Saudi Food and Drug Authority

Executive Regulations of the Medical Devices and Supplies System

issued by Board of Directors decision No. (3-29-1443), 1443/2/19H

.

The stamp "General Authority for Food and Drugs, Secretariat of the Board of Directors" appears at the bottom of each page in this document.

Article One:

terms and expressions have the definitions listed next to them, wherever they appear in this system, unless the context requires otherwise:

System: Medical Devices and Supplies System.

Authority: Saudi Food and Drug Authority.

Council: The Authority's Board of Directors.

Chief executive: The Executive President of the Authority.

Regulation: The Executive Regulations of the System.

Medical Device: Any machine, tool, application device, implant, laboratory detectors, laboratory calibration materials, software, or operating materials for medical devices, or any related or similar tool made alone or in conjunction with other devices used in the diagnosis of diseases or injuries, or their prevention, monitoring, control, treatment, relief, alleviation, or compensation for injuries. It is also used in examination, replacement, modification, anatomical support, or affecting the functions of body organs, supporting or enabling life (vital human functions to continue, regulate pregnancy or assist in it, and sterilize medical devices and supplies). And providing medical or diagnostic information extracted from laboratory tests of samples taken from the human body, as well as those that cannot achieve the purpose for which they were made in or on the human body by means of a drug, an immune agent, or metabolic transformations, but only assist in achieving their effects.

Medical Supply: Materials and medical products used in diagnosis, treatment, substitution, correction, or disability cases, or other medical uses for humans, including medical gases.

Medical Device and Supply Accessories: Any material or product designed specifically for use with a medical device or supply. It allows the device or supply to perform the function for which it was designed.

Innovative Medical Device and Supply: A medical device or supply that has a novel idea in terms of technology, application, or performance that has not previously been introduced in domestic or international markets.

Assembled Medical Devices and Supplies: Assembled Medical Devices and Supplies: Everything that is collected in one kit to meet the needs of the user. It may include non-medical devices or supplies.

Single-Use Medical Device and Supply: Anything designed for use during a single medical procedure on a patient and then discarded.

Radioactive Medical Materials: A material that emits ionizing radiation, either alone or within other medical devices or supplies used for diagnosis and treatment.

Counterfeit Medical Devices and Supplies: Those whose identity or source is deliberately altered with the intent to deceive. A medical device or supply is considered counterfeit if its content has been altered, compromising its safety and security, or if it is packaged in bogus packaging.

Reprocessing: Procedures performed on previously used medical devices and supplies in order to reuse them safely. This includes cleaning, disinfection, sterilization, testing, and restoring its technical functions and related safety.

User: Anyone who uses the medical device or supply, whether they are a specialist, an ordinary person, or a patient.

Facility: A legal entity that performs an activity related to medical devices and supplies.

Manufacturer: Any national or foreign establishment whose purposes include designing medical devices or supplies or manufacturing them for use under its name, whether within the Kingdom or abroad.

Manufacturing includes: renewing, assembling, packing and wrapping, and placing identifying information on them.

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

Authorized Representative: A person with juristic personality based in the Kingdom, authorized in writing by a manufacturer residing abroad to represent them within the Kingdom in connection with the application of the system and regulations.

Medical device and supply trade: Providing them for free or in exchange, whether for distribution or use.

Licensing: A document issued by the authority to carry out any of the system's activities.

National Register: The authority's national register of establishments, devices, and medical supplies.

Registration: A registration process in which medical devices, supplies, and establishments that carry out any of the system's activities are registered in the national register.

Marketing Authorization: A document issued by the authority for any medical device or supply allowing its trading in the markets.

Free Sale Certificate: A document issued by the authority to the manufacturer stating that the manufacturer is registered in the Kingdom and that the medical devices and supplies intended for export have obtained marketing authorization.

Verification of Clinical Studies: An applied research in which a medical device or supply is used on one or more human(s) to evaluate its safety and sufficiency when used.

Classification System: A system adopted by the authority that works on evaluating the degree of risk associated with the medical device or supply and evaluating its safety.

Quality Management System: A system adopted by the authority to verify the quality, efficacy, and safety of the medical device or supply in accordance with the most recent version of the technical specification (ISO 13485) or its equivalent, as specified by the regulation.

Quality Assurance: A set of tests, measurements, and technical calibration adopted by the authority to ensure the safety of medical radiation devices, their safety, image accuracy, and quality, ensuring the effectiveness and sufficiency of diagnosis and treatment.

Technical Regulations: Mandatory documents issued by the authority specifically for medical devices and supplies that define safety principles, performance, manufacturing, and regulating instructions, including terminology, symbols, packaging, and requirements for identifying information.

Standard Specifications: Non-binding documents approved by the authority that include rules, guidelines, or characteristics for medical devices and supplies or related production processes and methods, including: terminology, symbols, packaging, and identification information requirements.

Identification Information: Any statement or information drawn or depicted, written or printed on the medical device and supply. This includes information related to its identification, technical description, usage instructions, and methods of storage and transportation.

Technical and Clinical Specifications: A set of standards that determine the quality, effectiveness, and safety of using radioactive material in medical applications.

Safety Alert: A notice issued by the center illustrating the risk associated with the medical device or supply and the corrective actions required to avoid it.

