الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Medical Devices Regulation
(SFDA Overview and Updates)

GHWP 26th Annual Meeting

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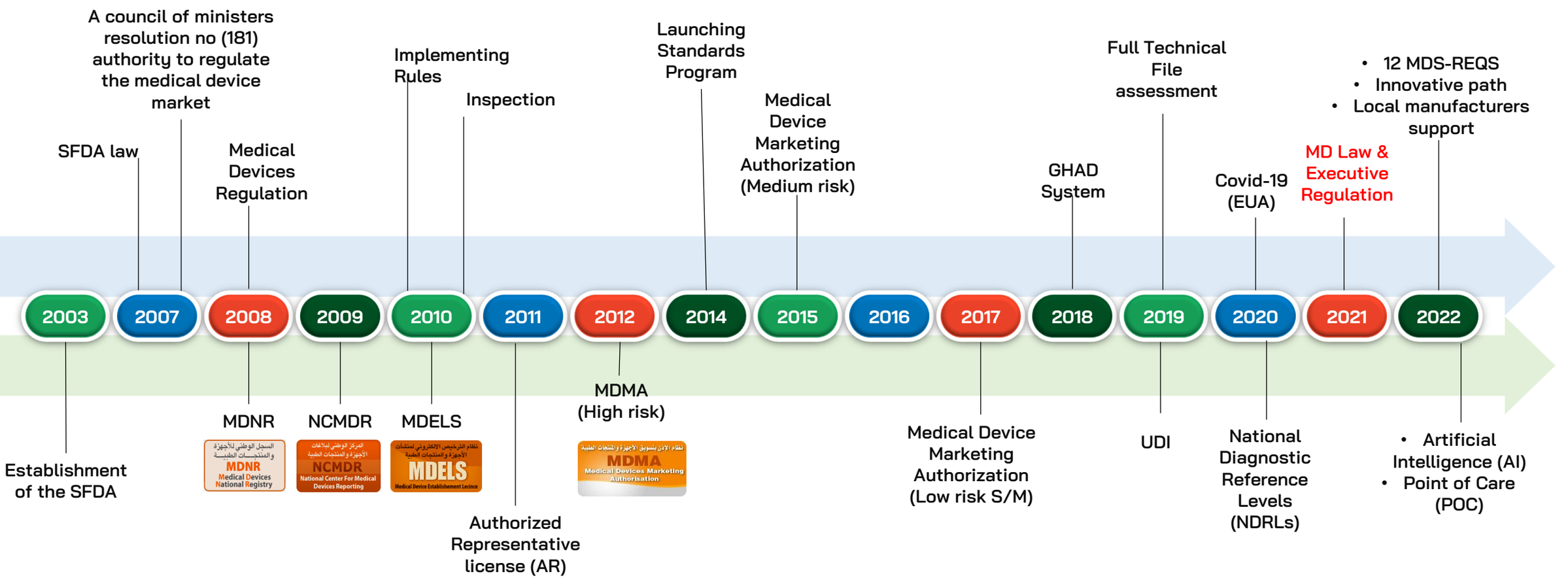
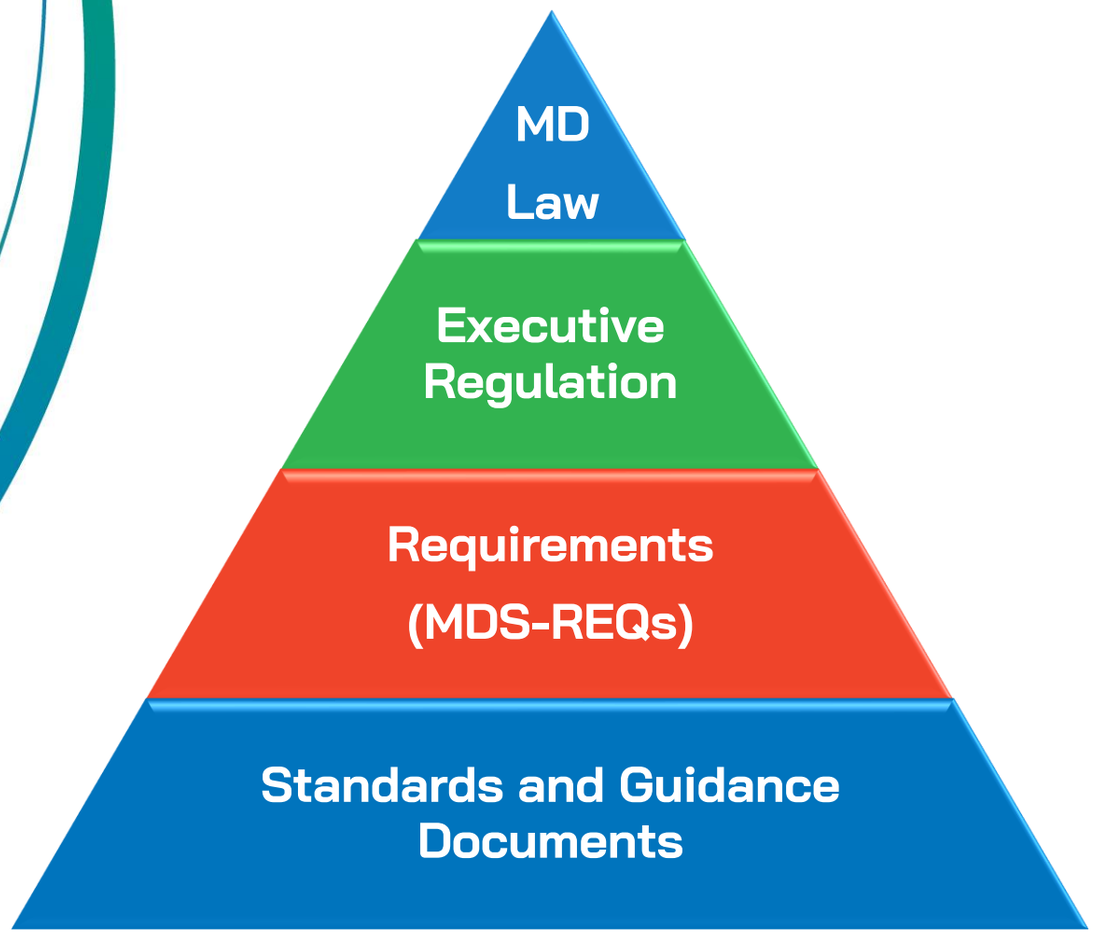
5. SFDA Global Role & Current Strategic projects

