Implementing Regulation of the Law of Medical Devices

Issued by SFDA Board Decision No. (3-29-1443) dated 19/02/1443 AH

"Translated Copy"

Implementing Regulation of the Medical Devices Law

Article 1

The following terms and expressions shall have the meanings assigned thereto respectively, unless the context requires otherwise:

Law: Medical Devices Law.

SFDA: Saudi Food and Drug Authority.

Board: SFDA Board of Directors.

CEO: SFDA Chief Executive Officer.

Regulation: Implementing Regulation of the Medical Devices Law.

Medical Device: Any instrument, apparatus, applied devices, implant devices, in vitro diagnostic reagent or calibrator, software, or material used for operating medical devices, any other similar or related article, intended to be used alone or in combination with other devices for diagnosis, prevention, monitoring, controlling, treatment, or alleviation of disease or injury, or for compensation for an injury; investigation, replacement, modification, or support of the anatomy or a physiological process; supporting or sustaining life; controlling or assisting conception; sterilization of medical devices; providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in return it may be assisted in its intended function by such means.

Medical Supplies: Medical materials and products used in diagnosis, treatment, replacement, modification, disability cases or other medical uses for humans, including medical gases.

Medical Device Accessories: Any material or product made to be used with a medical device to enable it to achieve the purpose for which it was manufactured.

Innovative Medical Device: A medical device with an innovative idea in technology, use or performance, and which has not been previously placed on the market, locally or internationally.

Procedure Packs: Everything that is combined in one set to fulfill the user's requirements. It may contain non-medical devices

Single use Medical Device: Manufactured for the purpose of use on one patient during a single procedure, and then disposed thereof.

Radioactive Medical Materials: A material from which ionizing radiation is emitted, whether by itself, or in other medical devices used for diagnosis and treatment.

Adulterated Medical Devices: Have had their identity or source intentionally changed with the intent of deception. Medical devices are considered adulterated if their contents have been changed in a way that adversely affects their safety and security, or if they are packaged in counterfeit packages.

Reprocessing: Measures made on the previously used medical device to be reused safely, including:

- cleaning;
- disinfection;
- sterilization; and
- testing and restoring the technical and safety functions related to it.

User: A professional, lay person, or a patient who uses a medical device.

Establishment: A legal entity involved in an activity related to medical devices.

Manufacturer: Any national or foreign establishment whose purposes include designing or manufacturing medical devices to offer them for use in its own name, whether inside or outside the Kingdom. Manufacturing includes:

- refurbishing;
- assembling;
- packaging;
- wrapping; and
- labelling.

Healthcare Provider: Any government or private establishment that provides healthcare services.

Authorized Representative: A legal person based in the Kingdom who is authorized, in writing, by a Manufacturer located outside the Kingdom to represent it within the Kingdom with regard to the implementation of the "Medical Devices Law and its Regulation".

Trading of Medical Devices: Providing devices on a free or fee-paying basis, whether for distribution or use.

License: A document issued by the SFDA to practice any of the activities subject to the Law.

National Registry: The National Registry of Medical Establishments, Devices established by the SFDA.

Registration: The procedure by which medical devices, and establishments that practice any of the activities subject to the law are registered in the National Registry.

Marketing Authorization: A document issued by the SFDA for any medical device it allows to be traded in the markets.

Free Sale Certificate: A document issued by the SFDA to the Manufacturer stating that:

- the Manufacturer is registered in the Kingdom; and
- that the medical devices to be exported have a Marketing authorization.

Clinical Trial / Investigation: Applied research in which a medical device is used on one or more persons to assess its safety and sufficiency when used.

Classification System: A system adopted by the SFDA that assesses the level of risk related to the medical device and its safety.

Quality Management System: A system adopted by the SFDA to verify the quality, effectiveness, and safety of the medical device at all stages in its life cycle in accordance with the latest version of the technical standard (ISO 13485), or its equivalent, as set out in the Regulation.

Quality Assurance: A set of technical tests, measurements and calibration adopted by SFDA, to ensure the safety and security of medical radiography devices, as well as the accuracy and quality of radiographs, in order to ensure the efficacy and adequacy of diagnosis and treatment.

Technical Regulations: Mandatory documents issued by the SFDA for medical devices that specify the principles and requirements for design, manufacture safety and performance of Medical Devices.

Standards: Non-mandatory documents adopted by the SFDA which include:

- rules and / or guidelines;
- characteristics of medical devices; and / or
- related production processes and methods, including:
    - terminology;
    - symbols;
    - packaging; and
    - identifying information requirements.

Identifying Information: Any statement or information drawn or illustrated / written or printed on the medical device, including:

- Name of the device;
- Code / lot or serial number;
- technical description;
- method of use; and / or
- manner of storage and transportation.

Technical and Clinical Specifications: Documentation that determines the quality, efficacy and safety of specified devices or substances.

Safety Alert: A notification issued by NCMDR indicating the risk associated with a medical device and the corrective action to be taken to mitigate the associated risk.

Filed Safety Corrective Action: An action taken by the Manufacturer to eliminate or reduce the risks affecting the safety of a medical device.

Medical Device Adverse event: Any defect, malfunction or change in the characteristics or performance of a medical device that may directly or indirectly cause or contribute to the death or serious injury of a user.

NCMDR: The National Center for Medical Devices Reporting.

Regulation

1.1. In addition to the terms and expressions provided in the Law, the following terms and expressions, wherever mentioned throughout this document, shall have the following meanings assigned to them, unless the context requires otherwise:

Complaint: Any form of written or oral communication regarding deficiencies related to the medical device. These include, but are not limited to:

- quality;
- efficacy;
- efficiency;
- usability;
- safety or performance; and / or
- deficiencies related to maintenance that affect the performance of the medical device.

Combination Products: a product consists of two or more components subjected to the SFDA Regulations.

Medical Imaging Materials: Any contrast media used in humans to enhance images obtained using medical imaging techniques.

Refurbished Medical Device: A used medical device which has been returned to a state that allows it to undergo the same conformity assessment procedures that apply to the original medical device.

Home-Use Medical Device: A medical device intended for use in any environment outside of a healthcare facility or emergency vehicle.

Lay Person: A person who has not received any accredited training or education in a relevant field or specialty.

Supply Chain: A set of activities that a medical device goes through, from the design and manufacturing stage until it reaches the user.

Importer: An establishment in the supply chain that imports a medical device to the Kingdom.

Distributor: An establishment in the supply chain which provides a medical device to another distributor or its end user.

Exporter: An establishment responsible for exporting the medical device from the Kingdom.

Traceability: Procedures and / or measures that enable the tracing of medical devices at any stage of the supply chain.

Advertising: Any written, audible, or visible or other media displays intended to promote a medical device or its technology, or to facilitate a direct or indirect sale.

Inspection: A systematic and documented procedure carried out by the SFDA to verify the establishment and / or the Manufacturer's obligations with regard to the particular conditions and requirements for establishments and medical devices set forth in the Law and its Regulation.

Corrective Action: An action taken to address nonconformity reasons for the establishment, manufacturer, or medical device.

Technical Documents: Technical and scientific documentation and information related to the medical device and Manufacturer, including documented and approved procedures, which prove that the medical device conforms to the safety, efficacy, and quality requirements specified in the Law and its Regulation.

Intended Use: The purpose specified by the Manufacturer for the use of the medical device.

Implantable Medical Device: A medical device surgically introduced into the human body or to replace a superficial / epithelial surface, or the surface of the eye and intended to remain in place after the surgical procedure. This includes devices intended to:

- be partially or wholly absorbed.
- remain in the body for thirty (30) days or more.

Consulting Services Establishments: establishments that provide technical consulting services related to regulatory affairs for establishments operating in the field of medical devices in the Kingdom's market.

Contract Research Organizations (CRO): Take charge of follow up clinical trials and conduct all activities related to clinical trials verification.

Establishments for the Conformity of Medical Devices, Quality Management System, and Quality Assurance: Establishments licensed by the SFDA operating as a third-party located in the Kingdom.

Surveillance: A set of procedures to control the safety, efficacy, quality, and effectiveness of medical devices during their circulation within the Kingdom.