Corrective Action for Safety Alert: An action taken by the manufacturer to minimize or reduce the risks that affect the safety of the medical device or supply.

Incidents for Medical Devices and Supplies: Any failure or change in the characteristics or performance of the medical device or supply that may directly or indirectly cause or contribute to the user's death or serious injury.

The Center: The National Center for Medical Devices and Supplies Reports.

Regulation

1/1 In addition to the words and phrases mentioned in the system, the following words and phrases wherever they appear in this regulation have the meanings shown next to each one unless the context requires otherwise:

Complaint: Any type of written or verbal communication about deficiencies related to the medical device or supply, or its quality, efficiency, safety, usability, performance, in addition to deficiencies related to maintenance that affect the performance of the medical device or supply.

Intersecting Products: A product made up of two or more parts that must adhere to rules set forth by the authority.

Medical Imaging Materials: Anything used to improve the contrast obtained through medical imaging techniques.

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

Home Medical Device or Supply: A device or medical supply intended for use in any environment other than a healthcare facility.

Ordinary User: A person who has not received any accredited training or education in a related field or specialty.

Supply Chain: A series of activities that the medical device or supply goes through from the design and manufacturing stages until it reaches the user.

Importer: A facility in the supply chain that provides the Kingdom with the medical device or supply.

Distributor: A facility in the supply chain that provides the medical device or supply to another distributor or the end user.

Exporter: The facility in charge of exporting the medical device or supply outside the Kingdom.

Traceability: procedures and measures that allow tracking the path of medical devices or supplies at any stage of the supply chain.

Advertising: Any statement, whether written, heard, visual, or otherwise, intended to promote the medical device or supply, or technology on the medical device or supply, or direct or indirect sales.

Inspection: An action taken by the authority to ensure that the facility or manufacturer complies with the system's and its regulations' requirements and conditions for facilities, devices, and medical supplies.

Corrective Action: An action taken to address the reasons for noncompliance discovered on the facility, manufacturer, device, or medical supply.

Technical Documents: Documents and technical and scientific information about the medical device or supply and the manufacturer, including documented and approved procedures that prove the device or supply's conformity to the safety, efficiency, and quality requirements specified in the system and

its regulation.

Intended Use: The manufacturer's stated purpose for using the medical device or supply.

Implanted Medical Device: A medical device that is surgically implanted into the human body, replaces the external surface of the body, or is placed on the eye surface, including those that are partially or completely absorbed by the body and remain in the body following the surgical medical intervention. This includes devices that have been partially surgically implanted and will be used for 30 days or longer.

Consultancy Service Facilities: Facilities that provide technical consulting services related to regulatory affairs for facilities operating in the Kingdom's medical devices or supplies market.

Clinical Study Verification Facilities: Facilities that oversee clinical study verification and carry out all activities related to clinical study verification.

Medical Device and Supply Conformity Verification and Quality Management System Assurance Facilities: Facilities licensed by the authority to act as a third party located in the Kingdom.

Control: A set of procedures for regulating the safety, efficiency, quality, and effectiveness of medical devices or supplies during their circulation in the Kingdom.

Custom-Made Medical Device: A device or medical supply that meets at least the following criteria:

1- created for a specific individual (patient or medical professional).

2- manufactured in response to a written request from a licensed healthcare professional who provides specific design characteristics under his responsibility.

3- It is intended to treat the anatomical, physiological, or pathological condition of the person for whom it is designed.

Patient-Specific Medical Device: A medical device produced based on a standard device design model (for example, minimum and maximum dimensions or mechanical performance limits and other related medical factors), which matches the patient's anatomy using techniques such as device sizing based on anatomical references, or using full anatomical characteristics from patient imaging, and which is produced through a verifiable process.

Adaptable Medical Device: A medical device that is mass-produced and then modified or shaped by the healthcare provider according to the manufacturer's instructions to fit the specific anatomical and physiological features of the patient before use.

Non-commercial Purposes: Circulation of medical devices or supplies for research or humanitarian purposes and in limited quantities.

The applicant: is a natural or legal person who meets the requirements and has been authorized by the facility.

Software: The set of applications, protocols, and computer processes used to operate a specific system.

Warehouse: A building or part of it licensed by the authority and dedicated to storing the medical device or supply.

Medical Gases: Gases used to operate or sterilize medical devices and supplies, or used for treatment or diagnosis, do not cause any drug, immune, or metabolic reactions to achieve their primary purpose of use.

Unmodified Human-Origin Biological Products: Products consisting of human cells or tissues that have not been altered in their biological characteristics and are intended for implantation or transplantation into the human body.

Identification Coding: A series of numbers and letters created according to approved standards with the aim of uniquely and clearly identifying the medical device or supply during all stages of its circulation.

Article Two:

The following activities are subject to the provisions of the system:

1. Designing and manufacturing medical devices and supplies.
2. Importing, marketing, distributing, and storing medical devices and supplies.
3. Providing verification services to ensure that medical devices and supplies comply with technical regulations and quality management system, and verifying quality assurance.
4. Conducting clinical study verifications.
5. Providing technical consulting services in the field of medical devices and supplies.
6. Providing inspection services for medical devices and supplies to ensure their compliance with technical regulations and standard specifications.
7. Providing maintenance services for medical devices and supplies.
8. Representing the manufacturer residing outside the Kingdom.