Medical Devices Regulation framework

Medical Devices Regulation Key Milestones



SFDA Medical Devices Regulation Framework



- ✓ **Protect the public health** in Saudi by applying the procedures and requirements that assures the patient's safety as well as end user.
- ✓ **Support investments** by having harmonized law which encourages manufactures and big corporates to invest and launch branches in the Kingdom.
- ✓ **Support innovation** and medical devices technology development.
- ✓ **Effective economic impact** for the Saudi market.
- ✓ **Enhance the Kingdom's leading role** internationally in the medical devices field.

Medical Devices Framework Covers:

REQ number	Scope
MDS-REQ1	Medical Devices **Marketing Authorization**
MDS-REQ2	**Clinical Trials** of Medical Devices
MDS-REQ3	**Safe Use** of Medical Devices
MDS-REQ4	**Medical Imaging and Accelerators** Used for Medical Applications
MDS-REQ5	Shipments **Clearance and Importation**
MDS-REQ6	**Radioactive Materials** Used in Medical Applications
MDS-REQ7	**Unique Device Identification** (UDI)
MDS-REQ8	**Advertising** of Medical Devices
MDS-REQ9	Establishments **Licensing**
MDS-REQ10	**Inspection and Quality Management** System
MDS-REQ11	**Post-Market Surveillance**
MDS-REQ12	**transportation and storage** of medical devices

- **In addition, several guidelines covering MD Advanced Technology and Applications**

- ✓ Medical devices **Cybersecurity**
- ✓ **Software** as a Medical Device
- ✓ **3D printing** in medical devices
- ✓ **Innovative** Medical Devices
- ✓ **Artificial intelligence** (AI)
- ✓ **MD Biotechnology**

