Premarket Submission and Approval Requirements in Kingdom of Saudi Arabia

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SFDA History

- Saudi Food & Drug Authority (SFDA) was established on March 10\textsuperscript{th}, 2003.
- A royal decree was issued on Feb. 13\textsuperscript{th}, 2007 to establish the law of SFDA.
- A council of ministers decision number 181 was issued on June 18\textsuperscript{th}, 2007 giving the SFDA a full authority to regulate the medical device market in Saudi Arabia.
- SFDA is an independent body with an independent budget.
- SFDA reports directly to the premier of the council of ministers.
Medical Device

Any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article:

a) Intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific 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 for medical purposes by means of in vitro examination of specimens derived from the human body,

b) Which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.
Medical Devices Sector areas of responsibility:

- Laser surgical equipment for cosmetic and their accessories
- Radiation emitting electronic devices
- Contact lenses and their solutions
- Medical devices
- Medical In Vitro Diagnostics
- Prescription eye glasses
Implementing Rule on Safeguard Procedures
Implementing Rule on Designation and Oversight of Conformity Assessment Bodies
Implementing Rule on Establishment Registration
Implementing Rule on Post-Marketing Surveillance
Implementing Rule on the Validation of Documents to be provided to the SFDA
Implementing Rule on Licensing of Authorized Representatives
Implementing Rule on Medical Devices Listing
Implementing Rule on Establishment Licensing
الخدمات الإلكترونية للأجهزة الطبية

MDES
Medical Devices Electronic System

السجل الوطني للأجهزة والمنتجات الطبية
MDNR
Medical Devices National Registry

نظام الترخيص لمنشآت الأجهزة والمنتجات الطبية
MDELS
Medical Device Establishment License

مكاتب التحقق من المطابقة
CAB online
Application Confirmatory Assessment Bodies

الإذن بتسويق الأجهزة والمنتجات الطبية
MDMA
Medical Devices Marketing Authorization

نظام الإبلاغ عن الشحنات للأجهزة الطبية
MDSNS
Medical Device Shipment Notification System

قسم المنافذ الحدودية
DPOE
Designated Port of Entry

المركز الوطني لبلاغات الأجهزة والمنتجات الطبية
NCMDR
National Center for Medical Devices Reporting
Medical Devices Life Cycle

- Conception and Design
- Manufacture
- Packaging and Labelling
- Importing
- Sale
- Use
- Disposal

Pre-market
On-market
Post-market
Requirements for Medical Device to be replaced in Saudi market

Interim Regulations

MDNR

MDMA

MDEL

Authorised Representative
Medical Device National Registry (MDNR)

- MDNR is an on-line REGISTRATION scheme includes the medical device establishments information and devices listing
  - manufacturers, exporters, importers, distributors, authorised representative of
    - medical devices and their accessories,
    - in vitro diagnostics,
    - prescription eye glasses,
    - contact lenses and their solutions,
    - laser surgical equipment for cosmetic rather than medical purposes and their accessories.
Medical Device National Registry (MDNR)

- To register these organisations with the SFDA.
- Retail pharmacy, Healthcare Providers that distribute medical devices are required to enrol for these activities alone
- It is not an approval system
- It is mandatory & its Free to register
Medical Device Establishment License (MDEL)

• Medical Device Establishment License (MDEL)
  – Interim Regulation: Chapter 5
  – Implementing Rules: IR4

WHAT?

• MDEL is an on-line enrolment scheme for importers, distributors and authorised representative of medical devices, located in the Kingdom of Saudi Arabia. Local manufacturer involved in distribution must also apply.
Medical Device National Registry (MDEL)

WHO?

• The following parties who operate their business in Saudi Arabia are required to be enrolled. Importers, Distributors of
  – medical devices and their accessories,
  – in vitro diagnostics,
  – prescription eye glasses,
  – contact lenses and their solutions,
  – laser surgical equipment for cosmetic rather than medical purposes and their accessories.