Regulation:

1/2 In addition to what is stated in the system regarding aspects of activity, the provisions of the system and its regulations apply to the following establishments, devices, and products:

First, consider the establishments listed below:

A. Organizations that carry out activities subject to the system's and its regulations electronically.
B. Companies that import and export medical radioactive materials, medical imaging materials, or particle accelerators used in the production of radioactive isotopes for medical applications.
C. Organizations that export medical devices and supplies.

Second: The following devices and products:

A. Interrelated products.
B. Cosmetic devices and products that have medical applications, and the authority publishes an updated list of these devices and products.
C. Cosmetic contact lenses.
D. Particle accelerators used in the formation of radioactive isotopes for medical applications.
E. Biological products of pure human origin.

Article Three:

Accessories, and the assembled medical devices and supplies are considered, for all purposes, medical devices and supplies subject to the provisions of the system.

Regulation:

1/3 The Authority shall issue the necessary requirements for assembled medical devices and supplies and publish them on its website.

Article Four:

Taking into consideration the authority's jurisdiction to grant licenses for activities pertaining to the use of radioactive medical materials, the authority's approval of the materials' technical and clinical specifications is necessary prior to the materials' licensing by the Nuclear and Radiation Control Authority.

Regulation:

1/4 Establishments / applicants seeking to import or re-export radioactive medical materials must meet the Authority's requirements for importing and re-exporting radioactive medical materials used in medical applications, which are available on the Authority's website.

2/4 The Authority shall approve or reject the technical and clinical specifications within ten days of receiving the import or re-export request for radioactive medical materials.

3/4 Applicants seeking to import particle accelerators used in the production of radioactive isotopes for medical applications must meet the Authority's requirements, which are available on the Authority's website.

Article Five:

The application of the provisions of the system does not infringe upon the jurisdiction of the Nuclear and Radiation Control Authority in relation to issuing radiation protection licenses issued by medical devices.

Regulation

1/5 The Authority issues certificates of marketing authorization for radiation-emitting medical devices.

2/5 Radiation-emitting medical devices may not be distributed unless they have a marketing authorization certificate issued by the environment.

3/5 The Authority monitors radiology, nuclear medicine, and radiotherapy departments at healthcare providers for compliance with the Authority's requirements for safe use of devices and medical supplies, which are published on its website.

4/5 The Authority monitors healthcare providers' compliance with the application of technical and clinical specifications for radioactive medical materials within healthcare facilities and refers violations to the Nuclear and Radiation Control Authority.

Article Six:

Taking into account what was stated in Article Four of the system, no establishment may engage in any of the system's activities without first registering and obtaining a license, as well as obtaining an industrial license from the competent authority for factories.

Regulation:

1/6 The Authority assigns a unique registration number to each establishment, subject to the system's and its regulations' provisions.

2/6 Establishments that engage in any activity subject to the system's provisions must obtain a license from the Authority for the establishment, its branches, and its warehouses, in accordance with the conditions and requirements outlined in this regulation.

Article Seven

According to the regulation, those licensed to conduct clinical study verifications must obtain approval from the authority before beginning any verification processes.

Regulation

1/7 The Authority grants approval for the following:

1- Clinical trials of medical devices and supplies
2- Studies on the performance of laboratory and diagnostic devices

2/7 Applicants seeking approval to conduct clinical studies before they begin must provide the following information:

1. The approved study work plan
2. Approval by the local research ethics committee
3. Information about the researchers
4. A clinical study agreement between the study sponsor and the clinical study verification establishment
5. A study that satisfies all of the Authority's technical requirements.
6. compliance with any other requirements established by the authority and published on its website.

3/7 A Saudi national, full-time responsible person for clinical studies, with appropriate academic qualifications not less than a bachelor's degree and clinical study experience of at least three years, must be appointed.

4/7 The clinical study for medical devices and supplies must meet the requirements published on the website and be compatible with the Kingdom's system of research ethics on living creatures.

5/7 The Authority does the following:

1. Reviews applications for conducting clinical studies and grants approval when requirements are met within a maximum period of sixty days from the date of fulfilling the requirements.
2. Conducts site visits to studies to ensure compliance with the implementation of the study as approved.
3. Grants import permits for medical devices, supplies, and other products necessary to conduct the clinical study.

6/7 The entities authorized by the Authority to conduct clinical studies are required to notify the Authority within five days of the completion of clinical studies, or in the event of major deviations in the study course, or the occurrence of anything that affects the safety and rights of the individuals under study.

7/7 The authority has the authority to halt the study if any deviation from the approved study course is discovered or if anything occurs that could jeopardize the safety of the participants.

8/7 The manager of the clinical studies verification establishment must be a full-time Saudi national, holding at least a bachelor's degree in one of the health or scientific specialties related to medical devices and supplies.

Article Eight:

No medical device or supply may be traded without first registering it and obtaining marketing authorization. The Authority has the authority to exempt some medical devices and supplies from the requirement of obtaining marketing authorization after ensuring their safety and non-commercial use in accordance with Council-ratified rules.