Requirements for Obtaining a Medical Device Marketing Authorization (MDMA)

Quality Management System (ISO13485)

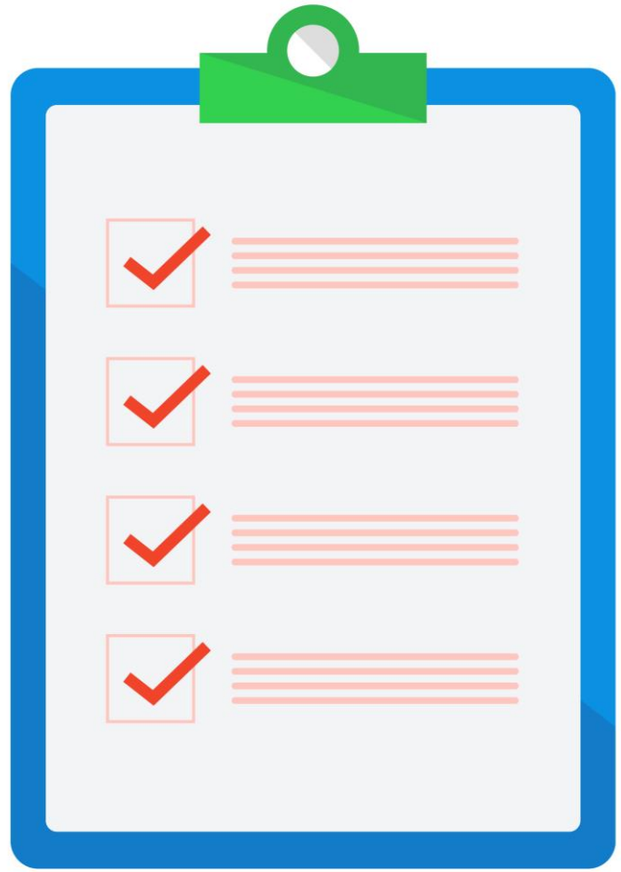
1. SFDA Has adopted the latest version of ISO 13485:2016.

2. Local and Overseas Manufacturers of Medical Devices Shall establish, document and maintain an effective Quality Management System (QMS).

Reference: SFDA MDS-REQ10

Assign Authorized Representative (AR)