• Local Manufactures who Import / Distribute Medical Device will require an Establishment License It is mandatory

• Authorised Representative who Import / Distribute Medical Device will require an Establishment License
Medical Device Establishment License (MDEL)

- Manufacturer
- AR
- Dealing with SFDA
- Complete MDMA
- Post Market Surveillance
- Inform SFDA of Incidents Outside KSA
- Cooperate with Importers Distributors Installation Maintenance
MDEL- Authorised Representative responsibility

The mandate shall, at a minimum, allow the authorised representative to:

1. Represent the manufacturer in its dealings with the SFDA.

2. List each medical device category intended to be supplied to the KSA market.

3. Complete the Marketing Authorisation on-line application form (MDMA)

4. Cooperate with the SFDA on evaluations and actions taken during market surveillance and/or vigilance procedures

6. Inform the SFDA of any incidents that have occurred outside the KSA

7. Inform the SFDA of all field safety corrective actions resulting from post-market surveillance

8. Cooperate with parties involved in distribution activities, installation and maintenance of medical devices that have been placed on the KSA market under its mandate.
Authorized Representative (AR)

Definition:

- **Authorised Representative (AR):**

  means any natural or legal person established within the KSA who has received a written mandate from the manufacturer to act on his behalf for specified tasks including the obligation to represent the manufacturer in its dealings with the SFDA.

  *(Article 1, Chapter 1, MDIR)*
• When the manufacturer is located outside the KSA he shall appoint an authorised representative to act on his behalf. *(Article 11, MDIR)*

• Chapter Six of the Medical Devices Interim Regulation requires organizations authorised by a manufacturer to act on his behalf in the KSA to have an establishment license for this activity, issued by the SFDA. *(Article 4A, MDS-IR 5)*
Activities to be performed by an AR

Part I: Pre-License Activities
- Designation of Authorized Representatives
- Applying for establishment registration
- Mandate between the manufacturer and Authorized Representative

Part II: Applying for a License
- Applying for establishment Licensing

Part III: Post-License Activities of Authorized Representatives
- Post-Marketing Responsibility for Advertising and Marketing Material
- Post-Marketing Surveillance of Medical Devices
Applying for a License

Applications for Medical Devices Systems can be applied online through The Medical Device Electronic Services.

1st. Apply for Establishment registration and obtain MDNR number through MDNR system.

2nd. Apply for Authorized Representative license online through MDEL system.
Medical Devices Marketing Authorization (MDMA)

It is a pre-market process of validation & evaluation of a medical device by which SFDA, if applicable, will issue a written Marketing authorization to the manufacturer that allows placing the medical device on Saudi market.
Steps toward obtaining Medical Devices Marketing Authorization

1. Application Submission
2. Fulfillment of Marketing Authorization Requirements
3. Evaluation & Validation of the submitted documents
4. Make a Decision
Medical devices may be placed on the market and/or put into service **only if** they comply with the applicable provisions of this **Interim Regulation**, as signified by the SFDA issuing the manufacturer with a written marketing authorization.
Same User Name & Password from the MDNR
New Application
1. Manufacturer
2. General Info
3. Jurisdiction
4. Product Categories
5. Product Verification
6. Manufacturers QS status
7. Other National Provisions
Medical devices marketing authorization requirements in KSA

- Documentation
- Language
- DOC
- Attestation
- Labeling
- Recalls
- Environmental conditions
- Storage, transportation, installation and maintenance
MDMAs Incorporating More Than One Medical Device Type

• Where the applicant’s MDMA groups more than one medical device type (referred to as ‘bundling’ in some jurisdictions) within a single application procedure,

* MDS-G5 (( GUIDANCE ON MARKETING AUTHORIZATION PROCEDURES))
Bundling/Grouping Criteria MD

There are **FOUR TYPES FOR MDMA APPLICATION SUBMISSION** for medical devices other than IVD medical devices as follow:

1. SINGLE medical device.
2. FAMILY of medical devices.
3. System:
   - A. Medical device SYSTEM.
   - B. Medical device SYSTEMS GROUP
4. PROCEDURE PACK of medical devices.

