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MRG

Medical Devices Regulatory Saudi Arabia & Egypt

Outline

- **Medical Devices in Egypt**
  Laws & Regulations
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  Laws & Regulations
- **Medical Devices in Saudi Arabia**
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Medical Devices in Egypt

Medical Devices in Egypt

Laws & Regulations

Laws & Regulations

Regulatory Authority

Egyptian Drug Authority

Classification

As per EU & FDA Classification

Quality System

ISO 13485

Applicant:

Egypt Registration Holder (ERH)

Timeframe:

4-8 months

Validity:

10 years

Medical Devices in Egypt

Laws & Regulations

Registration Tracks

Class	Pathway	Class	Pathway
I Sterile	Registration with EDA	**I Non-Sterile**	No need for Registration (optional listing)
IIa Sterile	Registration with EDA	**IIa Non-Sterile**	Registration with EDA
IIb Sterile	Registration with EDA	**IIb Non-Sterile**	Registration with EDA
III Sterile	Registration with EDA	**III Non-sterile**	Registration with EDA
Instruments	No need for registration (Listing)		
Accessories exclusively used with instruments	Registration with EDA (S.C. Approval)		

Medical Devices in Egypt

Laws & Regulations

Registration Fees

Service	Normal Track (EGP)	Fast Track (EGP)
Registration of imported medical devices		
New Registration	10,000	20,000
Re-Registration	10,000	20,000
Variation		
Major Variation: All the variation processes including major Artwork Update.	6,000	12,000
Changing the manufacturing site	6,000	12,000
Minor Variation: -Changing the Importer's name keeping the same address. -Changing the Importer address.	4,000	8,000
Minor Artwork Update	2,000	4,000
Changing the Importer name	7,000	14,000
Others		
Checking Non-Sterile file before submission	2,000	NA
Scientific Committee	3,000	NA
Variation for Scientific Committee	500	NA

Medical Devices in Egypt

Laws & Regulations

Bundling/Grouping Criteria

- ***To register MDs within a single application, they must have common:***
  - *Brand Name*
  - *GMDN or UMDN*
  - *Classification*
  - *Intended Use*
  - *Legal Manufacturer*
  - *Raw Materials*
  - *Patient Population (Except Size)*

Medical Devices in Egypt

Laws & Regulations

Registration Requirements

A. Certificates:

- FDA certificate mentioning GMP (needed legalized)
- ***OR***
- Free Sale Certificate (FSC):
  - *Legalized and from a Reference Country*
- Quality Certificates:
  - CE Full Quality Assurance, Design examination certificate for class III
  - ISO 13485:2016 (Legalized if not posted the Notified Body Website)
- Declaration of Conformity (DOC) (signed and stamped by the legal manufacturer)
- ***Note: All the certificates must mention the legal and actual manufacturers.***