Custom-Made Medical Device: A medical device that meets, at a minimum, the following requirements:

- intended for a particular individual (patient or Healthcare Professional);
- manufactured as a result of a written request from an authorized Healthcare Professional who, at their responsibility, gives specific design characteristics;
- aims to address the anatomical, physiological features or pathological condition of the individual for whom it is manufactured.

Patient-Matched Medical Device: A medical device produced based on a standard device design model (e.g. minimum and maximum dimensions or limits for mechanical performance and other relevant medical factors) that conforms a patient's anatomy by:

- using techniques such as device sizing based on anatomical references, or
- using the full anatomical characteristics of the patient's imaging.

which are produced through a verifiable process.

Adaptable Medical Device: A mass-produced medical device that is modified or molded by a healthcare provider, according to the Manufacturer's instructions, to suit the patient-specific anatomical and physiological characteristics prior to use.

Non-Commercial Purposes: Circulating medical devices for research or humanitarian purposes, in limited quantities.

Circulated/Circulating: Placed or made available on the Kingdom market whether for profit or for free.

Applicant: a natural or legal person who meets the necessary conditions and has authorization from the establishment.

Software: A set of applications, protocols, and computations used to operate a device.

Warehouse: A building or part thereof, licensed by the SFDA and designated for storing the medical device.

Medical Gases: Gases that are used to operate or sterilize medical devices, or that are used for treatment or diagnosis without medication, immunological or metabolic interactions to achieve its intended purpose.

Minimally Manipulated Biological Products of Human Origin: Products consisting of human cells or tissues without any changes in their vital properties and which are intended for transplantation or transfer to the human body.

Unique Device Identification (UDI): A series of numbers and letters created according to a globally accepted device identification and coding with the aim of identifying the medical device specifically and clearly during all stages of trading.

Article 2

The following activities shall be subject to the provisions of the Law:

1. The design and manufacture of medical devices.
2. The importing, marketing, distributing, and storing of medical devices.
3. The provision of auditing or other services to verify the conformity of medical devices with regulations and standards.
4. The conduct of clinical trials.
5. The provision of medical device consultancy.
6. The provision of laboratory or technical services for examining medical devices in order to ensure that they comply with technical regulations and standards.
7. The provision of maintenance services for medical devices.
8. Representing manufacturers located outside the Kingdom

Regulation

2.1 In addition to the provisions stated in the Law regarding aspects of activity, the provisions of the Law and its Regulation shall apply to the following establishments, devices and products:

First: The Following Establishments:

A. Establishments practice electronic activities subject to the provisions of the Law and its Regulation.
B. Establishments for import and export of Radioactive Medical Materials, medical imaging materials, or particle accelerators used in the formation of radioactive isotopes for medical applications.
C. Establishments for exporting medical devices.

Second: The Following Devices and Products:

A. Combination products.
B. Cosmetic devices and products that have medical applications, and SFDA shall publish an updated list of such devices and products.
C. Cosmetic contact lenses.
D. Particle accelerators used in the formation of radioactive isotopes for medical applications.
E. Non-genetically modified bioproducts of human origin.

Article 3

Procedure Packs, and their accessories shall be treated as medical devices, subject to the provisions of the Law.

Regulation

3.1 The SFDA shall issue and publish on the SFDA's website the necessary requirements for medical device procedure packs.

Article 4

Subject to the competencies of the Nuclear and Radiological Regulatory Commission (NRRC) to issue the necessary licenses to practice activities related to the use of radioactive medical materials; the SFDA's approval of the technical and clinical specifications of such materials is required before they are licensed by the NRRC.

Regulation

4.1 Establishments and / or applicants involved in importing or re-exporting radioactive medical materials shall fulfill the SFDA's requirements for importing and re-exporting such materials used in medical applications, with these requirements being published on the SFDA's website.

4.2 The SFDA shall issue the approval or refusal of the technical and clinical specifications within ten (10) days of the SFDA's receipt of the application for importing or re-exporting radioactive medical materials.

4.3 Applicants for importing particle accelerators used in the formation of radioactive isotopes for medical applications shall fulfill the SFDA's requirements published on the SFDA's website.

Article 5

The application of the provisions of Law shall not prejudice the competencies of the NRRC with regard to issuing an Ionizing Radiation Protection License for emissions from medical devices.

Regulation

5.1 The SFDA shall issue Marketing Authorization Certificates for radiation-emitting medical devices.

5.2 Radiation-emitting medical devices may be circulated only after obtaining a Marketing Authorization Certificate issued by the SFDA.

5.3 SFDA shall monitor the compliance of the Radiology, Nuclear Medicine and Radiotherapy Departments of healthcare providers to the SFDA's requirements for the safe use of medical devices published on the SFDA's website.

5.4 SFDA shall monitor the compliance of healthcare providers with the technical and clinical specifications for radioactive medical materials within healthcare facilities, and refer violations to the NRRC**.**

Article 6

Subject to Article (4) of the Law, an establishment may only practice any of the activities subject to the Law after they have registered and obtained a License. In addition, an industrial License must be obtained from the Competent Authority for manufacturers.

Regulation

6.1 SFDA shall issue a special registration number for each establishment subject to the provisions of the Law and its Regulation.

6.2 Establishments practicing any of the aspects of activity subject to the provisions of the Law shall obtain a license for the establishment, its branches and warehouses from SFDA in accordance with the conditions and requirements set forth herein.

Article 7

The licensee conducting a clinical trial shall obtain the approval of the SFDA before starting any clinical trial or investigation, as determined by the Regulation.

Regulation

7.1 The SFDA will issue the approval to conduct the following:

1. Clinical trial/ investigation for medical devices.
2. Clinical Performance studies for in vitro and diagnostic devices.

7.2 Applicants seeking approval to conduct clinical trials shall provide the following information prior to initiation:

1. The approved Clinical Investigation Plan (CIP).
2. The approval of the Institutional Review Board (Ethics Committee).

3. Information on investigators.
4. The clinical trial agreement between the clinical trial Sponsor and the Contract Research Organisation (CRO).
5. The clinical trial agreement between the Manufacturer and the Sponsor, if the Sponsor is not the manufacturer.
6. Technical documentation which meets the essential principles and any other requirements specified by this regulation.
7. Fulfilment of any / all other requirements specified by the SFDA and published on the SFDA's website.

7.3 A full-time Saudi national responsible for clinical trials shall be appointed, with an appropriate academic qualification of no less than a bachelor's degree, and experience in the field of clinical trials of not less than three (3) years.

7.4 The clinical trial of medical devices shall meet the requirements published on the website and comply with the Saudi Arabia Law on Ethics of Research on Living Creatures.

7.5 The SFDA shall:

1. Review requests to conduct clinical trials and grant approval, if the requirements are met, no later than sixty (60) days from the date of fulfilling the requirements.
2. Conduct visits to the clinical trial sites to ensure compliance with the implementation of the study, as approved.
3. Grant an Import Permit for medical devices and other products needed to conduct a clinical trial.

7.6 The entities authorized by the SFDA to conduct clinical trials shall notify the SFDA of:

1. The completion of clinical trials.
2. Major deviations from the plan of the trial.
3. Any occurrence that affects safety or breaches the rights of the persons subject to the study.

The SFDA must be notified within five (5) days of any / all of the above, and no later.

7.7 The SFDA may stop a clinical trial if it is proven that:

- a breach has occurred in the approved plan of the clinical trial; or
- an issue has arisen that may affect the safety of the participants.

7.8 The manager of the Contract Research Organization (CRO) shall be a full-time Saudi national holding a bachelor's degree, as a minimum, in one of the health or scientific disciplines related to medical devices.

Article 8

No medical device shall be traded in the Kingdom, unless it is registered and obtains Marketing Authorization from the SFDA. The SFDA may exclude some medical devices from the necessity of obtaining Marketing Authorization, after ensuring that they are safe and not used for commercial purposes, in accordance with rules approved by the Board.

Regulation

8.1 No medical device shall be circulated in the Kingdom without being scientifically assessed by the SFDA, in accordance with the requirements for Medical Devices Marketing Authorization (MDMA), published on the SFDA's website to ensure its safety and security, and obtaining Marketing Authorization.

8.2 After obtaining the marketing authorization, the medical devices shall be listed in the National Registry, and the same shall be deemed a registration thereof.

