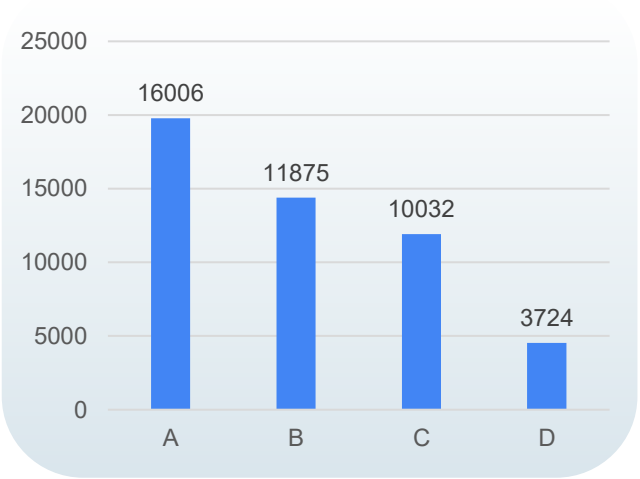
Since 2015, a total of 367 medical device clinical trial applications were submitted and reviewed, as shown in the table



Marketing Authorization Statistics MDMA Updates

Statistics in 2026	
# Request	**7877**
# Products	**41637**

Classification	# Products
A	**16006**
B	**11875**
C	**10032**
D	**3724**



Thank You!

To access SFDA-MD Regulations and Requirements