Regulation:

1/8 No medical device or supply may be traded in the Kingdom, except after its scientific evaluation by the Authority, in accordance with the requirements for marketing authorization of medical devices and supplies published on the Authority's website, to ensure its safety and security, and obtaining marketing authorization.

2/8 After obtaining marketing authorization, the medical devices and supplies are registered in the national register, which is considered their registration.

3/8 First: First, the Authority may exempt certain medical devices and supplies from the requirement of obtaining marketing authorization for humanitarian and research purposes, subject to the following rules:

A. General emergency cases such as natural disasters, wars, or epidemics.
B. Personal use in accordance with the requirements outlined in Article (2/13) of the Regulation.
C. Research or educational uses.
D. Pre-marketing clinical studies that have received the Authority's approval for the study.
E. If they are manufactured specifically for a particular patient at the request of the treating team.
F. Samples of medical devices and supplies used in exhibitions, festivals, or workshops.

Second: import authorization from the authority for the medical devices and supplies mentioned in the first item is required, in accordance with the requirements for importing, exporting, and clearing medical devices and supplies published on the website.

Article Nine:

The Authority has the authority to exempt an innovative medical device or supply from some of the requirements and procedures required for marketing authorization without compromising its safety or security when used, as determined by the regulations.

Regulation:

1/9 If the following conditions are met, a medical device or supply is considered innovative::

1. It is designed with innovative properties/features, whether in technology, methods of use, or performance characteristics, and there are no similar technologies in the local and global market.
2. It has a clinical/medical benefit that surpasses available alternatives.
3. Any other conditions determined by the Authority and published on its website.

2/9 According to the requirements for marketing authorization of medical devices and supplies published on the Authority's website, the applicant is required to provide the necessary information to prove that the innovative medical device or supply complies with what is stated in Article (1/9).

3/9 The authority may request additional information from the applicant before making a final decision on whether the device or medical supply is innovative.

4/9 Innovative medical devices and supplies are exempted from some of the requirements and procedures required to obtain marketing authorization, based on the type and technology used, according to the requirements of innovative medical devices published on the Authority's website, and it has exceptions from the following requirements:

1. Verification and assurance of the product, including clinical studies.
2. Periodic safety reports and post-marketing surveillance reports.
3. Detailed information about design and manufacture.

5/9 The applicant is required to verify the clinical studies in accordance with the requirements of clinical studies for medical devices and supplies when requested by the Authority.

6/9 The Authority determines and updates the requirements of innovative medical devices according to technological developments.

Article Ten:

The regulation determines the conditions and procedures necessary for registration, issuance of marketing authorization, obtaining a license, renewal, amendment, transfer, and cancellation.

Regulation:

1/10 Requirements and procedures for obtaining a marketing authorization certificate:

Before distributing any device or medical supply in the Kingdom, the manufacturer must obtain a marketing authorization certificate from the Authority in accordance with the system's and its regulations.

2/10 2/10 The manufacturer must submit the electronic application form for obtaining a marketing authorization certificate for medical devices and supplies, which is available on the Authority's website, and provide the Authority with supporting documentation in accordance with the requirements for marketing authorization of medical devices and supplies, which include, but are not limited to:

1. The manufacturer's contact information
2. the authorized representative's contact information, the national registry number of his establishment, and the license number issued by the authority, if the applicant is an authorized representative.
3. The name and contact information of the person who is in charge of completing the application for marketing authorization for medical devices and supplies.
4. a pledge from the manufacturer to notify the Authority of any actions or measures taken, whether inside or outside the Kingdom, that may have an impact on the medical devices and supplies supplied to the Kingdom, as outlined in the post-marketing surveillance requirements for medical devices and supplies.

3/10 The following technical requirements, among others, must be met in order to obtain a marketing authorization certificate for medical devices and supplies:

1. The necessary documents proving that the device or medical supply to be marketed complies with the basic principles of safety and performance, as specified in the requirements for marketing authorization of medical devices and supplies.
2. Submission of technical documentation for the device or supply as determined by the environment, which includes:

a) Description of the device or medical supply and its features, including differences and accessories.
b) Design and manufacturing information.
c) Risk management evaluation file.
d) Product verification and validation, including clinical trials.
e) Post-marketing surveillance plan.
f) Periodic safety update reports and post-marketing surveillance reports.

3. A copy of the identifying information and assurance of fulfilling the elements and contents of the identity card for the purpose for which the device or medical supply was made.
4. Information on environmental measures and/or use in the Kingdom.
5. Classification of the device, medical supply, or diagnostic laboratory device in accordance with the classification rules specified in this regulation.
6. Evidence that the manufacturer uses the quality management system referred to in Article (1/22).
7. Evidence of compliance with related technical regulations or standard specifications established and published by the Authority.
8. A pledge of the device or medical supply's compliance with the provisions of this regulation.
9. Any other requirements specified by the authority and published on its website.
10. The Authority has the right to request additional technical documents when needed before deciding on the marketing authorization application.

4/10 Different medical devices and supplies may be combined in a single marketing authorization application, as defined by the authority's marketing authorization requirements for medical devices and supplies.

5/10 The Authority issues a marketing authorization certificate for the device or medical supply when the applicant fulfills all marketing authorization requirements. The certificate is valid for a maximum of three years from the date of issuance.