Medical Devices in Egypt

Laws & Regulations

Registration Requirements

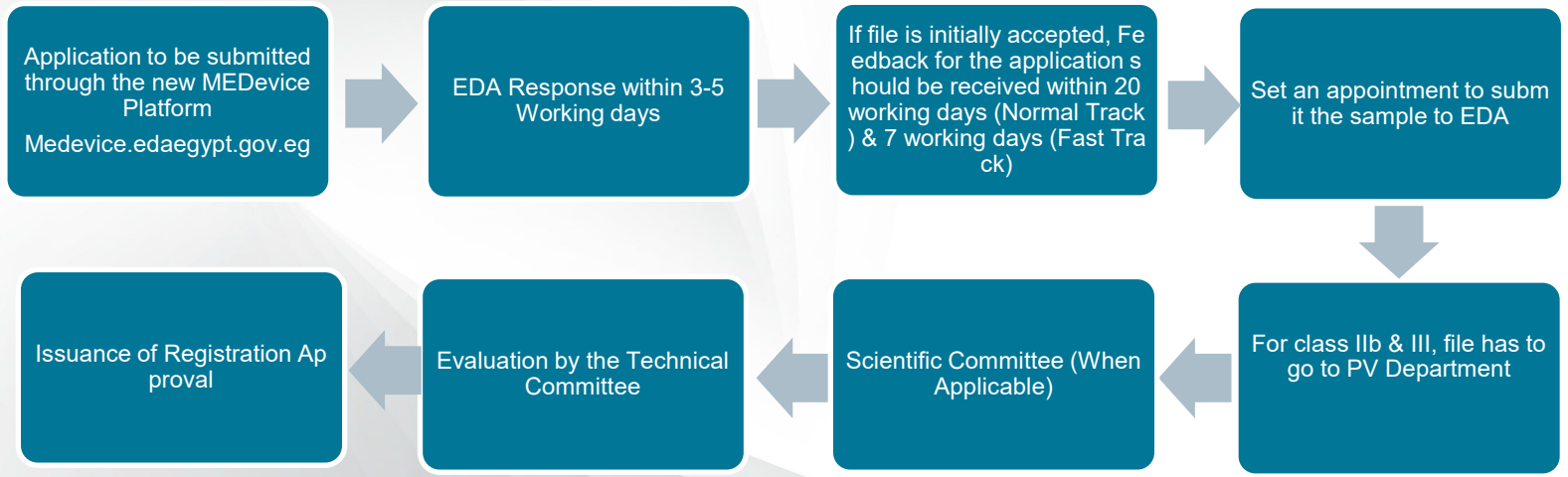
B. Technical file (all signed and stamped by legal manufacturer) contains the following:

- Raw materials. (Parts and components)
- Sterilization. (For sterile medical devices)
- Packaging.
- GMDN code.
- Analysis certificate (mentioning sterility test) plus Covering letter of analysis (mentioning the standards and the responsibility of the manufacturer)
- IFU.
- Storage conditions and Shelf life.
- Catalogues or Brochures.
- Artwork for inner and outer labels. (2 copies)

C. Commitment letter for the Pharmacovigilance signed and stamped by the manufacturer. (for class I & IIa)

D. Representative Sample.

Registration Process



Pre-Market Updates: Non-Sterile MDs

1. ***Temporary file to be submitted to EDA to obtain a 6 months grace period for release approvals***

2. ***Product File Submission through MEDevice Portal to obtain a 1 year grace period for release approvals***

3. ***The Components of the temporary file:***
   - *Declaration of Conformity*
   - *CE Certificate*
   - *ISO 13485:2016*
   - *Free sale certificate from reference country for medical devices Class IIb, III*
   - *Free sale certificate from country of origin for medical devices Class IIa, Class I*
4. ***Bundling criteria:***
   - *Same Legal Manufacturer*
   - *Same Classification*
   - *Same Generic/ Proprietary Name*
   - *Common Intended Use*
   - *Similar or Close Design*
   - *Be within the scope of the permissible variants that may be evaluated from the Scientific Committee*
   - ***Note: It Is not essential to have common: Raw Materials- GMDN- Patient Population***

Pre-Market Updates: Non-Sterile MDs

Fees for Non-Sterile Medical Devices- New Registration (EGP)		
	Normal Track	Fast Track
From 2-10 Device	7,000	22,000
From 11-20 Device	9,000	24,000
From 21-30 Device	11,000	26,000
From 31-40 Device	13,000	28,000
From 41-50 Device	15,000	30,000
Fees for Non-Sterile Medical Devices- Re Registration (EGP)		
From 2-10 Device	12,000	22,000
From 11-20 Device	14,000	24,000
From 21-30 Device	16,000	26,000
From 31-40 Device	18,000	28,000
From 41-50 Device	20,000	30,000

Pre-Market Updates: Labeling Requirements

Product Related Info

- Trade name
- Product code or model or Ref.
- batch number or serial no (if necessary)
- Any special handling precautions (if present).
- Any special storage precautions (if present).
- an indication of single use (in case of single use devices)
- Expiry date in accepted format (if applicable) Or manufacturing date and shelf-life time
- UDI on the label of the device or on its packaging (when implemented)