8.3

First: The SFDA may exclude some medical devices from the necessity of obtaining Marketing Authorization for humanitarian and research purposes, after ensuring their safety according to the following rules:

A. Public emergencies such as natural disasters, wars, or epidemics.
B. Personal use in accordance with the conditions set forth in Article (13.2) of the Regulation.
C. Research or educational uses.
D. Pre-marketing clinical trials that obtained the SFDA's approval for the clinical trial.
E. If they are custom-made for a specific patient, at the request of the treatment team.
F. Samples of medical devices used in exhibitions, festivals or workshops.

Second: An import permit shall be obtained from the SFDA for the medical devices mentioned in Clause (First), in accordance with the requirements for importing, exporting, and clearing medical devices published on the SFDA's website.

Article 9

The SFDA may exclude an innovative medical device from some of the conditions and procedures required to obtain Marketing Authorization in a way that does not affect its safety and performance when used as intended, as determined by the Regulation.

Regulation

9.1 A medical device shall be deemed innovative if the following conditions are met:

- It is designed with innovative characteristics / features, (technology / methods of use / performance characteristics), and there are no similar technologies in the local and international market.
- It has a clinical / medical benefit that exceeds the available alternatives.
- Any other conditions set by the SFDA and published on the SFDA's website.

9.2 The applicant shall provide the necessary information to prove the conformity of the innovative medical device with Article (9.1) in accordance with the requirements for Medical Devices Marketing Authorization, published on the SFDA's website.

9.3 The SFDA has the right to request further information from the applicant before making the final decision on whether to consider the medical device innovative.

9.4 Innovative medical devices shall be excluded from some of the requirements and procedures required to obtain Marketing Authorization based on the type and technology used, as determined by the requirements of innovative medical devices published on the SFDA's website. The SFDA has the right to exclude from the following requirements:

- Verification and validation of the product, including clinical trials.
- Periodic safety update reports and Post-Market Surveillance reports.
- Detailed information on design and manufacturing.

9.5 The applicant shall conduct clinical trials in accordance with the requirements of medical device clinical trials, if requested by the SFDA.

9.6 SFDA shall determine and update the requirements for innovative medical devices in accordance with the technical development.

Article 10

The Regulation determines the conditions and procedures required for registration, issuance of Marketing Authorization, and obtaining, renewing, modifying, transferring and revoking the license.

Regulation

10.1 Conditions, requirements and procedures for obtaining a Marketing Authorization Certificate:

The manufacturer shall obtain a Marketing Authorization Certificate from the SFDA before circulating any medical device in the Kingdom, in accordance with the provisions of the Law and its Regulation.

10.2 The Manufacturer shall submit the e-application form for obtaining a Marketing Authorization Certificate for medical devices published on the SFDA's website, and provide the SFDA with supporting documents in accordance with the requirements for of Medical Device Marketing Authorization including, but not limited to:

1. Contact details of the Manufacturer.
2. Contact details of the Authorized Representative, the national registry number of its establishment, and the License number issued by the SFDA, if the applicant is an Authorized Representative.
3. Name of the person authorized to complete the application for Marketing Authorization of medical devices, and their contact details.
4. An undertaking from the Manufacturer to keep the SFDA informed of all actions taken to preserve the safety and compliance of medical devices that were imported to the Kingdom, as set out in the requirements for Medical Device Post -Market Surveillance.

10.3 The following technical requirements shall be submitted to obtain a Marketing Authorization Certificate for medical devices, including but not limited to:

1. The necessary documents proving that the medical device to be marketed is compatible with the safety and performance essential principles specified in the Requirements of Medical Device Marketing Authorization.
2. Submitting the Technical Documents for the medical device determined by the SFDA, including:
    A. Description of the medical device and its characteristics, including variations and accessories.
    B. Design and manufacturing information.
    C. Risk management file
    D. Verification and validation of the product including clinical trials
    E. Post Market Surveillance Plan
    F. Periodic Safety Update Reports and Post-Market Surveillance reports.
3. A copy of the labelling and a guarantee of the fulfillment of the labelling content, according to its intended purpose.
4. Information on measures related to environmental conditions and / or usage in the Kingdom.
5. Classification of the medical device or in vitro diagnostic device in accordance with the classification rules provided herein.
6. Proof indicating that the Manufacturer has applied the Quality Management System as referred to in Article (22.1).

7. Proof of compliance with the relevant technical regulations or standards set and published by the SFDA.
8. Attestation indicating that the medical device is compatible with the provisions hereof.
9. Any other conditions required by the SFDA and published on the SFDA's website.

The SFDA has the right to request further Technical Documents, when needed, before deciding on whether to proceed with the Marketing Authorization application.

10.4 Different medical devices may be bundled into a single Marketing Authorization application, as determined by the requirements for medical device Marketing Authorization

10.5 The SFDA shall issue a Marketing Authorization Certificate for the medical device when the applicant fulfills the Requirements for Medical Device Marketing Authorization. The Certificate shall be valid for a term of up to three years (3) from its date of issue.

10.6 The SFDA shall notify the applicant of the reasons for refusal of an application for Marketing Authorization. The applicant may object to the refusal in accordance with the applicable legal procedures.

10.7 The Manufacturer or Authorized Representative shall renew the Marketing Authorization Certificate before the Certificate expires and submit the updated documents, if necessary, through the electronic system.

10.8 The information and documents submitted to the SFDA via the electronic system shall be updated within ten (10) days of any material change to the information or thirty (30) days for non-material changes, as determined by the Requirements for Medical Device Marketing Authorization.

10.9 To obtain the necessary licenses to practice any of the activities subject to the Law, the following procedures shall be fulfilled:

1. Creating / opening an account in the SFDA's electronic system and obtaining an establishment number.
2. Submitting an application in the SFDA's electronic system for the purpose of obtaining an Activity Practicing License.
3. Paying the fees for the establishment the establishment category and / or for the Activity Practicing License, if the application is accepted.
4. Submitting all required documents through the SFDA's electronic system.
5. Any other procedures required by the SFDA and published on the SFDA's website.

In addition, the SFDA shall:

1. Visit the establishment to ensure that the establishment's documentation, and implementation of the Quality Management System, meets the requirements of Article (22.1).
2. The SFDA shall be notified if the License is modified through the electronic system, and the required documents shall be submitted.

10.10 The SFDA shall determine the scope of activities of the Licensed establishments, and the technical and administrative requirements necessary to practice their activities.

10.11 Importers and distributors licensing requirements:
Importers and distributors of medical devices shall fulfill the requirements below to obtain a License from the SFDA:

1. Provide the Manufacturer's information and information on the medical devices to be imported, in addition, the information of the Authorized Representative for a Manufacturer located outside the Kingdom.
2. Submit a documented procedure for tracking the medical device during the importing or distribution phase and submitting an undertaking to implement and adhere to the procedure.
3. Submit a documented procedure for the storage and transportation of the medical device in accordance with the requirements of the Manufacturer. Submit an undertaking to implement and adhere to the procedure.
4. Submit proof of the implementation of the Quality Management System referred to in Article (22.1) of the Regulation.
5. Appoint an authorized person to deal with the SFDA, on behalf of the establishments, in accordance with the requirements set by the SFDA.
6. Fulfil any other requirements determined by the SFDA and published on the SFDA's website.

10.12 Licensed importers and distributors shall comply with the following requirements:

1. Work in accordance with the requirements referred to in Article (10.11).
2. Comply with the Manufacturer's requirements in addition to the requirements for Transportation and Storage of Medical Devices published on the SFDA's website.
3. Ensure that all necessary documents are submitted with each medical device:
    A. Marketing Authorization Certificate.
    B. Declaration of Conformity declaring that the medical device meets the requirements of the Medical Devices Law and its Regulation, signed by the Manufacturer.
    C. Unique Device Identification (UDI) of the medical device, which includes the machine-readable code according to the Unique Device Identification for medical devices requirements.
    D. Labelling information and other relevant documents.

E. Contact details of the Manufacturer, and the Authorized Representative, if the Manufacturer is outside the Kingdom.

4. Only import and / or distribute medical devices that comply with the requirements of the Medical Devices Law and its Implementing Regulation.
5. Provide sufficient and appropriate human resources and other resources to meet the requirements determined in the Medical Devices Law and its Implementing Regulation.
6. Fulfil any other requirements set by the SFDA and published on the SFDA's website.

