IMDRF International Medical Device Regulators Forum

Examples of Applying Standards

SFDA’s Regulatory Perspectives

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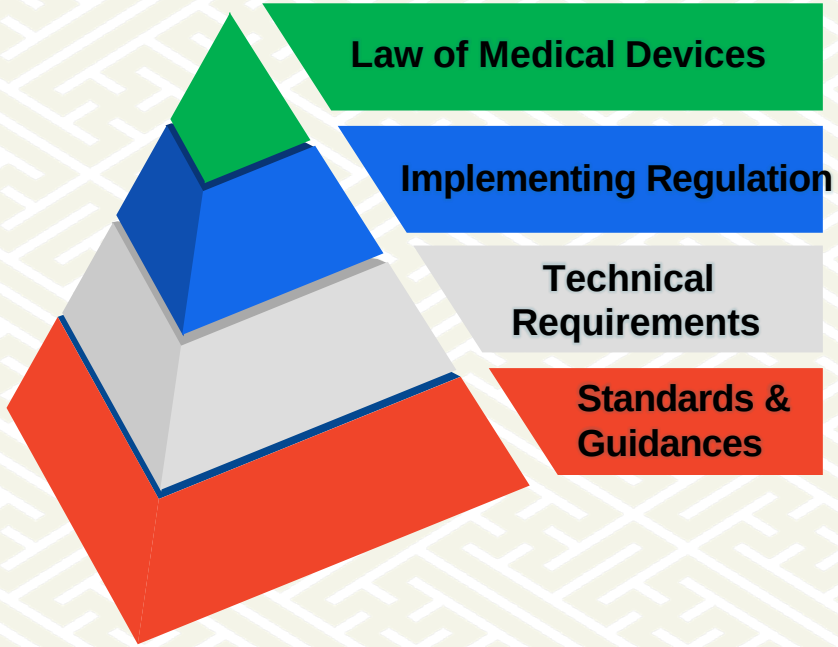
Regulatory Framework

- **Protecting public health** in the Kingdom of Saudi Arabia by implementing procedures and requirements that ensure the safety of the patient as well as the end user.
- **Supporting investments** through the existence of a unified law that encourages manufacturers and major companies to invest and open branches in the Kingdom.
- **Encourage innovation** and development of medical device technology.
- **Effective economic impact** on the Saudi market.
- **Strengthening** the Kingdom's leading global role in the field of medical devices.