Manufacturer Related Info

- Manufacturer Name & Address
- Country of Origin

Pre-Market Updates: Labeling Requirements

Sterile Products Related Info

- Symbol of Sterilization must be present along with the sterilization method
- ***Note: Chemical Sterilization can be mentioned on the inner leaflet of the MD***

Importer Related Info

- Importer Name & Address
- ***Note: this can be done by the importer at customs (Commitment letter)***

Pre-Market Updates: IVDs

31st December 2023

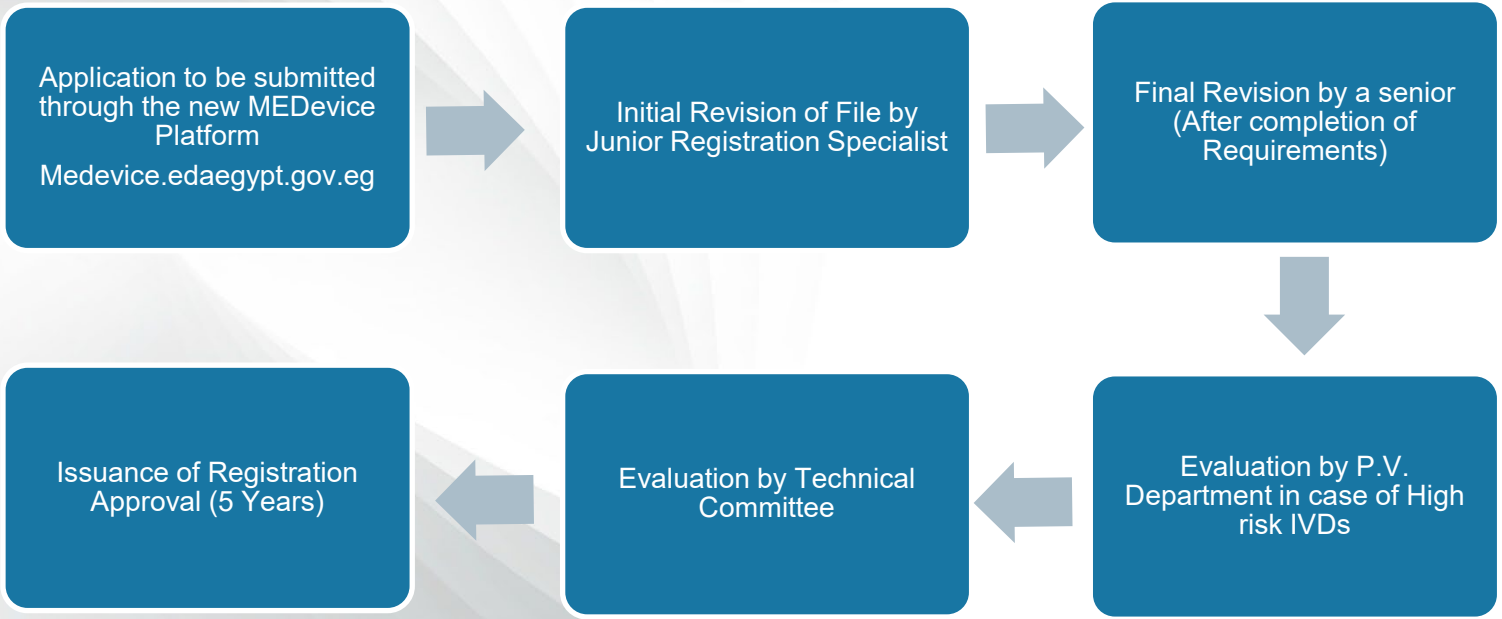
IVDS classified as List A and List B under registration with EDA will have a grace period to import without approval

31st December 2023

IVDS classified as General and Self-testing will have a grace period to import without approval under the following conditi ons:

1. Import the first 6 months with no registration
2. Submit an application for the EDA before 30/6/2023 and From 1/7/2023 they can import till 31/12/2023