10.13 Requirements for Licensing of Medical Devices Warehouse, the establishment shall:

1. Undertake not to store any medical device which violates the SFDA's requirements.
2. Obtain the necessary licenses from the Competent Authorities.
3. Appoint a full-time Technical Manager for the warehouse who is a biomedical engineer, a technician or qualified in a related discipline.
4. Comply with any other requirements determined by the SFDA and published on the SFDA's website.

10.14 Requirements for Medical Devices Warehouses:

1. Compliance with the Manufacturer's requirements and the requirements for Transportation and Storage of Medical Devices published on the SFDA's website
2. Apply for license renewal in accordance with Article (10.35) of the Regulation.
3. Any other requirements determined by the SFDA and published on the SFDA's website.

10.15 Third-Party Storage Requirements:

1. The main lessor shall be licensed by the SFDA.
2. A contract shall be signed between the main lessor and the lessee, including the details of both parties and their obligations in accordance with the requirements of the SFDA that includes information on the areas and spaces designated for storage.
3. Any other requirements determined by the SFDA and published on the SFDA's website.

10.16 Requirements for Licensing a Manufacturer in the Kingdom:

1. Establishing and implementing the Quality Management System, as referred to in Article (22.1).
2. Appointing a full-time Technical Manager for the Manufacturer who is a biomedical engineer or technician or qualified in one of the relevant disciplines.
3. Appointing a full-time Quality Manager for the Manufacturer who is a biomedical engineer or technician or qualified in one of the relevant disciplines.
4. Specifying the Manufacturer's activity and the risk class for the medical devices to be manufactured.
5. Obtaining the necessary licenses from the Competent Authorities.
6. Signing a declaration of conformity in which the manufacturer takes full responsibility regarding the quality of all manufactured batches.
7. Any other requirements determined by the SFDA and published on the SFDA's website.

10.17 The Manufacturer shall comply with the Requirements for Unique Device Identification. The SFDA shall determine any excluded medical devices.

10.18 Language requirements for Technical Documents shall be submitted to the SFDA or kept available for inspection:

1. Technical Documents shall be submitted to the SFDA in English, unless the SFDA has previously agreed to accept another language. If a language other than English is used, an English translation of the relevant parts of these documents shall be provided.
2. Labelling information in English shall be accepted if the medical device user is professionally qualified. If the device is intended for a lay person, the label shall be in both Arabic and English.
3. The instructions related to dealing with, storage, transportation, installation, maintenance, and disposal of medical devices shall be in English, as well as in Arabic if the user is a lay person.
4. The promotional, advertising and marketing information shall be in English. If the medical devices user is a lay person, it shall be in both Arabic and English.

10.19 Manufacturers of implantable medical devices shall attach a card containing the following details:

1. Identification of the medical device, including the device name, serial number, lot number, Unique Device Identification data and device model, as well as the Manufacturer's name, address, and website.
2. Any warnings, precautions or measures to be taken by the patient or healthcare provider with respect to cross-interference with anticipated externalities, medical examinations, or expected environmental conditions.
3. Information on the lifespan of the device and any periodic follow-up necessary for the performance of the device.
4. Any other information to ensure the safe use of the device.

10.20 The SFDA may exclude some implantable devices from Article (10.19) in accordance with the conditions determined by the SFDA and published on the SFDA's website.

10.21 Requirements for licensing establishments to verify the conformity assessment of medical devices and the Quality Management System:

The applicant shall provide the SFDA with documents and information in accordance with the requirements for medical device establishment licensing, published on the SFDA's website.

10.22 Requirements for licensing providers of quality assurance and radiation measurements services for healthcare facilities:

The providers of quality assurance and radiation measurements services for healthcare facilities shall fulfill the following requirements:

1. Filling out the form published on the SFDA's website and submit all required documents.
2. Providing professionals / technicians from an accredited authority to practice the activity.
3. Providing measuring devices compatible with international standards.
4. Any other requirements determined by the SFDA and published on the SFDA's website.

10.23 Requirements to be met by providers of quality assurance and radiation measurements services for healthcare facilities:

1. Working in accordance with the requirements referred to in Article (10.22).
2. Compliance with the instructions mentioned in the general guidelines for protection from ionizing radiation in the Kingdom and the national instructions for transporting radioactive materials, or any other documents issued by the Competent Authorities later.
3. Unlicensed sources in terms of number, type and radioactivity shall not be used.
4. The radioactive sources held by the licensee shall not be sold, rented, lent, or donated to another establishment without obtaining approval from the Competent Authorities.
5. Fixed radioactive sources shall not be transferred to any other place within the establishment without obtaining approval from the Competent Authorities.
6. Disposal of radioactive sources, if not needed, shall be carried out according to the general guidelines for radioactive waste management and the general guidelines for protection against ionizing radiation in the Kingdom.
7. Commit to notify the SFDA in the event of:
    a. failure in one of the daily quality assurance tests for radiology and medical imaging devices; and / or
    b. a defect in the shielding of the radiology rooms,

    within three (3) days from the date of the test results report, along with attaching a copy of the report. The report shall include a recommendation on whether the device may continue to be used.
8. Compliance with the SFDA's requirements for safe use published on the SFDA's website.
9. Any other requirements determined by the SFDA and published on the SFDA's website.

10.24 Requirements for licensing contract research organizations.

The contract research organization shall meet the following requirements in order to obtain a License from the SFDA:

1. Completing the application available on the SFDA's website and submitting all the documents mentioned in the Requirements for Clinical Trials of Medical Devices
2. Attaching the CV, Certificates, and experience of the person responsible for the clinical trials.
3. Any other requirements determined by the SFDA and published on the SFDA's website.

10.25 Requirements to be met by contract research organizations:

1. Proof of compliance with good clinical practice for clinical investigation of medical devices (SFDA.MD/ISO 14155:2020), or latest version.
2. Implementation of documented standard operating procedures for the organization.
3. Any other requirements determined by the SFDA and published on the SFDA's website.

10.26 Requirements for licensing establishments for technical advisory services in the field of medical devices:

The applicant shall provide the SFDA with documents and information in accordance with the requirements for the medical device establishments licensing published on the SFDA's website.

10.27 Requirements for licensing providers of medical devices testing / inspection services:

The applicant shall provide the SFDA with documents and information in accordance with the requirements for the medical device establishments licensing published on the SFDA's website.

10.28 The SFDA shall determine the technical regulations and standards for medical devices that are subject to the provisions of the Medical Devices Law and its Regulation.

10.29 Requirements for licensing medical device maintenance service providers:

1. Providing technical staff who are biomedical engineers and technicians, according to the following conditions:
    A. Academic or technical qualifications in biomedical engineering / technology or any relevant discipline.
    B. Receive specialized training from the Manufacturer or from a person trained by the Manufacturer on their medical devices.
2. Availability of appropriate test equipment to examine the medical device function, its calibration, performance efficiency and safety, which shall be compatible with the Measurement and Calibration Law issued by Royal Decree No. (M/51) dated 13/11/1434 AH, its Implementing Regulation and relevant instructions.
3. Any other requirements determined by the SFDA and published on the SFDA's website.

10.30 Requirements to be met by medical maintenance service providers:

1. Working in accordance with the conditions referred to in Article (10.29).
2. Providing a maintenance management system and inventory management system to collect, store, organize, analyses and record medical device information, in addition to the necessary spare parts, and a list of all spare parts suppliers approved by the Manufacturer.
3. Providing original spare parts to the department / person requesting maintenance service at the healthcare facility immediately. Delays are not acceptable, except if they are justified in cases where corrective maintenance is required.

4. Applying the instructions issued by the Manufacturer regarding corrective maintenance and calibration. If the instructions are not available, it shall be referred to the standard approved by the SFDA.
5. Any other requirements determined by the SFDA and published on the SFDA's website.

10.31 Requirements for licensing Authorized Representative:

1. Obtaining a documented and approved authorization from the Manufacturer indicating the activities practiced by the Authorized Representative on behalf of the Manufacturer. The authorization must ensure the appropriate application of the provisions of the Medical Devices Law and its Regulation.
2. Implementing a Quality Management System as referred to in Article (22.1).
3. Any other requirements determined by the SFDA and published on the SFDA's website.