Definition of Standards

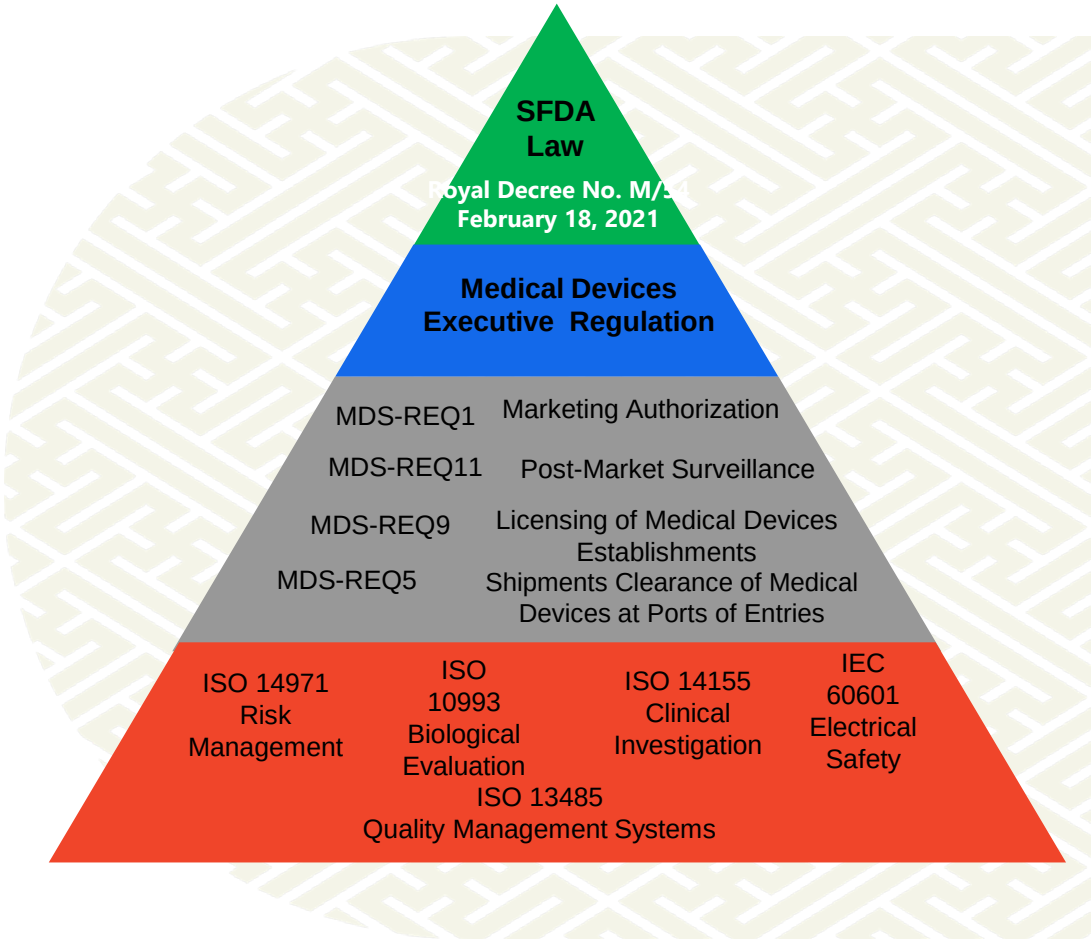
- Documents issued by a national/regional/international standardization body through specialized technical committees. Such documents contain rules, instructions or specifications of products or associated production processes and systems (e.g. Quality Management System and Risk Management System).

  - This is done by setting qualitative and quantitative acceptance limits, specifying verification and validation requirements, and test methods associated with them.

  - Conformity to a standard is not mandatory unless it is enforced by a Regulatory Authority.

Importance of Standards

- **Improve** safety and health
- **Protect** life, environment, consumer and product
- **Facilitate** communication and discussion between the parties involved
- **Reduce** costs
- **Increase production competitiveness** in the local & international markets
- **Remove technical obstacles** encountered by trade movements



SFDA MD Requirements

MD Life Cycle

DESIGN AND DEVELOPMENT	MANUFACTURE	PACKAGING AND LABELING	CLEARANCE	ADVERTISING	SALE	USE	DISPOSAL

✓	REQ number	✓	Title
✓	MDS-REQ1	✓	Medical Devices Marketing Authorization
✓	MDS-REQ2	✓	Clinical Trials of Medical Devices
✓	MDS-REQ3	✓	Safe Use of Medical Devices Inside Healthcare Facilities
✓	MDS-REQ4	✓	The Import and Clearance of Medical Imaging Materials and Particle Accelerators Used in the Formation of Radioisotopes for Medical Applications
✓	MDS-REQ5	✓	Requirements on Importation and Shipments Clearance of Medical Devices and Supplies
✓	MDS-REQ6	✓	Importation and Re-Exportation for Radioactive Materials Used in Medical Applications
✓	MDS-REQ7	✓	Unique Device Identification (UDI) for Medical Devices
✓	MDS-REQ8	✓	Approval of Advertising and Conducting Awareness or Charitable Campaigns of Medical Devices
✓	MDS-REQ9	✓	Medical Devices Establishments Licensing
✓	MDS-REQ10	✓	Inspection and Quality Management System
✓	MDS-REQ11	✓	Post-Market Surveillance of Medical Devices
✓	MDS-REQ12	✓	Transportation and storage of medical devices