6/10 The authority notifies the applicant of the reasons for rejecting the marketing authorization application, and the applicant may object in accordance with the regulatory procedures outlined below.

7/10 The manufacturer or authorized representative must renew the marketing authorization certificate before it expires and, if necessary, submit updated documents through the electronic system.

8/10 The information and documents provided to the environment must be updated via the electronic system within ten days for any substantial change to the information or thirty days for non-substantial changes as defined by the requirements for marketing authorization of medical devices and supplies.

9/10 The following procedures must be followed in order to obtain the necessary licenses to carry out any of the system's activities:

1. Create/open an account in the authority's electronic system and obtain a business number.
2. Submit an application for an activity practice license through the authority's electronic system.
3. Pay the financial fee for the establishment category license to practice the activity if the application is accepted.
4. Submit all required documents electronically through the authority's system.
5. Visit the establishment to ensure the establishment, documentation, and application of the quality management system referred to in Article (1/22).
6. The Authority must be informed in case of license modification through the electronic system and the required documents should be submitted.
7. Any other procedures requested by the authority and made available on the authority's website.

10/10 The Authority defines the areas of operation for licensed institutions and the necessary technical and administrative requirements for carrying out their activities.

11/10 Licensing requirements for importers and distributors.

Importers and distributors of medical devices and supplies must meet the following requirements to obtain a license from the Authority:

1. Provide data on the manufacturer and the medical devices and supplies to be imported, as well as information on the approved representative of the manufacturer residing outside the Kingdom.

2. Provide a documented procedure for tracking the device or medical supply during the import or distribution phase, and provide a commitment to implement and comply with the procedure.

3. Provide a documented procedure for storing and transporting the device or medical supply in accordance with the manufacturer's specifications, as well as a commitment to follow the procedure.

4. Provide evidence of the use of the quality management system mentioned in Article 1/22 of the regulations.

5. Appoint a person authorized by the institution to deal with the Authority in accordance with the requirements set by the Authority.

6. Meet any other requirements set by the Authority and published on its website.

12/10 Licensed importers and distributors must meet the following requirements:

1. Comply with the requirements referred to in Article 11/10.

2. Comply with the manufacturer's requirements in addition to the requirements published on the Authority's website concerning the transport and storage of medical devices and supplies.

3. Ensure that each device or medical supply comes with all necessary documentation:

    a) Certificate of Marketing Authorization

    b) The Declaration of Conformity, signed by the manufacturer, indicating that the device or medical supply meets the system and regulatory requirements.

c) The identifier code for the device or medical supply, including the machine-readable code in accordance with the requirements of the identification coding for medical devices and supplies.

d) Identifying information and other related documents.

e) Contact information for the manufacturer, as well as its authorized representative if the manufacturer is located outside the Kingdom.

f) Import and distribute medical devices and supplies that meet system and regulatory requirements.

g) Provide an adequate and appropriate amount of human resources and other resources to meet the requirements specified in the system and regulations.

h) Comply with any other requirements imposed by the Authority and published on its website.

13/10 Requirements for licensing a medical devices and supplies warehouse:

1. commitment not to keep any device or medical supply that violates the authority's requirements.
2. obtaining the necessary licenses from the appropriate authorities.
3. appointment of a full-time warehouse technical manager who is a medical device engineer or technician, or qualified in one of the related specialties.
4. Any other requirements that the authority determines and publishes on its website.

14/10 Required medical device and supply warehouse requirements:

1. Compliance with the manufacturer's requirements, in addition to the requirements published on the authority's website, for the transportation and storage of medical devices and supplies.
2. Application for renewal of the license in accordance with Article (35/10) of the regulations.
3. Any other requirements determined by the Authority and published on its website.

15/10 Storage requirements at a third party:

1. The primary landlord must be licensed by the Authority.
2. A contract must be signed between the primary landlord and the tenant that includes information about both parties and their obligations in accordance with the Authority's requirements, including data about the areas and spaces designated for storage.
3. Any other requirements that the authority determines and publishes on its website.

16/10 Requirements for licensing a factory within the Kingdom:

1. Establishing and implementing a quality management system in accordance with what is referred to in Article (1/22).
2. Appointment of a full-time technical manager for the factory who is a medical device engineer or technician, or qualified in one of the related specialties.
3. Appointment of a full-time quality manager for the factory who is a medical device engineer or technician, or qualified in one of the related specialties.
4. Determining the factory activity and the risk level of the medical devices and supplies that are to be manufactured.
5. Obtaining necessary licenses from the appropriate authorities.
6. Commitment of the factory to take full responsibility regarding the quality of all manufactured operations.
7. Any other requirements determined by the Authority and published on its website.

17/10 The factory must comply with the identification coding requirements for medical devices and supplies, and the Authority determines the exempted devices and supplies.

18/10 Language requirements for technical documents submitted to authorities or kept on file for inspection

1. The technical documents must be submitted to the Authority in English unless the Authority 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 must be provided.
2. The identification information is accepted in English if the user of the device or medical supply is professionally qualified; if the device is intended for the ordinary user, the identification card must be in both Arabic and English.
3. 3. Instructions for handling, storing, transporting, installing, maintaining, and disposing of medical devices and supplies should be written in both English and Arabic if the user is a layperson.