10.32 The License shall be valid for one year or similar periods, and is renewable, as referred to in Article (10.35) of the Regulation.

10.33 The SFDA may refuse to issue a License for establishments when the requirements are not met, subject to the provisions of the Law. The applicant will be notified of the reasons for refusal.

10.34 The Licensee shall notify the SFDA of any change in the information submitted to obtain the License within ten (10) days of the change.

10.35 The establishment may apply for License renewal sixty (60) days before the expiry date of the valid License by submitting a renewal application through the SFDA's electronic system, attaching all required documents, and paying the fee.

10.36 The applicant may revoke the License in accordance with the requirements for licensing establishments of medical devices published on the SFDA's website.

10.37 The establishment wishing to revoke the License or upon its expiry shall fulfill the following:

1. Submit the application through the SFDA's electronic system or notify the SFDA.
2. Submit proof that the establishment has no obligations.
3. Submit any other documents required by the SFDA.

Article 11

Imported medical devices may be cleared only after the SFDA's approval.

Regulation

11.1 Imported medical devices may be cleared only after obtaining a Marketing Authorization from the SFDA, or an Import Permit if they are excluded from obtaining Marketing Authorization, as referred to in Article (8.3).

11.2 Medical devices containing chemicals, restricted gases, or radioactive medical materials may be cleared only after obtaining a Marketing Authorization and Import Permit from the SFDA.

11.3 Imported medical devices shall be:

1. In conformity with the provisions of the Medical Devices Law, its Implementing Regulation, the approved technical regulations, and any decisions, conditions or requirements contained in the circulars issued by the SFDA.
2. Imported by an establishment with a valid license.
3. Made by a Manufacturer having an Authorized Representative with a valid License.
4. Accompanied by the official documents and Certificates set forth in the approved technical regulations, decisions and circulars issued by the SFDA.
5. Without warnings issued against them by the SFDA.

11.4 Used medical devices may be imported for the purpose of maintenance or Refurbishment in the Kingdom, provided that an import permit is obtained. The establishment shall re-export them as circulating them in the Kingdom is prohibited.

11.5 Used medical devices, which were exported based on a prior export permit from the SFDA, may be imported to the Kingdom for the purpose of:

- Maintenance.
- Calibration.
- Display as marketing samples.
- Correction according to a safety alert notice if required.
- Testing.

They must have an Import Permit before their re-entry into the Kingdom.

11.6 Medical devices may be re-exported only after obtaining the SFDA's approval and in accordance with the requirements published on the SFDA's website.

11.7 Medical imaging materials may be circulated only after fulfilling the requirements for importing and clearing the medical imaging materials published on the SFDA's website, and obtaining an Import Permit from the SFDA.

11.8 Medical devices may not be imported in the following cases:

- Used medical devices for the purpose of circulation, except as provided for in Articles (11.4) and (11.5).
- If the product expiry date at the port of entry is less than the time periods set out in the clearance requirements published on the SFDA's website.

11.9 Particle accelerators used in the formation of radioactive isotopes for medical applications may be circulated only after fulfilling their import and clearance requirements published on the SFDA's website.

11.10 The SFDA may take random samples from incoming shipments through customs ports to ensure their safety and security, without bearing any costs of such samples or the costs of examining them in laboratories.

Article 12

The Regulation determines the conditions necessary for the issuance of a Free Sale Certificate.

Regulation

12.1 For the purpose of export and at the Manufacturer's request, SFDA shall issue a Free Sale Certificate to the Manufacturer according to the following conditions:

1 The Manufacturer shall be licensed in the Kingdom.
2 The medical devices to be exported should have a Marketing Authorization Certificate.
3 Any other requirements required by the SFDA and published on the SFDA's website.

Article 13

The SFDA may allow the entry of medical devices for personal use, based on a medical report and in limited quantities, provided that they are not used for any business purpose.

Regulation

13.1 The SFDA's approval shall be obtained before importing medical devices for personal use, or devices which are custom-made, along with submitting the required documents and undertakings.

13.2 Imported devices shall be deemed for personal use in the following cases:

1. The home medical devices are intended for lay person use and imported infrequently.
2. The medical devices are custom-made.

3. Submitting the required documents and undertakings to the SFDA.

13.3 A medical device shall not be deemed custom-made if it is:

1. An adaptable medical device.
2. A patient-matched medical device.

13.4 The SFDA may refuse a consignment if it deems that the medical devices are inconsistent with the documents and undertakings submitted to the SFDA.

13.5 The Manufacturer of home-use medical devices shall provide the following:

1. Labelling (including display screens) of the medical device in both Arabic and English.
2. Contact details of technical support centers for users in the Kingdom.

Article 14

Anyone who discovers a fraudulent or unregistered medical device, or disburses or sells a or a device which does not have Marketing Authorization, shall inform the SFDA upon becoming aware of the fact:

- All information related to the medical device that was disbursed or sold.
- Its quantity.
- The name and address of the person to whom the medical device was distributed or sold.

They shall refund the cost of the device to the purchaser.

Regulation

14.1 Establishments and healthcare providers shall:

1. Inform the SFDA of any medical devices that violate the provisions and requirements of the Medical Devices Law and its Regulation, including fraudulent and / or unregistered devices and those which do not have Marketing Authorization.
2. Provide information on such medical devices, including supply and sale details, quantities, the name of the person to whom the medical devices were distributed or sold, and contact details.
3. Provide the SFDA with a corrective plan for medical device.

Article 15

Subject to the provisions of the Commercial Agencies Law, a Manufacturer located outside the Kingdom who wishes to trade its products within the Kingdom shall appoint an Authorized

Representative. The Regulation determines the conditions to be met by the Authorized Representative, as well as the obligations and responsibilities of both parties.

Regulation

15.1 Conditions to be met by the Authorized Representative:
The Authorized Representative shall:

1. Be located in the Kingdom.
2. Hold a license as an Authorized Representative issued by the SFDA for each Manufacturer that it represents in the Kingdom:
    a. in accordance with the agreement concluded with the Manufacturer pursuant to Article (15.2), and
    b. subject to the Regulations in force in the Kingdom
3. Implement a Quality Management System as referred to in Article (22.1).
4. Document the implementation of the necessary operations to perform the tasks entrusted to them and preserve for inspection by the SFDA the records generated by those tasks.
5. Comply with any other requirements required by the SFDA and published on the SFDA's website.

15.2 The Authorized Representative agreement shall include at least the following details:

1. The scope of the activities in which the Authorized Representative is acting on behalf of the Manufacturer in its dealings with the SFDA.
2. The category or group of medical devices, subject to the Medical Devices Law and its Regulation, to be marketed in the Kingdom.
3. The Authorized Representative's commitment to all Post-Market Surveillance requirements published on the SFDA's website.
4. Determination of the term of the agreement concluded between both parties.

Either party may terminate the agreement in accordance with the provisions of the Medical Devices Law.

15.3 Manufacturer obligations and responsibilities:

1. The Manufacturer may not appoint more than one Authorized Representative for the same category or general group of medical devices. The Manufacturer may appoint a different Authorized Representative for each category or general group of medical devices.
2. If the Manufacturer wishes to terminate their agreement with the Authorized Representative, they shall notify the Authorized Representative in writing.
3. The Manufacturer shall appoint a new Authorized Representative and transfer all previous obligations to them immediately upon termination or non-renewal of the agreement with the former Authorized Representative, and the Manufacturer shall notify the SFDA of the change.