Essential Principles and Related Standards

Essential Principles (Eps)		Apply to the Device?	Relevant Standards Applied (Ref; Date; Clauses)	Method of Conformity	Identity of Specific Documents
1	General Requirements				
1.	Devices shall achieve the performance intended by their manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose. They shall be safe and effective and shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art.	Applicable	– ISO 13485:2016, Medical devices - Quality Management Systems - Requirements for regulatory purposes – ISO 14971:2019, Medical devices - Application of risk management to medical devices	To ensure that the device can be safely used, involved the following, but is not restricted to: – Certification and compliance to the Quality Management as per ISO 13485:2016; • Quality Manual • Quality Objectives • Quality Policy	Below are the list of specific documents related to the conformity and/or solutions applied: – Industries ISO 13485:2016 Certification (####) Quality Manual – QM-001 Rev.1 – Risk Management Plan, Form(####) Rev.1
16.5	Imaging medical devices shall be capable of automatically recording dose, protocol data, and patient information such as age, gender and weight in standardized formats.	Not applicable	Not Medical Imaging Device		

The SFDA's Role in Recognizing Standards

- **First**: Study and determine the need to prepare/adopt standards through:
  - Identifying the legislative need, the latest scientific and technical developments and practices, health and economic impact.
  - Determining the need by the Authority and involved parties.
  - Forming technical working groups.
  - Preparing and studying projects and adopting international standards.
  - Adopting and publishing standards and technical requirements.

The SFDA's Role in Recognizing Standards

- **Second**: Verifying the application of standards in all stages of medical device life cycle through:
  - Scientific evaluation of requests for approval and ensuring compliance with the principles of safety and performance.
  - Post-marketing inspection and control procedures and safe use.
- **Third**: Reviewing and developing international and regional standards through active participation in the technical committees of standardization organizations with the aim of:
  - Enhancing the Kingdom's presence
  - Following up on technical developments and updates to international standards

The SFDA's Considerations When Recognizing Standards

- Ensuring the safety and quality of products
- Protecting public health
- Not hindering trade movement, and to achieve harmonization with international standards
- Supporting the national industry by facilitating its access to regional and international markets
- Fulfilling the requirements of the Islamic law
- Engaging the private sector by receiving feedback related to legislation

The SFDA's Global Role in Standardization and Specifications

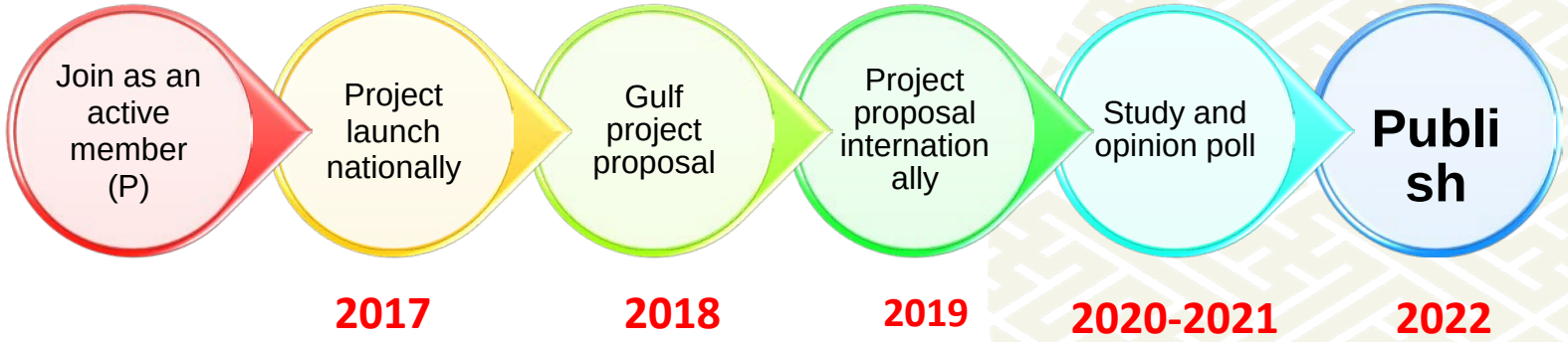
- The work is carried out through specialized technical experts within the field in addition to SFDA experts.
- Through them, the need is determined according to the legislative need, latest scientific and technical developments and practices, and health/economic impact.
- Working on developing the relevant standards to include them in the regulatory legislation to ensure safety, quality, and performance. For example:

Health Informatics ISO/IEEE 11073 series	QMS ISO 13485	Biocompatibilities ISO 10993 series
Sterilization ISO 11137 series	Risk Management ISO 14971	Clinical Trials ISO 14155
Dentistry ISO 9917 series	Electrical equipment IEC 60601 series	IVD's ISO 15197
Medical Syringes ISO 7886 series	Symbols ISO 15223	Implanted ISO 13175

List of Medical Devices Standards National Technical Committees

TC No.	TC Name
SFDA/MDS/TC 45	Medical Textiles and Wound Dressing Products
SFDA/MDS/62 A & D	Common Aspects of Medical Equipment, Software, and Systems
SFDA/MDS/62 B & C	Medical Imaging, Radiotherapy and Nuclear Medicine Equipment
SFDA/MDS/TC 76	Transfusion, Infusion and Injection, and Blood Processing Equipment
SFDA/MDS/TC 84	Needles, Syringes and Catheters
SFDA/MDS/TC 106	Dentistry
SFDA/MDS/TC 121	Anaesthetic and Respiratory Equipment
SFDA/MDS/TC 150	Implants for Surgery
SFDA/MDS/TC 157	Contraceptives and STI Barrier Prophylactics
SFDA/MDS/TC 168	Prosthetics and Orthotics
SFDA/MDS/TC 172	Ophthalmic Optics and Instruments
SFDA/MDS/TC 173	Assistive Products for Persons with Disability
SFDA/MDS/TC 194	Biological and Clinical Evaluation of Medical Devices
SFDA/MDS/TC 198	Sterilization of Health Care Products
SFDA/MDS/TC 210	Quality Management and Corresponding General Aspects for Medical Devices
SFDA/MDS/TC 212	Clinical Laboratory Testing and In Vitro Diagnostic Test Systems
SFDA/MDS/TC 215	Health Informatics
SFDA/MDS/TC 249	Traditional Chinese Medicine
SFDA/MDS/TC 276	Biotechnology

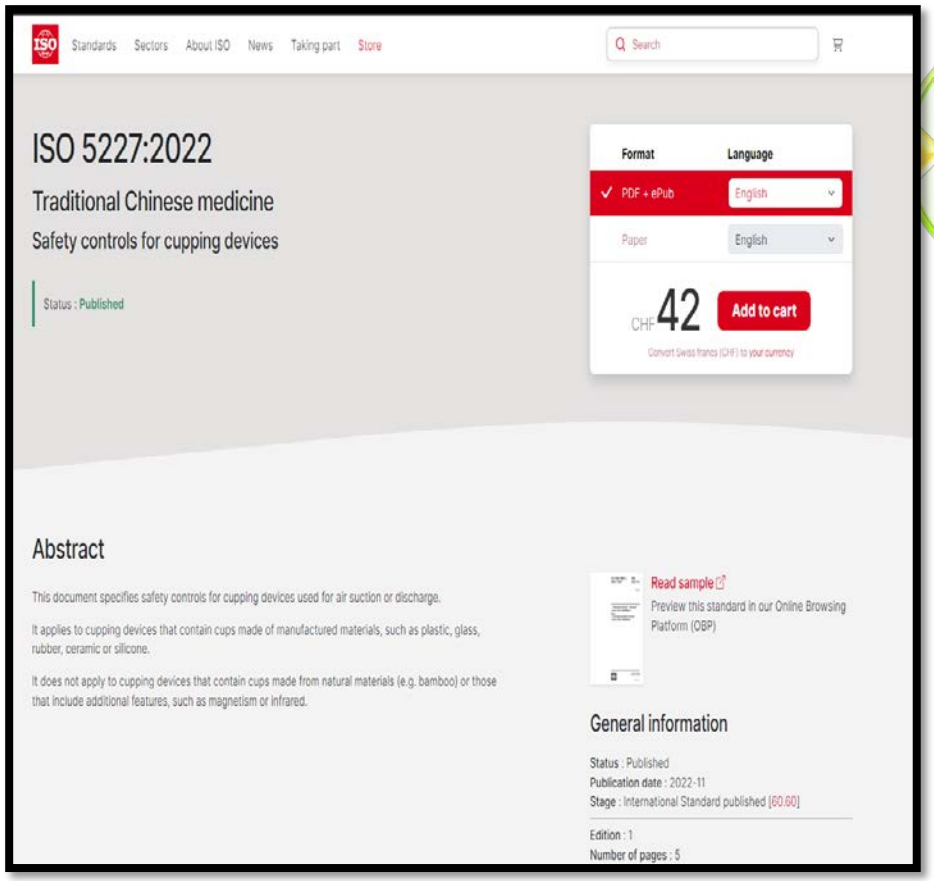
Example of SFDA's Initiatives in the Field of International Standards