Pre-Market Updates: IVDs Registration Process



Pre-Market Updates: IVDs Registration Fees

Service	Fees (EGP) Normal Track	Fees (EGP) Fast Track
New Registration	10,000	20,000
Re-Registration	10,000	20,000
Major Variation: All the variation processes including major Artwork Update	6000	12,000
Changing the manufacturing site	6000	12,000
Minor Variation: -Changing the Importer's name keeping the same address. -Changing the Importer address.	4000	8000
Minor Artwork Update	2000	4000
Changing the Importer name	7000	14,000

Pre-Market Updates: IVDs Registration Requirements

Basic Documents required:

- ***FDA/ FSC, CE, ISO, DOC***

Technical Documents

Administrative:

- *Name of manufacturer*
- *Address of manufacturer*
- *Address of any associated manufacturing sites*
- *Statement of legal liability*
- *License of manufacturing no.*
- *Name of authorized person.*
- *Authorized person Delegation Letter.*
- *Name of contact person*
- *Tel*
- *Fax*
- *E- mail*
- *Web address*

Pre-Market Updates: IVDs Registration Requirements

Technical Documents

Device Description:

- *Name of the device*
- *Brand name*
- *Variant: codes, references, and sizes*
- *Intended use*
- *Description of individual components included in the IVD*
- *Where applicable, the following should also be provided*
    - *A description of the accessories, other IVDs and other products that are not medical devices which are intended to be used in combination with the IVD*
    - *For assays requiring instrumentation, a description of the relevant instrumentation characteristics or details of dedicated instrumentation to be used*
    - *A description of any software to be used*
    - *A complete list of any configurations or variants of the IVD, other than kit size, that will be made available.*

Pre-Market Updates: IVDs Registration Requirements

Technical Documents

Device History:

- *A summary of the product history in domestic market and any other countries.*
- *A list of countries or regulatory jurisdictions, approximate numbers of IVDs and/or period of time supplied, summary of any adverse events, recalls, corrective/preventive actions or refusal to approve for supply*

Performance Evaluation:

- *Diagnostic Sensitivity*
- *Diagnostic Specificity*

Labelling:

- *Inner and outer Labels*
- *Instructions for use*
- *Advertising Materials (Where available)*

Manufacturer Testing Reports of the final product (Batch release certificate)

Commitment to follow up with medical device PMS

Medical Devices In Saudi Arabia

Medical Devices in Saudi Arabia

Laws & Regulations

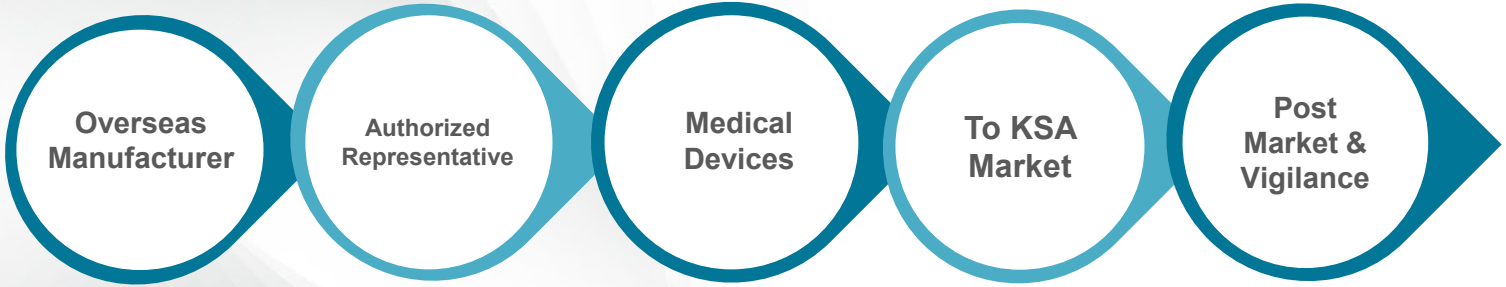
Laws & Regulations

- All Medical Devices are registered through the Saudi Food and Drug Authority (SFDA) which was Established on March 10, 2003
- SFDA is an independent body with independent budget reports directly to the premier of the council of ministers.
- SFDA “MEDICAL DEVICE SECTOR” areas of responsibilities :
  - Medical Devices
  - Contact lenses and their solutions
  - Medical Eye glasses
  - Medical In-Vitro Diagnostics
  - Laser surgical equipment for cosmetic and their accessories
- **In order for any Medical Device manufacturer to have the ability to enter its products to the Saudi Market, its mandate that the manufacturer assigns an Authorized Representative to act on behalf of the Manufacturer in dealing with SFDA, regarding regulations and product registration.**