4. The Manufacturer shall provide any other information or documents required by SFDA.

15.4 Authorized Representative obligations and responsibilities:

1. The Authorized Representative shall represent the Manufacturer in its dealings with the SFDA.
2. The Authorized Representative shall cooperate with the SFDA in undertaking Post-Market Surveillance activities.
3. The Authorized Representative shall inform the SFDA of any incidents that occur / occurred outside the Kingdom that have consequences on the medical devices circulated within the Kingdom. The Authorized Representative shall explain the circumstances and provide information on the corrective actions taken, or intended to be taken, by the Manufacturer.
4. The Authorized Representative shall inform the SFDA of all corrective actions resulting from any investigation conducted by the Manufacturer for medical devices circulated within the Kingdom. The Authorized Representative shall explain the reasons for the corrective actions and provide information on the actions taken, or intended to be taken, by the Manufacturer.
5. The Authorized Representative shall cooperate with persons who engage in activities, subject to the provisions of the Medical Devices Law and its Regulation, with regard to medical devices circulated in the Kingdom. This shall be documented in the agreement between Authorized Representative and the Manufacturer.
6. The responsibility of the Authorized Representative for the medical devices included in the agreement shall not end upon the Authorized Representative's request to terminate the agreement, unless the Manufacturer appoints an Authorized Representative to replace them, or the medical devices are no longer available on the market or in active use.
7. When it becomes necessary to terminate the agreement, the Authorized Representative shall notify the Manufacturer in writing.
8. The Authorized Representative shall provide any information or other documents required by the SFDA.

15.5 The SFDA shall:

1. Verify that the information provided by the applicant is sufficient and meets the requirements of the Regulation.
2. Verify that the executive procedures of the Authorized Representative are appropriate to perform their tasks.
3. Issue a License to the Authorized Representative, renewable for up to a maximum of five years, when the requirements provided for herein are met.
4. Assess any changes to the agreement concluded between both the Authorized Representative and the Manufacturer and take the appropriate action if necessary.

Article 16

The Manufacturer shall provide after-sales services for its medical devices. The provisions set forth in the Medical Devices Law and its Regulation shall apply.

Regulation

16.1 The Manufacturer shall provide after-sales services for its medical devices, including approved spare parts that meet standards and technical requirements of the device to ensure continuity of its function, according to the purpose for which it was manufactured.

16.2 The Manufacturer shall ensure the provision and qualifications of technical staff who have specialized training in the maintenance and operation of medical devices. Such training is to be supplied either directly or by another entity licensed by the SFDA in accordance with the requirements for the Licensing of Medical Devices Establishments.

Article 17

Establishments shall abide by requirements for identifying information to be recorded on medical devices. The Regulation determines such information.

Regulation

17.1 Establishments subject to the provisions of the Medical Devices Law shall abide by labelling requirements provided by the Manufacturer in all their procedures related to transportation, storage, installation, maintenance, and destruction.

Article 18

A healthcare provider shall not deal with any establishments that engages in any of the activities subject to the Medical Devices Law unless it is registered and holds a valid license in the same field of operation.

Article 19

Disposable medical devices may not be reprocessed.

Article 20

Used medical devices may only be destroyed, reprocessed, refurbished, resold, loaned, or donated, in accordance with the conditions determined by the Regulation.

Regulation

20.1 Establishments and healthcare providers wishing to destroy used medical devices shall abide by the following conditions for destruction:

1. Compliance with Post-Market Surveillance requirements for medical devices.
2. Obtain all approvals from authorities concerned within the Kingdom, if necessary.
3. A specialized authority shall implement the destruction in the presence of the establishment official or their representative, or in cooperation with the relevant authorities.
4. The destroyed medical device shall be unusable in any way.
5. All information on the destruction of medical devices shall be documented, and records shall be kept for at least three (3) years.
6. Any other requirements required by the SFDA and published on the SFDA's website.

20.2 Conditions for reprocessing of medical devices:

1. The medical device shall not be intended for single use.
2. Competence shall be determined and facilities shall be provided for those who perform reprocessing of medical devices.
3. The reprocessing of the medical device shall be implemented in accordance with the Manufacturer's instructions and the relevant technical specifications, characteristics and procedures approved by the establishment in a way that does not affect device safety, efficacy and performance efficiency.
4. All records of reprocessing operations that took place on a medical device throughout the entire period of use shall be kept with the healthcare provider.
5. Compliance with Post-Market Surveillance requirements for medical devices.
6. Any other requirements determined by the SFDA and published on the SFDA's website.

20.3 Refurbished medical devices shall be treated as new medical devices and shall comply with the Medical Devices Law and the requirements of its Regulation.

20.4 Conditions for refurbishing medical devices:

1. The medical device, prior to its refurbishment, shall have obtained a Marketing Authorization from the SFDA.
2. The refurbishment shall be implemented under the responsibility of the Manufacturer.
3. The primary intended use of the medical device or its accessories shall not change.

4. The medical device shall not be intended for single use.
5. The medical device shall be circulated after refurbishment only after fulfilling all the technical requirements mentioned in the Requirements for Medical Devices Marketing Authorization, and compliance with the technical regulations and standards approved by the SFDA.
6. Compliance with labelling requirements, including the date of refurbishment and confirmation that it is a refurbished medical device, in a clear and non-removable form, in addition to keeping the basic label.
7. Compliance with the Requirements of Post-Market Surveillance of Medical Devices
8. Any other requirements determined by SFDA and published on the SFDA's website.

20.5 Conditions for resale, loan or donation of used medical devices:

1. The medical device to be resold, loaned or donated shall have a Marketing Authorization.
2. Any medical devices that could present a transmissible source of infection shall not be resold, lent, or donated.
3. The SFDA shall be notified when medical devices are resold, lent or donated, in accordance with the Requirements of Post-Market Surveillance of Medical Devices.
4. The Manufacturer or its Authorized Representative shall be notified of the process of reselling, lending, or donating the medical device.
5. The recipient of the resold, loaned or donated medical device shall be provided with all Technical Documents that prove that the medical device meets the requirements of the SFDA, including periodic maintenance reports and performance efficiency.
6. The procedures and records of resale, donation and loan of medical devices shall be documented and made available to the SFDA, if requested.
7. Compliance with the Requirements of Post-Market Surveillance of Medical Devices.
8. Any other requirements determined by the SFDA and published on the SFDA's website.

Article 21

The Manufacturer shall classify the medical devices as per the classification system.

Regulation

21.1 The SFDA shall determine the rules for risk classification of medical devices and publish them on its website. The medical devices are classified based on their class of risk into four categories as follows:

1 Low risk, denoted by (A).
2 Low to medium risk, denoted by (B).
3 Medium to high risk, denoted by (C).
4 High risk, denoted by (D).

The Manufacturer shall comply with the above-mentioned classifications published on the SFDA's website.

21.2 The manufacturer shall:

1 Apply classification rules separately to each medical device when a medical device is intended for use with another device, whether from the same Manufacturer or another.
2 Adopt the highest classification of the medical device when two or more classification rules apply to the medical device, based on the purpose of the intended use of the Manufacturer.
3 Classify the medical device and its accessories separately from each other.
4 Document the justifications for its classification of its medical devices, keep the analysis within their Technical Documents, and submit them to the SFDA, when requested.
5 Adopt the classification of the highest medical device in the procedure pack in which each medical device is individually compatible with this Regulation, considering that the combination is to achieve the requirements of the user and does not change the purpose of use for the individual devices of which it is composed.

21.3 The software subject to the Medical Devices Law shall be classified as follows:

1 If it influences another medical device, it shall be classified according to the intended purpose of the devices considered together.
2 If it is independent of any medical device, it shall be classified according to its intended purpose, using the classification rules.

21.4 The SFDA shall review the published classification rules, if there is justification due to Post-Market Follow-up or technological development.

21.5 The SFDA may refuse the classification claim submitted by the Manufacturer if it is not satisfied with its justifications in following the classification rules published on the SFDA's website.

Article 22

Establishments wishing to trade in medical devices in the Kingdom shall to the implementation a Quality Management System.

Regulation

22.1 Manufacturers, importers, distributors, and Authorized Representatives shall obtain a Quality Management System Certificate according to the Saudi Standard No. (SFDA.MD/GSO ISO 13485:2017), or the latest version published by the SFDA from the SFDA’s designated Conformity Assessment Bodies (CAB) for medical devices and the Quality Management System.

Article 23

Medical devices classified as high-risk according to the classification system may not be distributed for use outside the healthcare provider's facility without a prescription. The SFDA shall issue a list of such medical devices.

Regulation

23.1 The SFDA shall issue a list of high-risk medical devices that may not be distributed for use outside the health care provider's facility without a prescription. The list published on the SFDA's website shall be updated periodically.

23.2 Healthcare providers shall provide a prescription for the medical devices included in the list referred to in Article (23.1).