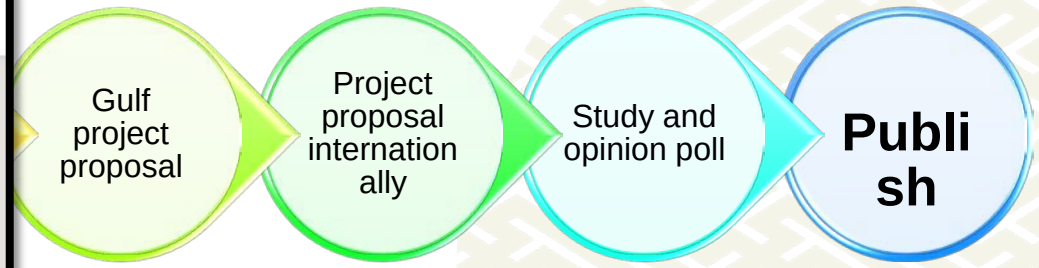


Issuance of the Saudi Standard Specification in the year (2017) in Arabic and English under the title:

SFDA.MD 0001:2017 Safe Use and Handling of Cupping Devices and their Applications

Example of SFDA's Initiatives in the Field of International Standards





Published in the ISO e-store

Example of SFDA's Initiatives in the Field of International Standards

Leading **an international team** to translate medical device quality management standards into Arabic Arabic translation task force Within the work program of the International Technical Committee for Quality Management standards and General Aspects of Medical Devices and Supplies ISO/TC 210	Submitting **international proposal** for initiating new technical standards to International Organization for Standardization

The SFDA's Recognized Standards Supporting Medical Device Premarket Submissions (MDS-G020)

- This list aims to Support Medical Device Premarket Submissions to fulfill medical device marketing authorization requirements through complying with the Essential Principles throughout the medical life cycle.
- Categorized standards classified based on the specific type/technology of the medical device.

The SFDA's Recognized Standards Supporting Medical Device Premarket Submissions (MDS-G020)

General	
1.	ISO 13485 :2016 Medical devices -- Quality management systems -- Requirements for regulatory purposes
2.	ISO 14971:2019 Medical devices — Application of risk management to medical devices
3.	ISO 13022:2012 Medical products containing viable human cells — Application of risk management and requirements for processing practices
4.	ISO 20417:2021 Medical devices — Information to be supplied by the manufacturer
5.	ISO 15223-1:2021 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements
6.	ISO 15223-2:2010 Medical devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 2: Symbol development, selection and validation
7.	ISO/TR 20416:2020 Medical devices — Post-market surveillance for manufacturers

The SFDA's Recognized Standards Supporting Medical Device Premarket Submissions (MDS-G020)