Medical Devices in Saudi Arabia

Laws & Regulations

Process of Registration



Sign the Authorized Representative Agreement

Obtain the AR License for the Manufacturer

Apply for Product Registration with SFDA

Supply the product

Monitor, Prevent & Correct

Medical Devices in Saudi Arabia

Laws & Regulations

Pre-Market: Product Registration

- Three pathways for Registration:
  - **GHTF: Global Harmonization Task Force (Updates & Renewals Only)**
  - **TFA : Technical File Assessment**
  - **Low Risk Registration: For Class I Non-Sterile & Non-Measuring (Not Effective from 27th September 2022)**

GHTF

Benefits:

- Follows one of the five jurisdictions: EU, USA, Canada, Australia, Japan
- Requirements are simple (Product Info, Quality Certificates related to Product and Manufacturer)

Challenges:

- Product cannot be registered if not approved in one of the five jurisdictions

TFA

Benefits:

- Manufacturers can submit for Product License Without approval from any of the five jurisdictions
- GHTF approvals can expedite the approval process

Challenges:

- All Technical documents related to the product have to be submitted ***separately***

Medical Devices in Saudi Arabia

Laws & Regulations

Pre-Market: Product Registration

Technical File Assessment Requirements

General Manufacturer Info:

- Approval Evidence from Other countries (If Applicable)

- Confirm the following (If No, then provide the required information):
  - o Design Facility Information is the same as the Legal Manufacturer Information
  - o Manufacturing Facility Information is the same as the Legal Manufacturer Information

- Critical Subcontractor Facilities Information (If Yes, provide Info)

Medical Devices in Saudi Arabia

Laws & Regulations

Pre-Market: Product Registration

Technical File Assessment Requirements

Devices and Accessories Information:

- If there are different variants for the same device, provide supporting documents stating the difference
- Supporting document showing the justification for the Classification Rule as per SFDA Guidance for Technical File Assessment
- GMDN code
- Where applicable, a description of any software to be used with the device
- Product Labels, Instructions for Use & Catalogue
- Where applicable, declaration from the manufacturer if the device contains animal tissue/ medicine/ human blood derivatives)

Medical Devices in Saudi Arabia

Laws & Regulations

Pre-Market: Product Registration

Technical File Assessment Requirements

Design and Manufacturing Information:

- Full Design and Manufacturing Processes
- Applied Parts
- Technical Specification
- Requirements Documentations
- Design Traceability
- Design Stages
- Manufacturing Processes
- Manufacturing Structure

Medical Devices in Saudi Arabia

Laws & Regulations

Pre-Market: Product Registration

Technical File Assessment Requirements

Quality Management System:

- Manufacturer QMS Evidence
- Recent Audit Report
- Where applicable, Subcontractor QMS evidence

Essential Principles Checklist, Conformance Evidence:

- Essential Principles (EPs)
- Evidence of Conformance to Applicable EPs.

Benefit-Risk Analysis, and Complete Risk Management File (RMF) provided according to a recognized standard

Medical Devices in Saudi Arabia

Laws & Regulations

Pre-Market: Product Registration

Technical File Assessment Requirements

Product Verification and Validation:

- Results of tests, such as engineering laboratory, simulated use and animal tests
- Detailed information regarding test design
- Software verification and validation
- Evidence supporting life of product Stability, including shelf life.
- Supporting documents for product performance and safety
- Clinical evaluation report and its updates, the clinical evaluation plan, CV(s) for author(s) of clinical evaluation report, and referenced and cited literature
- Clinical investigation report(s), clinical investigation plan(s), and CV(s) for investigators
- The Post-Market Clinical Follow-up (PMCF) plan and PMCF evaluation report or a justification why a PMCF is not applicable.