23.3 Establishments may distribute any high-risk medical device to the user only after obtaining a prescription.

Article 24

Medical devices may be advertised or promoted only after obtaining the SFDA's approval and in accordance with the conditions determined by the Regulation.

Regulation

24.1 The SFDA's approval shall be obtained for the format of the advertising material before publishing it in accordance with the following requirements and conditions:

1. The medical device shall have a Marketing Authorization Certificate.
2. The advertisement shall not contain any information which could mislead the user or be contrary to the claims made by the Manufacturer.
3. Advertising information which could mislead the lay person in advertising and publications directed to the public, including information on the internet shall be avoided.
4. Advertising and publications directed at those persons concerned with the use of medical devices shall contain information compatible with their needs.
5. The persons concerned with marketing medical devices shall have sufficient information provided to them on said devices to ensure that the correct marketing information is provided.

6. Advertisements shall not denigrate, directly or indirectly, any other medical device.
7. Advertisements shall not contain anything that contradicts the provisions of Islamic Shariah and public morals.
8. The language used in the advertisement shall be Arabic if the advertisement is directed at the lay person. If the advertisement is directed to healthcare practitioners, the language shall be English. Other languages may be used, provided they are in conformity with the language used in the advertisement.
9. Any other requirements required by the SFDA.

Article 25

Campaigns aiming to raise awareness, charity donations or similar which are related to medical devices may be organized only after obtaining the SFDA's approval and in accordance with the conditions determined by the Regulation.

Regulation

25.1 Whoever wishes to organize awareness or charitable campaigns related to medical devices shall obtain prior approval from the SFDA and fulfill the following conditions:

1 The medical device shall be registered with the SFDA and obtain Marketing Authorization.
2 Awareness and education shall be conducted by professional and qualified persons.
3 There shall be no marketing references or advertising materials for commercial purposes.
4 Medical devices may be used on the participants /attendees / the public during awareness or charitable campaigns only after ascertaining the participant's approval of the declaration form.
5 No free samples shall be distributed to the participants, attendees, and the public for the purpose of marketing.
6 The material used in the campaigns shall be written in English when it is intended to address professional persons, as well as Arabic when it is intended to address lay users.
7 All necessary approvals shall be obtained from the relevant authorities.
8 Any other requirements required by the SFDA and published on the SFDA's website.

25.2 The SFDA shall ensure that those involved in awareness and charitable campaigns related to medical devices adhere to the implementation of the SFDA's requirements.

Article 26

SFDA shall monitor the compliance of healthcare providers with the implementation of technical regulations within healthcare facilities to ensure the safety, security and adequacy of medical devices in diagnosis and treatment.

Regulation

26.1 Healthcare providers shall adhere to:

1. The requirements for safe use of medical devices inside healthcare facilities referred to in the Post-Market Surveillance requirements for medical devices.
2. The SFDA's requirements for radiology, nuclear medicine and radiotherapy departments are published on the SFDA's website.
3. Any other requirements required by the SFDA and published on the SFDA's website.

26.2 Healthcare providers shall periodically conduct quality assurance tests for radiology and medical imaging devices through qualified and trained professionals within the healthcare facility or one of the entities licensed by the SFDA to provide this service.

26.3 Healthcare providers shall, in the event of a failure in one of the quality assurance tests of their radiology and medical imaging devices, notify the SFDA and attach a Corrective Action Plan to address such failure within three (3) working days from the date of the tests result report, along with attaching a copy of the report. Continuing to use the device shall be restricted by the recommendations contained in the report.

Article 27

Both the establishment and Authorized Representative shall provide the SFDA with any document or information required by the SFDA to practice its competencies set forth in the Medical Devices Law and its Regulation.

Regulation

27.1 Establishment and Authorized Representative shall provide the SFDA with documents and information within ten (10) working days of a request.

Article 28

The Manufacturer, Authorized Representative and healthcare provider shall report any adverse event relating to their medical devices to the NCMDR.

Regulation

28.1 Healthcare providers shall appoint a liaison officer with the NCMDR in accordance with medical device Post-Market Surveillance requirements.

28.2 The Manufacturer, Authorized Representative and the healthcare provider shall comply with medical device Post-Market Surveillance requirements, report any incidents related to medical devices to the NCMDR, and provide the latter with all necessary information and documents, including supply and distribution information.

Article 29

The NCMDR shall issue a safety alert to alert both the user and healthcare provider of the risks resulting from the use of medical devices.

Regulation

29.1 The NCMDR shall issue a safety alert for medical devices after assessing the risks and proving that the Kingdom has been affected by them.

29.2 The NCMDR shall publish safety alerts on the SFDA's website or use any other means of communication according to the applicable procedures.

Article 30

Both the Manufacturer and Authorized Representative shall inform the NCMDR of the following with regard to their medical devices:

1. Safety alerts issued by similar regulatory authorities outside the Kingdom.
2. Risks that affect the safety of the medical device.
3. Completion of a Field Safety Corrective Action.

Regulation

30.1 Both the Manufacturer and Authorized Representative shall:

1. Inform the NCMDR of safety alerts affecting the Kingdom, according to a time plan approved by the NCMDR.
2. Determine the risks related to safety alerts affecting the Kingdom and provide information on supply and distribution.

3. Submit a Field Safety Corrective Action plan, including determining the date for the completion of the implementation.
4. Provide proof of the completion of the implementation of the Field Safety Corrective Action for the safety alert in accordance with the implementing plan approved by NCMDR.

30.2 NCMDR shall issue a notification of completion of the implementation of the Field Safety Corrective Action to both the Manufacturer and Authorized Representative after fulfilling all Post-Market Surveillance requirements.

Article 31

In the event of a safety alert being issued, both the establishment and healthcare provider shall stop trading in medical devices, until a notification of completion is issued by the NCMDR for the safety alert corrective action.

Regulation

31.1 Both establishment and healthcare providers shall:

1. Use the medical device according to the recommendations contained in the safety alert.
2. Refrain from importing or distributing any medical device against which a decision has been issued to recall or suspend use.
3. Suspend the circulation of the medical device if the Field Safety Corrective Action stipulates the same.
4. Provide information and reports required for the safety alert.

Article 32

The establishment and Authorized Representative shall respond to the SFDA's request to trace medical devices and Supplies, according to procedures laid down by the regulation.

Regulation

32.1 Both the establishment and the Authorized Representative shall provide the SFDA with information on the supply and distribution of their medical devices circulated in the Kingdom.

32.2 Both the establishment and the Authorized Representative shall trace the medical device in the Kingdom and provide the SFDA with the information requested by the latter according to the following:

1. Contact details of the medical device Manufacturer.
2. Details of supply, distribution and places of display or sale.
3. Supplied quantities and their transportation and storage details.
4. List of names and contact details of the users.
5. Information of the circulated medical device, including its name, trademark, identification number, serial numbers, batches supplied, and other information necessary to identify and track it.
6. Any other information requested by the SFDA and published on the SFDA's website.

32.3 The SFDA has the right to ensure that the establishment or Authorized Representative has developed and implemented effective tracking procedures for medical devices during their circulation within the Kingdom.

Article 33

The SFDA shall inspect the establishments and medical devices to ensure the application of the provisions of the Medical Devices Law, its regulations and the technical regulations, through the use of inspectors from the criminal investigation offices to be nominated by the decision of the Board Chairman. The inspectors shall have the right to:

1 Confiscate the medical devices violating the provisions of the Medical Devices Law.
2 Deal with the violating seizures, as follows:
   A. Seizing them and the relevant documents, when necessary.
   B. Taking samples for analysis.
   C. Recommending the destruction of the medical device proven to be adulterated or harmful.

The destruction shall take place after a decision is issued by the SFDA, in accordance with recognized technical principles. The Board Chairman shall form a committee for this purpose, the committee shall oversee the destruction. The violator shall bear the costs of the destruction process.

Regulation

33.1 The SFDA shall inspect the Manufacturer's Quality Management System at the pre-marketing stage. The inspection report, issued by SFDA or by a recognized conformity assessment body of

medical devices and Quality Management System, shall be deemed one of the documents required to obtain a Marketing Authorization Certificate.

33.2 The SFDA may conduct inspection visits to Manufacturers at the post-marketing stage. The SFDA has the right to appoint conformity verification and auditing establishments to take this role on its behalf.