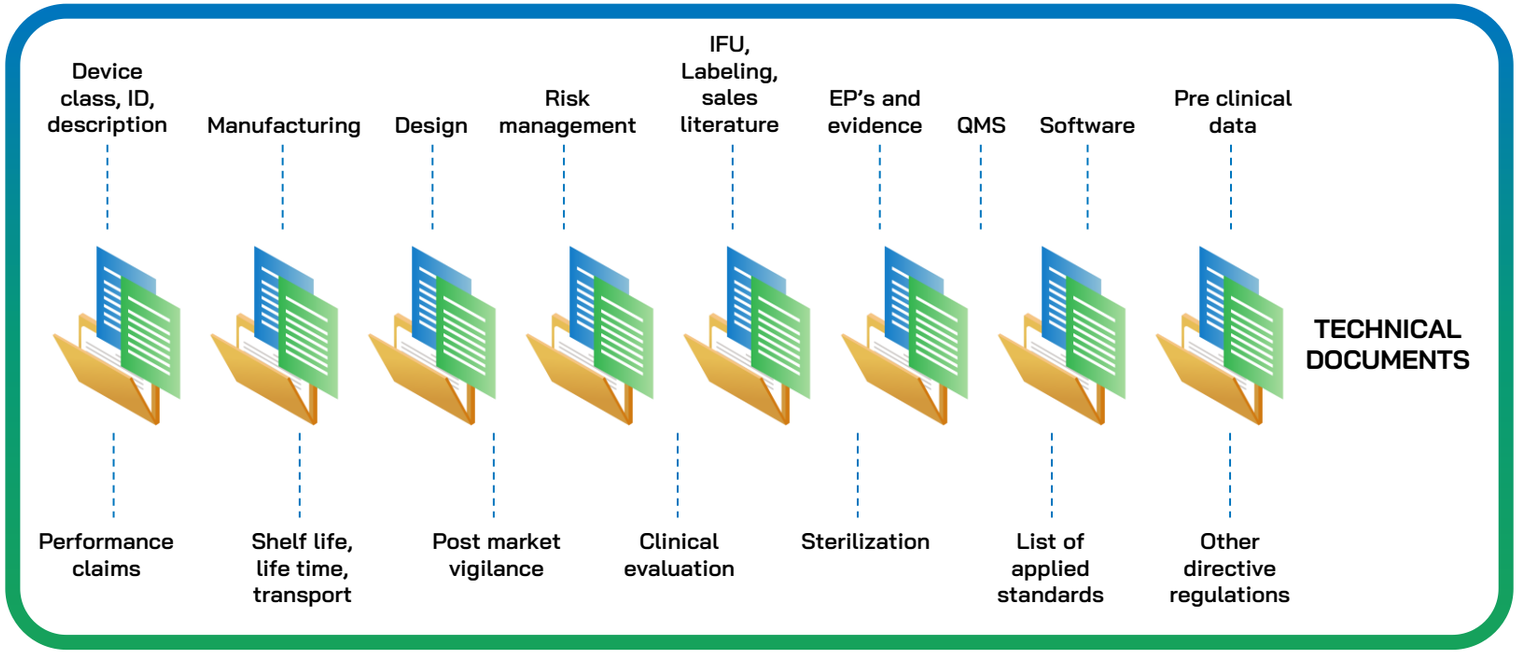
Authorized Representative (AR): Means any natural or legal person established within the KSA who has received a written mandate from the manufacturer to act on his behalf for specified tasks including the obligation to represent the manufacturer in its dealings with the SFDA.

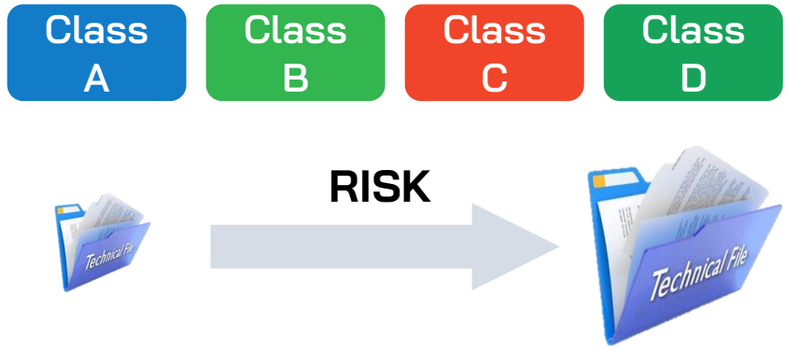


Reference: SFDA MDS-REQ9

Submit Technical Requirements for Scientific Evaluation

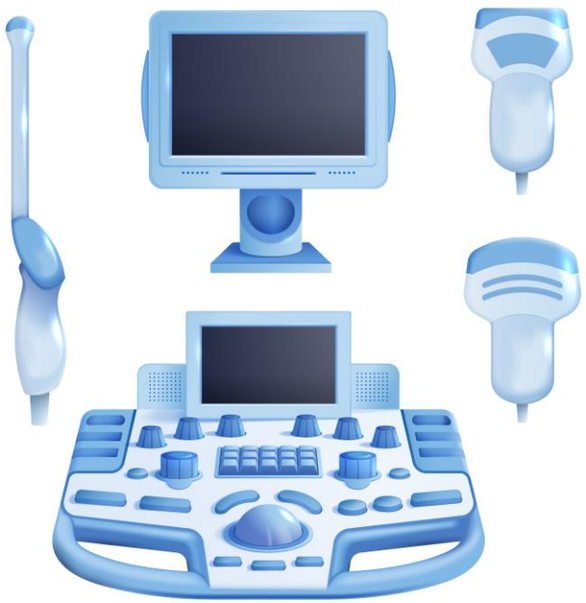
- ✓ Manufacturers of Medical Devices Shall submit the Technical File To SFDA.
- ✓ Technical File Contents are specified clearly in MDS-REQ 1
- ✓ Approvals from Other Authorities are considered as supporting documents.