4. Advertising, promotional, and marketing information must be in English, and if the user is an ordinary person, it must be in both Arabic and English.

19/10 Manufacturers of implantable medical devices must include the following information on a card:

1. Device identification information includes the device name, serial number, batch number, device coding, and model data, as well as the manufacturer's name, address, and electronic site.
2. Any warnings, precautions, or measures that the patient or healthcare provider must take in regards to the expected external interactions, medical examinations, or expected environmental conditions.
3. Any information about the expected life of the device and any necessary regular follow-up for the device's performance.
4. any other information required to ensure the device's safety.

20/10 The Authority has the authority to exempt some implanted devices from Article (19/10), subject to the conditions determined by the Authority and published on its website.

21/10 Medical device and supply licensing requirements, conformity verification facilities, and a quality management system the applicant must provide the Authority with documents and information in accordance with the requirements for medical devices and supply facilities as published on the Authority's website.

22/10 Licensing requirements for quality assurance and radiometric service providers in health facilities must include the following:

1. Completing the form available on the Authority's website and submitting all required documents.
2. Provide specialists / technicians from an accredited entity to practice the activity.
3. 3. Provide measurement devices that meet international standards.
4. Any other requirements determined by the Authority and published on its website.

23/10 Requirements for quality assurance and radiometric service providers to health facilities:

1. Work in accordance with the requirements outlined in Article (22/10).
2. 2. Adherence to what is stated in the kingdom's general instructions for ionizing radiation protection and national instructions for the transport of radioactive materials, as well as any other documents issued later by the competent authorities.
3. Avoiding the use of unlicensed sources in terms of number, type, and radioactive activity.
4. Not selling or renting or lending or donating the radioactive sources owned by the licensee to another facility without obtaining approval from the competent authorities.
5. No moving fixed radioactive sources within the facility without prior approval from the appropriate authorities.
6. Disposal of radioactive sources when they are no longer required, as specified in the general instructions for radioactive waste management and the general instructions for ionizing radiation (IR) protection in the kingdom.

7. Commitment to notify the Authority within three days of the date of the test results report if one of the daily quality assurance tests for X-ray and medical imaging devices fails or if there is a defect in the shielding of the X-ray rooms, attaching a copy of the report, provided that the report includes a recommendation on the continuation of device usage.
8. compliance with the authority's secure use requirements, as published on its website.
9. Any other requirements that the authority determines and publishes on its website

24/10 Licensing requirements for clinical study verification facilities.
To obtain a license from the Authority, clinical study verification facilities must meet the following requirements:

1. Complete the application, which is available on the authority's website, along with all of the documents listed in the requirements for clinical studies of medical devices and supplies.
2. Include the person in charge of clinical studies' curriculum vitae, certificates, and work experience.
3. Any other requirements established by the authority and made available on its website.

25/10 Requirements for clinical study verification facilities.

1. Demonstrate compliance with good clinical practice for clinical studies of medical devices (SFDA.MD/ISO2020: 14155) or its latest version.
2. Implement the facility's documented work procedures.
3. Any other requirements defined by the Authority and published on its website.

26/10 Licensing requirements for technical consulting services facilities in the field of medical devices and supplies. The applicant must provide the Authority with documents and information in accordance with the requirements for medical devices and supplies facilities as published on the Authority's website.

27/10 Licensing requirements for medical device and supply inspection service providers. The applicant must provide the Authority with documents and information in accordance with the requirements for medical devices and supplies facilities as published on the Authority's website.

28/10 The Authority determines the technical regulations and standard specifications for medical devices and supplies subject to the provisions of the system and regulations.

29/10 Licensing requirements for medical maintenance service providers.

1) Provide a technical staff of engineers and medical maintenance technicians in accordance with the following conditions:
   a) They have academic or technical qualifications in biomedical technical engineering or any related specialty.
   b) They receive specialized training from the factory or from a person trained by the factory on their medical devices and supplies.
2) Provide suitable test equipment to check the function of the device or medical supply, calibrate it, and its performance efficiency and safety, which must be compatible with the measurement and calibration system issued by Royal Decree No. (M/51) dated 1434/11/13H, its implementing regulations, and related instructions.
3) Any other requirements defined by the authority and published on its website.

30/10 Requirements needed for medical maintenance service providers.

1) Comply with the requirements outlined in Article 29/10.
2) Provide a maintenance management system and an inventory management system to collect, store, organize, analyze, and record data for medical devices and equipment, as well as necessary spare parts and a list of all spare parts suppliers approved by the manufacturer.

3) Original spare parts must be readily available for the person requesting maintenance service in a healthcare facility. Delays are only accepted with justification in cases of corrective maintenance.
4) Apply the manufacturer's instructions regarding corrective maintenance and calibration, and if instructions are not available, refer to the technical specifications approved by the Authority.
5) Any other requirements defined by the authority and published on its website.

31/10 The authorized representative's licensing requirements..

1) Obtain an authenticated and approved delegation from the manufacturer detailing the activities practiced on behalf of the manufacturer, ensuring that the delegation is suitable to ensure appropriate application of the system's provisions and its regulations.
2) Implement a quality management system in accordance with the provisions of Article (22/1).
3) Any other requirements defined by the Authority and published on its website.

32/10 The license period is one year or similar periods that are renewable in accordance with Article (35/10) of the regulations.