33.3 The SFDA shall issue inspection requirements and the Quality Management System for medical devices, which contains the inspector's duties, powers, duties and rights.

33.4 Establishments shall be inspected in accordance with the Requirements for Inspections and Quality Management System for Medical Devices.

33.5 If the inspector discovers a medical device which violates the Medical Devices Law, its Regulation, provisions, requirements, or technical regulations approved by the SFDA, the same shall confiscate and seize the medical device in accordance with the procedures set forth in the inspection requirements.

33.6 The inspector, upon presenting proof of their identity, may carry out the following:

1 Enter and inspect the establishment and its appurtenances, including warehouses, storage areas, means of transportation, etc.
2 Request to open any closed site inside the establishment.
3 Seek help from the security authorities to enable them to perform their duties, if necessary.
4 Recommend any of the precautionary measures mentioned in Article (39.1) of the Regulation.

33.7 When samples are collected, the inspector shall implement the procedures as stated in the requirements for inspection and quality management system for medical devices.

Article 34

Anyone subject to the provisions of the Medical Devices Law shall maintain confidentiality of any information received during the course of their work.

Article 35

The inspector shall present their job card when performing inspection and seizure works. The establishment shall enable the inspector to perform their work and not hinder them.

Article 36

The SFDA's inspectors may, by a decision of the CEO, be granted financial remunerations for the work they perform.

Article 37

Following a decision by the CEO, an incentive remuneration of not more than 25% of the due fine may be granted to whoever assists, other than the SFDA's inspectors, in detecting a violation of the provisions of the Medical Devices Law and its Regulation.

Article 38

The SFDA shall, in agreement with the Ministry of Finance, develop the controls governing the granting of remuneration referred to in Articles (36) and (37) of the Law.

Article 39

The SFDA may take the necessary precautionary measures if given cause to believe that there:

- Is a damage
- Is a misleading claim
- Is an impact on the safety, performance or adequacy

of medical devices, as determined by the Regulation.

Regulation

39.1 The SFDA may take preventive and precautionary measures in case of harm, misleading claims or an impact on the safety and efficacy of medical devices, as follows:

1. Seizing the medical device until its safety and efficacy is verified.
2. Temporarily closing the establishment or part thereof in accordance with the procedures determined by the regulation as follows:
   A. Proof of incident under a seizure report that includes a description of the potential harm and its location.
   B. Recommending the type of closure that is appropriate to the potential for harm.

C. The closure shall continue until the potential harm is past or the corrective action and risk assessment are completed.
D. A closed establishment may be reopened only upon approval by the SFDA.

3. Suspending the establishment's license until the potential to cause harm been removed.
4. Taking a sample to be examined in a laboratory and conducting the necessary tests, at the expense of the establishment.
5. Any other actions taken by the SFDA that would preserve public health or the medical device user, as required by the nature of the incident and the potential harm.

39.2 If the SFDA finds that the medical device is in violation of the Medical Devices Law, its Regulation, or technical regulations, it may take one or more of the following actions:

1. Issue and publish a safety alert.
2. Continuing to hold the medical device, if it was previously seized, until the corrective action is completed, if it is correctable.
3. Ban the circulating of the medical device.
4. Stop the production line / lines where harm is proven.
5. Issue an order to conduct the destruction at the expense of the violating establishment, according to the decision of the Committee set forth in Article (33) of the Law.
6. Any other actions taken by the SFDA to maintain the safety of medical devices, as required by the nature of the case.
7. Imposing any of the penalties set forth in Article (42) of the Law.

39.3 The Manufacturer, Authorized Representative and establishment shall implement the SFDA's decisions related to precautionary measures until the safety and efficacy of the medical devices affected by the decision are ascertained.

Article 40

Medical devices may not be traded if the SFDA decides to recall them from the market or ban their trading.

Article 41

Whoever commits any of the following acts:

1. Adulterates or attempts to adulterate any medical device.
2. Sells, distributes, or knowingly possesses, with the intention of trading adulterated medical devices.
3. Brings into or attempts to bring into the Kingdom a device which is unregistered, adulterated or not having Marketing Authorization.
4. Manufactures a medical device in violation of any of the provisions of the Medical Devices Law, its Regulation and technical regulations.

5. Uses false information to promote medical devices, whether on them or in advertising for them.
6. Transports or stores a medical device in violation of the transportation and storage conditions determined by the SFDA.
7. Brings into or attempts to bring into the Kingdom packages or covers of a medical device with the intention of adulteration.
8. Manufactures, prints, possesses, sells, or displays packages or covers for a medical device with the intention of adulteration.
9. Commits any other violation of the provisions of the Law.

Shall be deemed in violation of the provisions of the Law.

Article 42

1. Without prejudice to any more severe punishment stipulated in any other law, whoever commits any violation of the Medical Devices Law or its Regulation; shall be punished with one or more of the following penalties:
   A. A fine not exceeding SAR (five million).
   B. Temporary closure of the establishment for a period not exceeding (one hundred and eighty) days.
   C. Suspension of Marketing Authorization of medical devices, subject of the violation, for a period not exceeding one year.
   D. Revocation of the Marketing Authorization for the medical devices which are the cause of the violation.
   E. Prevention of the violator from practicing any activity related to medical devices for a period not exceeding (one hundred and eighty) days.
   F. Revocation of the License.

   The penalty imposed in accordance with sub-clauses (A), (B), (C) and (E) of this Clause may be doubled in case the violation is repeated. The violation shall be deemed repeated, if it is committed within one year from the date of the first violation.
2. If the violation consists of committing any of the acts stipulated in Clauses (1), (2), (3), (7) and (8) of Article (41) of the Law, the penalty shall be imprisonment for a period not later than (ten) years and/or a fine not exceeding SAR (ten million). In addition, any of the penalties stipulated in sub-clauses (B), (C), (D), (E) and (F) of Clause (1) of this Article may be imposed, and the penalty shall be doubled in case of recurrence.
3.

Article 43

SFDA shall impose the penalties stipulated in Article (42.1) of the Law, in accordance with a table issued by the SFDA Board that includes a classification of violations and the penalties prescribed for each of them, considering the nature of the activity and the violation committed and its seriousness in each case separately and the aggravating and mitigating circumstances thereof. These penalties shall be approved by a decision of the CEO or their representative. In all cases, SFDA may, when necessary, take any precautionary measures it deems appropriate.

Regulation

43.1 The violator shall be notified of the penalty decision issued in one of the following ways:

1. Delivering the penalty decision to the violator by hand with confirmation of receipt or proof of its refusal.
2. Delivering the penalty decision to the violating establishment at its headquarters, with proof of receipt from any of the establishment personnel and documenting the same.
3. Sending the approved decision to the violator's national address registered with the SFDA.
4. Sending the approved decision to the e-mail of the violating establishment or the owner registered with the SFDA.

Article 44

1. By a decision of the Board, a Committee (or more) shall be formed, with members of not be less than three (3) members, one of whom, at least, shall be a legal advisor; to consider appeals submitted to the SFDA against the decisions of penalties imposition issued in accordance with Article (42.1) of the Law.
2. The Committee's work rules and procedures, and the remuneration of its members shall be determined by a decision of the Board.
3. The Committee's decisions may be appealed before the Administrative Court.

Article 45

If the violation is covered by Article (42.2) of the Law, it shall be referred to the Public Prosecution for investigation and referred to the competent court in accordance with the legal procedures.

Article 46

The judgment or decision imposing the penalty, as the case may be, may include a provision for publishing its operative part at the expense of the violator in a local newspaper issued at its place of residence, if there is no newspaper at its place of residence; in the nearest area thereto, or publishing it in any other appropriate means, depending on the type, severity and impact of the violation committed. Provided that the publication takes place after the judgment becomes definitive and final, the decision is fortified by the expiry of the time limit for appealing it, or a final judgment dismissing the appeal is rendered.

Article 47

Persons affected by any violation of the provisions of the Law have the right to claim for compensation, before the competent court, for the damage caused by such violation.

Article 48

The Board shall issue the Regulation within (one hundred and eighty days) from the publication date of the Law in the Official Gazette. The Regulation shall come into force as of the date the Law comes into effect.

Article 49

The Law shall come into force after one hundred and eighty (180) days from the date of its publication in the Official Gazette.