Medical Devices in Saudi Arabia

Laws & Regulations

Pre-Market: Product Registration

Technical File Assessment Requirements

Vigilance and Post Market Surveillance:

- Post-market surveillance plan
- Periodic Safety Update Report (PSUR) and Post-Market Surveillance report.

Declarations of Conformity/ Other Supporting Documents:

- Draft DoC (as per SFDA Guidance)
- Other Supporting Documents

Medical Devices in Saudi Arabia

Laws & Regulations

Pre-Market: Bundling Criteria

- A Maximum of 5 Technical Files are allowed per application
- Total number of listed products per application shall not exceed 50 items (Excluding accessories)
- **Medical Device Family:**
    - Same Legal Manufacturer
    - Same Intended Use/ Purpose
    - Same Risk Classification
    - Same GMDN Code (Optional)
    - Common Physical Design, construction materials and manufacturing process

- **Medical Device System:**
    - Same Legal Manufacturer
    - All components used together serve a common intended purpose
    - Sold under a medical device system name

Medical Devices in Saudi Arabia

Laws & Regulations

Pre-Market: Bundling Criteria

- **Medical Device Procedure Pack:**
  - Same Intended Use/ Purpose
  - Same Legal Manufacturer
  - Under the same speciality
  - Same Risk Class
  - ***Note: Technical Documentation of each component should be available upon request***

- **IVDs:**
  - Same Legal Manufacturer
  - Same Risk Classification
  - Same Intended Use/ Same principle of operation
  - Closely similar design and manufacturing process

Medical Devices in Saudi Arabia

Latest Updates

Pre-Market: Latest Updates

1. Product Registration Update Requests Government Fees

Type of Change Request	Fees (USD)
Add Device/ Model/ Brand Name Change/ Change in device design	1,330
Update Label/ IFU/ Advertising Materials	294
Renew DE Certificate	400
Change Jurisdiction/ Classification/ Manufacturer Address or Name/ Notified Body	Full Fees
Change Notified Body with a transition period letter/ Change notified body due to Brexit (Same NB different number)	1,330

Medical Devices in Saudi Arabia

Latest Updates

Post-Market: Latest Updates

1. Stage 1: Reporting Incidents/Adverse Events

- *Required only for events occurring **inside KSA***
- *Period of Reporting:*
  - *Not later than (2) working days: Serious Public Health Threat*
  - *Not later than (10) working days: Unanticipated Death or Serious Injury*
  - *Not later than (30) calendar days: Not associated with high risks*
  - *Not later than (5) working days: If SFDA initiate a report of an adverse event*

- *Incidents and Complaints with No Risk associated or potential harm: Could be submitted **monthly or weekly** as bulk reports using a proper format*

Medical Devices in Saudi Arabia

Latest Updates

Post-Market: Latest Updates

2. Stage 2: Notifying Affected Users

- ***Notifying Channels:***
  - Emails, Fax, Visitations, Phone calls, etc…
- ***Permitted Period:***
  - No More than 5 Working days (Acknowledgment letters can be provided later)
- ***Note:***
- *Uncooperative users shall be contacted at least 3 times and in two different methods, if no response, SFDA shall be contacted*

Medical Devices in Saudi Arabia

Latest Updates

Post-Market: Latest Updates

3. Stage 3: Correction Plan

- ***Permitted Period:***
  - No More than 5 Working days to provide the correction plan

- ***Following shall be included in the plan:***
  - *Expected date for correction plan implementation*
  - *List of related healthcare providers/ customers*
  - *Category affected by the FSCA (Public, healthcare providers)*
  - *Details of the numbers of medical devices affected by the FSCA*
  - *Description of the procedures to be performed*
  - *FSCA Risk Assessment Form*
- ***Note: periodic reports should be provided if the correction plan is long***

Medical Devices in Saudi Arabia

Latest Updates

Post-Market: Latest Updates

4. Stage 4: Implementation

- If the correction plan cannot be completed in time, a request to extend the expected date shall be provided with the reason of delay
- For periodic reports, a notification shall be sent to SFDA if the report cannot be provided on time
- Periodic reports shall include the percentage of implementation of the corrective action