Technical File's Main Sections

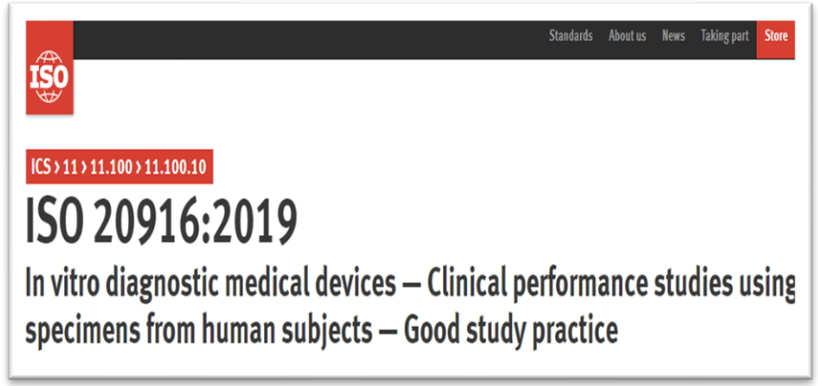
1. Device Description and Specification, Including Variants and Accessories
2. Information to be Supplied by the Manufacturer
3. Design and Manufacturing Information
4. Essential Principles of Safety and Performance
5. Benefit-risk Analysis and Risk Management
6. Product Verification and Validation
7. Post-market Surveillance Plan
8. Periodic Safety Update Report (PSUR) and Post-market Surveillance Report



Clinical Trials of Medical Devices

- Performance Evaluation Studies of In Vitro Diagnostics Medical Devices and
- Clinical Investigations (Trials) of Medical Devices within KSA Shall be approved by SFDA before commencement and comply with ISO 14155:2020 and ISO 20916:2019

All the requirements are clearly specified in SFDA MDS-REQ 2.

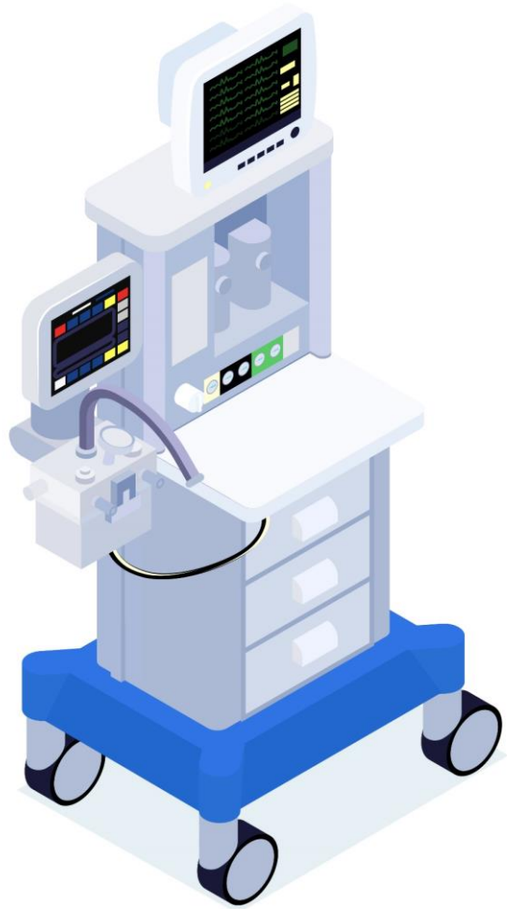


(MDMA) Risk Classes , Time & Fees

Risk Classes	Fees (SR)	Evaluation time
A	15000	35 days
B	19000	35 days
C	21000	35 days
D	23000	35 days

Lowest Risk

Highest Risk



Reference:

Requirements for Medical Devices Marketing Authorization (SFDA MDS-REQ 1)

Innovative Medical Devices Pathway

Article Nine of Medical Devices Law Supports innovation and medical devices technology development.