Sterilization and Disinfectants	
1.	ISO 11135:2014/AMD 1:2018 Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices — Amendment 1: Revision of Annex E, Single batch release
2.	ISO 11140-1:2014 Sterilization of health care products - Chemical indicators - Part 1: General requirements
3.	ISO 11140-3:2007, including Cor 1:2007 Sterilization of health care products - Chemical indicators - Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test
4.	ISO 13408-2:2018 Aseptic processing of health care products - Part 2: Filtration
5.	ISO 13408-3:2006 Aseptic processing of health care products - Part 3: Lyophilization
6.	ISO 13408-4:2005 Aseptic processing of health care products - Part 4: Clean-in-place technologies
7.	ISO 13408-5:2006 Aseptic processing of health care products - Part 5: Sterilization in place

The SFDA's Recognized Standards Supporting Medical Device Premarket Submissions (MDS-G020)

Electromedical	
5.	IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
6.	IEC 60601-2-1:2009 Medical electrical equipment - Part 2-1: Particular requirements for the safety of electron accelerators in the range of 1 MeV to 50 MeV
7.	IEC 60601-2-2:2017 Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories
8.	IEC 60601-2-3:2012+AMD1:2016 CSV Consolidated version Medical electrical equipment - Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment

- **EN 60601 a matrix series of standard:**
  - Collateral (60601-1-X)
  - Particular (60601-2-X) standards

- It is possible that a single device can be subjected to the requirements for several standards depending on its application or intended use.

The SFDA's Recognized Standards Supporting Medical Device Premarket Submissions (MDS-G020)

Biological Evaluation	
1.	ISO/TR 10993-22:2017 Biological evaluation of medical devices — Part 22: Guidance on nanomaterials
2.	ISO 10993-23:2021 Biological evaluation of medical devices — Part 23: Tests for irritation
3.	ISO/TR 10993-33:2015 Biological evaluation of medical devices — Part 33: Guidance on tests to evaluate genotoxicity — Supplement to ISO 10993-3
4.	ISO/TR 10993-55:2023 Biological evaluation of medical devices — Part 55: Interlaboratory study on cytotoxicity
5.	ISO/TS 11796:2023 Biological evaluation of medical devices — Requirements for interlaboratory studies to demonstrate the applicability of validated in vitro methods to assess the skin sensitization of medical devices
6.	ISO/TR 21582:2021 Pyrogenicity — Principles and methods for pyrogen testing of medical devices
7.	ISO/TS 21726:2019 Biological evaluation of medical devices — Application of the threshold of toxicological concern (TTC) for assessing biocompatibility of medical device constituents

The SFDA's Recognized Standards Supporting Medical Device Premarket Submissions (MDS-G020)

Implantable Devices	
1.	ISO 7197:2006 + Cor 1:2007 Neurosurgical implants — Sterile, single-use hydrocephalus shunts and components
2.	ISO 9713:2022 Neurosurgical implants — Self-closing intracranial aneurysm clips
3.	ISO 13179-1:2021 Implants for surgery — Coatings on metallic surgical implants — Part 1: Plasma-sprayed coatings derived from titanium or titanium-6 aluminum-4 vanadium alloy powders
4.	ISO/TR 14283:2018 Implants for surgery — Essential principles of safety and performance
5.	ISO 14607:2018 Non-active surgical implants — Mammary implants — Particular requirements
6.	ISO 14630:2012 Non-active surgical implants — General requirements
7.	ISO 16054:2019 Implants for surgery — Minimum data sets for surgical implants

The SFDA's Recognized Standards Supporting Medical Device Premarket Submissions (MDS-G020)

SFDA Recognized Standards (MDS-G020)

- Radiology
- Dentistry
- Optical and Ophthalmic
- Health Informatics
- Medical Face Masks
- Personal Protective Equipment for Medical Purpose
- Complementary and Alternative Medicine
- Contraception
- Other

Thank You