5. Stage 5: Closure

- The closure is not complete until confirmation is received from SFDA

Medical Devices in Saudi Arabia

Latest Updates

Post-Market: Latest Updates

2. Unique Device Identification (UDI) for Medical Devices

- *As per SFDA guidance, all imported items before the compliance dates can be distributed without UDI label*
- *The product UDI information, must be issued from one of the provisional UDI Issuing Agencies (GS1, HIBCC and ICCBBA), and the UDI-DI shall be globally unique at all levels*
- ***Only the Authorized Representative;*** *who is responsible for the Product Certificate can access the UDI Database and submit the related information*

Class	Compliance Date
Class D (High Risk)	1st September 2023
Class B & C (Medium Risk)	1st September 2023
Class A (Low Risk)	01st September 2024

Medical Regulations Gate

Medical Regulations Gate

MRG

Your Regulatory Bridge to Success

Saudi Arabia

Medical Regulations Gate (MRG) is an independent medical device consulting company, approved by the Saudi Food and Drug Authority (SFDA), to act as an “Authorized Representative” on behalf of the medical device manufacturers with its headquarters in Riyadh, Kingdom of Saudi Arabia.

As one of the leading Saudi Regulatory Affairs consultancy and licensing firms in the Kingdom, MRG is representing over 250 medical device manufacturers worldwide such as:

Abbott, BD, 3M KCI, Boston Scientific, Arthrex, sysmex, LR, CEDIC, MERIT MEDICAL, PHILIPS RESPIRONICS, W&H, GC, KULZER, ASP Advanced Sterilization Products, SeaSpine, optimumedical, Schölly, gama healthcare, TIMPEL, SKINS, OsteoCare Dental Implant System, LEPU MEDICAL, EMS, VITA

Medical Devices in Saudi Arabia

Laws & Regulations

Services in Saudi Arabia

- Registering the legal manufacturer's site and their subsites for Authorized Representative License (AR) with the Saudi FDA.
- Registering Medical Device Marketing Authorization (MDMA) with the Saudi FDA on behalf of the manufacture.
- Communicating with Saudi FDA of any changes in the product or any information about the manufacturer.
- Assisting manufacturers with their post-marketing and vigilance reporting.
- Classifying products with the Saudi FDA
- Registering local companies to obtain the Medical Device establishment license (MDEL) with the Saudi FDA
- Assist the manufacturer with their UDI submission to the Saudi DI database

Medical Regulations Gate

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Your Regulatory Bridge to Success

Egypt

MRG.Egpyt is an independent medical device consulting company, approved by the Egyptian Drug Authority (EDA) to act as an “Authorized Representative” on behalf of the medical device Manufacturers.

MRG can provide the required regulatory support to deal with the Egyptian Drug Authority (EDA).

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Elekta · mindray · OLYMPUS · perfect care · AROA · ALL TEST

Medical Devices in Egypt

Laws & Regulations

Services in Egypt

- Assemble and submit the product registration file to EDA
- Submit documentation to the scientific committee for review, if needed
- Notifying EDA of any changes / variations in the product or any information about the manufacturer
- Assisting manufacturer with their post marketing and vigilance
- Assist with preparing responses to additional information requests from EDA
- Transferring registration to another importer
- Shipment release requests

Medical Regulations Gate

Your Regulatory Bridge to Success

United Arab Emirates

MRG's office in Dubai was established back in 2016. Since then, MRG has assisted a variety of Medical Device Manufacturers, Importers/Distributors and Regulatory Bodies in order to comply with the current regulations set by Ministry of Health and Prevention in Dubai (MOHAP) and others. Some of those companies are:

Turkey

MRG TURKEY is a licensed company by the Turkish Health Authority to register products belonging to overseas and local manufacturers under its account, MRG can provide the required regulatory support to deal with the Turkish Medicines and Medical Devices Agency (TMMDA/TİTCK).

Medical Devices in Saudi Arabia

Laws & Regulations

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