Bundling/Grouping Criteria IVD

- IVD medical devices that are grouped/bundled within a single application of MDMA shall:
  - Be under **SAME MANUFACTURER**.
  - Have **SAME RISK CLASS**.
  - Have **SAME INTENDED USE/purpose**.
  - Be in **SAME ORIGINAL APPROVAL/CERTIFICATE** (if applicable).
  - The total **number of items shall not exceed 50 items**.

Evaluation & validation of the submitted documents

MDMA

SFDA

CABs
SFDA: Ensure that the medical device complies with the relevant provisions of MDIR (Article 18, Chapter 6, MDIR).

CABs: MD Sector at SFDA has signed Service Agreements with (5) International Conformity Assessment Bodies:

- The British Standards Institution
- TUV Rheinland
- SGS
- COSMOS Corporation
- UL
When satisfied, the SFDA shall issue a written marketing authorization, in both Arabic and English.

It will indicate:

- the details of the manufacturer
- sufficient information to identify the medical devices
- the period of its validity

The Authorization remains the property of the legal manufacturer, whether local or overseas, and not of an authorized representative or importer.
Medical Devices Marketing Authorization (MDMA)

Who Should Apply

1. Local manufacturers.
2. Overseas Manufacturers Authorised Representative

Certificates

Two types of Authorisation:
1. For multiple devices.
2. For single device.
Validity of MDMA

The validity of MDMA is:

- The **same** as that of the marketing authorization granted in the CE approval or US FDA

**UNLESS**

- It has an *open end*, or Where the device has been marketed through a *self-declaration process* (e.g. Class I devices that are not sterile or having a measuring function under EU regulations), MDMA should be valid for **3 years**.
# Medical Devices Marketing Authorization

## Current Applications in System

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<th>PMA Department</th>
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- **Medical Devices Marketing Authorisation**
  - **Issued**: 2590
  - **Under Process**: 481
  - **Waiting for Payment**: 294
  - **Expires within 2 Months**: 213

- **Current Applications**
  - **In Process**: 14%
  - **Waiting for Payment**: 9%
  - **Issued**: 77%
Summary

MDS Roadmap
Cont. MDS Roadmap
Cont. MDS Roadmap

Outputs

E- Services

Importer

Distributor

AR

Local Manuf.

MDNR

IR2

IR3

Regulations

MDNR Number
Cont. MDS Roadmap

OUTPUTS

MDNR Number

E- SERVICES

IMPORTER
DISTRIBUTER
AR
Local Manuf.

REGULATIONS

MDEL

IR4

IR5

IR2

IR3
Cont. MDS Roadmap
Cont. MDS Roadmap

OUTPUTS

E- SERVICES

REGULATIONS

MDMA

MDNR

MDEL

IMPORTER

DISTRIBUTER

AR

Local Manuf.

E. License

MDNR Number

IMPORTER

DISTRIBUTER

AR

Local Manuf.

IR1

IR4

IR2

IR3

IR5

IR6
Cont. MDS Roadmap

Market Authorization

E. License

MDNA

MDEL

MDNR

OUTPUTS

E- SERVICES

IMPORTER

DISTRIBUTER

AR

Local Manuf.

IR1

IR4

IR6

IR5

IR2

IR3

REGULATIONS

IMPORTER

DISTRIBUTER

AR

Local Manuf.

IR1

IR4

IR6

IR5

IR2

IR3

MDNR

Number

E. License

Market Authorization

IMPORTER

DISTRIBUTER

Local Manuf.

MDNA

MDEL

MDNR

IR1

IR4

IR6

IR5

IR2

IR3

E- SERVICES

IMPORTER

DISTRIBUTER

AR

Local Manuf.

IR1

IR4

IR6

IR5

IR2

IR3

REGULATIONS
Thank you