33/10 The Authority can refuse to issue a license to establishments subject to the system's provisions if requirements are not met and notify the applicant of the reasons for refusal.

34/10 Any changes to the information provided to obtain the license must be reported to the authority within ten days of the change.

35/10 The establishment can apply for a license renewal sixty days before the current license expires, by submitting the renewal application through the Authority's electronic system, attaching all required documents, and paying the fee.

36/10 The applicant may cancel the license in accordance with the licensing requirements for medical devices and supply facilities as published on the authority's website.

37/10 Establishments that want to cancel their license when it expires must do the following:

1. Submit the request through the Authority's electronic system/ notify the Authority.
2. Provide proof of no outstanding obligations on the establishment.
3. Provide any other documents required by the Authority.

Article 11

Medical devices and supplies cannot be cleared for import without the approval of the Authority.

Regulation:

1/11 Imported medical devices and supplies may not be cleared without obtaining a marketing authorization from the Authority or an import license if they are exempted from obtaining marketing authorization, as referred to in Article (3/8).

2/11 Medical devices and supplies that contain restricted chemicals or gases, or radioactive medical substances, may not be cleared without obtaining a marketing authorization and an import license from the Authority.

3/11 Imported medical devices and supplies must:

1. Comply with the system's provisions, its regulations, the approved technical regulations, and any decisions, conditions, or requirements mentioned in the Authority's circulars.
2. Be imported by a licensed facility.
3. Come from a manufacturer with a licensed authorized representative.
4. Be accompanied by the official documents and certificates stipulated in the approved technical regulations, decisions, and circulars issued by the Authority.

5. Not be under any warning from the Authority.

4/11 Used medical devices may be imported for the purpose of maintenance or refurbishment in the Kingdom if an import permit is obtained and the facility re-exports them without circulating them in the Kingdom.

5/11 Used medical devices may be imported into the Kingdom, which were exported based on a prior export permit from the Authority for the purpose of maintaining, calibrating, displaying as marketing samples, correcting as per a safety warning, or testing, provided that an import permit is obtained before entering the Kingdom.

6/11 The re-export of medical devices or supplies is not permitted without the approval of the Authority and in accordance with the requirements published on its website.

7/11 The circulation of medical imaging materials is not allowed until the requirements for importing and clearing medical imaging materials, published on the Authority's website, are met and an import permit is obtained from the Authority.

8/11 The importation of medical devices and supplies is prohibited in the following cases:

1. Used medical devices intended for circulation, except as provided in Articles (4/11), (5/11).
2. If the product's validity at the point of arrival is less than the periods specified in the clearance requirements published on the authority's website.

Article 9/11

Particle accelerators used in the production of radioactive isotopes for medical applications may not be circulated until the import and clearance requirements published on the authority's website are met.

Article 10/11

The Authority may take random samples from shipments arriving at customs ports to ensure their safety and security without bearing any costs for these samples or their laboratory testing.

Article 12

The regulations specify the conditions necessary to issue a free sale certificate.

Regulation

1/12 For the purpose of export and at the manufacturer's request, the Authority issues a free sale certificate to the manufacturer in accordance with the following requirements:

1. The manufacturer must be licensed in the Kingdom.
2. The medical devices and supplies to be exported must have a marketing authorization certificate.
3. Any other requirements specified by the Authority and published on its website.

Article 13

The Authority may allow the entry of personal medical devices and supplies based on a medical report and in limited quantities, provided they are not used for commercial purposes.

Regulation

1/13 Approval from the Authority must be obtained before importing medical devices and supplies for personal use or custom-made, along with submitting the required documents and pledges.

2/13 The importation is considered personal in the following circumstances:

1. Home medical devices and supplies intended for regular use and imported infrequently.
2. Custom-made medical devices and supplies.
3. Submission of the documents and pledges required by the Authority.

3/13 A medical device or supply is not considered custom-made if it is:

1. Adaptable.
2. Dedicated to a specific patient.

4/13 The Authority has the right to refuse the shipment if it deems that the medical devices and supplies are not consistent with the documents and pledges submitted to the Authority.

5/13 The manufacturer of home medical devices and supplies must provide the following:

1. Identification information (including display screens for the medical device or supply in Arabic and English).
2. Contact information for technical support centers for users in the Kingdom.

Article 14:

Anyone who has dispensed or sold a counterfeit, unregistered, or unauthorized marketed medical device or supply must report it to the authority as soon as they become aware of it, providing information about what was dispensed or sold and the quantity, the name of the person to whom the device or supply was dispensed or sold, and their address, and is required to refund the buyer.

Regulation

1/14 Healthcare providers and establishments must comply with the following:

1. Notify the Authority of medical devices and supplies that violate the provisions and requirements of the system and its regulations, including counterfeit, unregistered, and unauthorized marketed medical devices and supplies.
2. Provide information about the violating medical devices and supplies, including supply and sale data, quantities, the name of the person to whom it was dispensed or sold, and their contact information.
3. Provide the Authority with the corrective plan for the medical device or supply.

Article 15:

In accordance with the provisions of the Commercial Agencies Law, a manufacturer residing outside the Kingdom who wishes to circulate their products in the Kingdom must appoint an accredited representative. The regulation defines the conditions that must be met by the accredited representative, as well as the obligations and responsibilities of both parties.