"SFDA may exempt the innovative medical device from some of the requirements and necessary procedures to obtain a marketing authorization; in a manner that does not affect its safety and effectiveness"

- **SFDA Supports** **(** Developers ,Universities, Manufacturers and Research Centers) with:

Innovative Medical Device Designation Criteria

A medical device may be designated as an Innovative Medical Device if it meets the following conditions:

- ✓ Designed with innovative features in the technology, indications for use, or performance specifications that have no equivalence in the local/global market.
- ✓ Provides considerable clinical/medical advantage over an existing alternative treatment.
- ✓ Any other criteria to be determined by the SFDA and published through the website.

References:

Guidance on Innovative Medical Devices (MDS-G002)

Local Manufacturers & Investors (SFDA Supports)

- ✓ SFDA Supports investors and local manufacturers to **start transferring and localizing** medical devices manufacturing, in order to achieve the kingdom's vision 2030 and achieve the SFDA medical device Law’s objectives.
- ✓ Clarifying technical procedures requirements for Local manufacturers and investors.
- ✓ Cooperation and integration with partners from government agencies .

Manufacturing Pathways

Path 1 — Complete Manufacturing

Path 2 — Partial Manufacturing

Path 3 — Contract Manufacturing (Full or Partial)

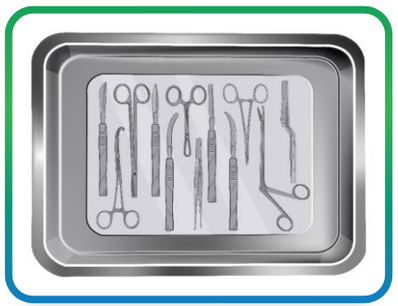
Some examples of Medical Devices Locally Manufactured:

Blood Glucose Monitor

Procedure Pack

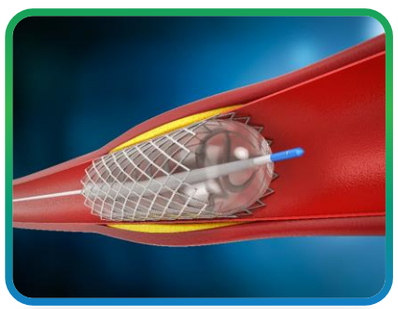
Covid-19

N-95

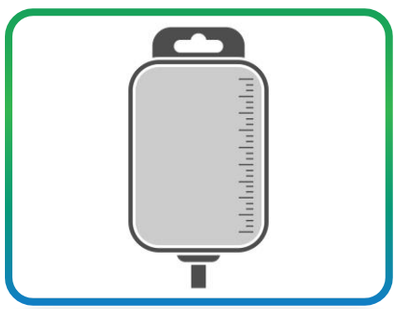


Surgical Instruments

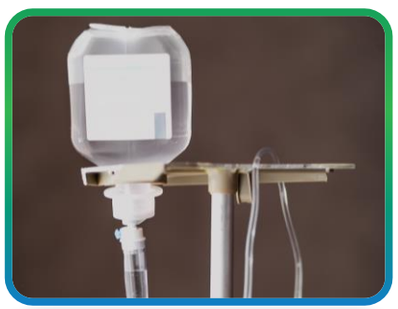
Ventilator



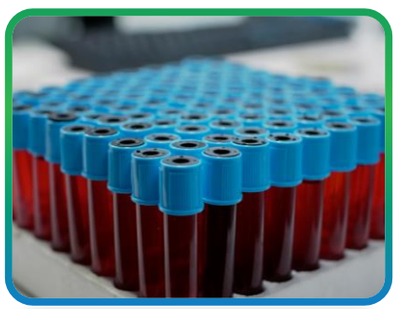
Catheter Balloon



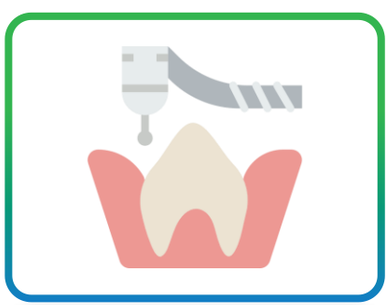
Urine meter



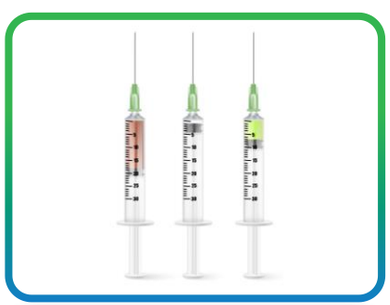
IV Sets



Vacuum blood collection tubes



Dental



Syringes

Medical Gloves

Breathing Circuit

Medical Gown

Safe Use of Medical Devices within Healthcare Providers

Reference:

SFDA MDS-REQ3 (Requirements for the Safe Use of Medical Devices)

Goals

1. Promote the quality and efficiency of health care.
2. Contribute to reduce the incidents related to calibration, maintenance, poor storage, transportation and disposal medical devices
3. To increase the lifetime and reduce the overall cost of health technologies within healthcare providers.
4. To mitigate the risks associated with the usage of medical devices within healthcare providers.
5. To ensure that medical devices within healthcare providers
   - Are utilized appropriately and effectively.
   - Are maintained in a safe and reliable condition.
   - Are operated in accordance with the manufacturer's instructions by trained users and professionals.

Radiological Health

1. The SFDA has formed a national committee, to determine the National Diagnostic Reference Levels (NDRLs) across the Kingdom of Saudi Arabia for various imaging modalities.
2. Follow-up with healthcare facilities to monitor patients' dose and compliance with NDRL.
3. Monitor the safe use of radiation emitting medical devices and imaging devices at healthcare facilities to ensure a high level of safety and protection from ionizing and/or nonionizing radiation.
4. Evaluate importing requests of medical radioactive materials.

المركز الوطني لبلاغات
الأجهزة والمنتجات الطبية

NCMDR

National Center For Medical Devices Reporting

Reference:

Requirements of Post-Market Surveillance (SFDA MDS-REQ11)

SFDA Global Role & Current Strategic Projects

SFDA chairs and participates in different Regional & International Organizations and Technical Committees

Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

World Health Organization

IMDRF International Medical Device Regulators Forum

ISO

IEC International Electrotechnical Commission

هيئة التقييس
لدول مجلس التعاون لدول الخليج العربية
GCC Standardization Organization

المنظمة العربية للتنمية الصناعية والتقييس والتعدين
ARAB INDUSTRIAL DEVELOPMENT, STANDARDIZATION AND MINING ORGANIZATION
A.I.D.S.M.O

WHO Collaborating Centre for medical devices regulations at SFDA

- ✓ **Aims to build capacities** in medical devices regulations regionally and globally.
- ✓ The center **became a global center** in 2022 to support Eastern Mediterranean region (EMR) and African countries.
- ✓ **Two training programs** in medical devices regulations are conducted annually by the center for regulators from EMR and African countries

World Health Organization

Current Startegic Projects

SFDA Regulatory Policies to Enhance Communication and Engagement with healthcare providers and patients in the following areas:

1. Patient Engagement: to enhance regulatory decision-making and include the patient voice in medical product evaluation.
2. Patient Experience: collection of patient experience data related to patients' use of medical devices.
3. Healthcare Practitioner (HCP) Engagement.

Current Startegic Projects

Capacity Building and regulatory framework development regarding biotechnology and new technologies (including AI). It aims to:

1. Improving efficiency and quality of the evaluation of medical devices developed based on biotech and new technologies.
2. Ensuring the accuracy of regulatory decisions taken through building a team with the necessary skills in the field of regulatory sciences to be able to provide solutions to face future challenges and keep pace with the continuous development in the field of the medical device industry
3. Enhancing the SFDA regulatory capabilities to ensure safer and more effective medical devices
4. Supporting the industries of innovative medical device in the Kingdom by providing the regulatory structure that is compatible with it.
5. Closing the regulatory gaps and develop internationally harmonized regulations to keep up with the continuous development of medical devices

شكراً
THANK YOU

To access SFDA-MD Regulations and Requirements

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