Regulation

1/15 The conditions that must be met by the accredited representative are that the representative must:

1. Be located in the Kingdom.
2. Have obtained a permit for the establishment as an accredited representative issued by the Authority for every manufacturer they represent within the Kingdom, in accordance with the agreement concluded with the manufacturer according to Article 2/15, and subject to the Kingdom's regulations.
3. Be committed to implementing the quality management system as referred to in Article 1/22.
4. Have documented the necessary processes to perform the tasks assigned to them, along with the relevant documents.
5. Comply with any other requirements demanded by the Authority and published on its website.

2/15 The conditions that must be met by the accredited representative are as follows:

1. Specification of the activities in which the accredited representative acts on behalf of the manufacturer in its dealings with the Authority.
2. The category or group of medical devices and supplies subject to the system and regulation intended to be marketed in the Kingdom.
3. The accredited representative's commitment to all post-marketing surveillance requirements published on the Authority's website.
4. Specification of the agreement's duration between the two parties, and either party may terminate it as per the system.

3/15 Manufacturer's obligations and responsibilities.

1. The manufacturer is not allowed to appoint more than one accredited representative for the same category or general group of medical devices and supplies. However, they can appoint a different accredited representative for each category or general group of medical devices and supplies.
2. The manufacturer is obliged to notify the accredited representative in writing if they wish to terminate the agreement.
3. The manufacturer is committed to appointing a new accredited representative and transferring all previous obligations to them immediately upon termination or non-renewal of the previous accredited representative agreement, and is obliged to notify the authority of this.
4. Provide any other information or documents required by the authority.

4/15 Obligations and responsibilities of the accredited representative.

1. Represent the manufacturer in its dealings with the Authority.
2. Collaborate with the Authority in studies and measures taken during post-marketing surveillance.
3. Notify the Authority of any incidents that occurred outside the Kingdom that have implications for medical devices and supplies traded in the Kingdom, explaining the circumstances and providing information on corrective measures taken or planned by the manufacturer.
4. Notify the Authority of all corrective actions resulting from the manufacturer's post-marketing follow-up investigations of the medical devices and supplies traded in the Kingdom, explaining the reasons for the corrective actions and providing information on the measures taken by the manufacturer or intended to be taken.
5. Collaborate with individuals who carry out activities subject to the system's and regulations' provisions regarding medical devices and supplies traded in the Kingdom under the agreement reached between them and the manufacturer.
6. The responsibility of the accredited representative towards the medical devices and supplies covered in the agreement does not cease when they request to terminate the agreement unless the manufacturer appoints an alternative accredited representative, or when the medical devices and supplies are no longer in the market and with the users.
7. Notify the manufacturer in writing if they wish to terminate the agreement.
8. Provide any additional information or documentation requested by the authority.

5/15 The authority should do the following:

1. Ensure that the information provided by the applicant is sufficient and meets the requirements of the regulations.
2. Ensure that the executive procedures of the accredited representative are appropriate to perform the tasks assigned to them.
3. When the requirements of these regulations are met, issue a license for the establishment for a period of one year, or similar periods of up to a maximum of five years, which is renewable.
4. Evaluate any changes that may occur to the agreement signed between it and the manufacturer and take appropriate action if necessary.

Article Sixteenth:

The manufacturer must provide after-sales services for its medical devices and supplies. In this regard, the provisions of the system and regulations apply.

Regulations:

1/16 The manufacturer is committed to providing after-sales services for its medical devices and supplies, including approved spare parts that are compatible with the device's specifications and technical standards, to ensure that it continues to function as intended.

2/16 The manufacturer is committed to ensuring the provision and qualification of technical cadres specialized in the maintenance and operation of medical devices and supplies, as well as training on them directly or through another party licensed by the authority in accordance with the requirements of medical device and supply facilities.

Article Seventeenth:

Facilities must adhere to the identifying information that must be available on medical devices and supplies, as specified by the regulations.

Regulations:

1/17 Facilities subject to the provisions of the system must comply with the identifying information provided by the manufacturer in all its procedures related to transportation, storage, installation, maintenance, and disposal.

Article Eighteenth:

Healthcare providers must not deal with any establishment that practices any of the activities subject to the system unless it is registered and licensed in the same field of dealing.

Article Nineteenth:

Reprocessing of single-use medical devices or supplies is prohibited.

Article Twentieth:

It is not permitted to destroy used medical devices or supplies, nor is it permitted to reprocess, refurbish, resell, lend, or donate them, except under the conditions specified by the regulations.

Regulations:

1/20 Establishments and healthcare providers wishing to destroy used medical devices or supplies must adhere to the following destruction conditions:

1. Comply with the post-marketing surveillance requirements for medical devices and supplies.
2. Obtain all necessary approvals from the Kingdom's concerned authorities.
3. The destruction should be carried out by a specialized entity in the presence of the facility's manager or his deputy, or in collaboration with relevant entities.
4. The destroyed medical device or supply is rendered inoperable in any way.
5. All destruction data for medical devices and supplies must be documented and destruction records must be kept for at least three years.
6. Any other requirements imposed by the authority and published on its website.

2/20 Conditions for reprocessing medical devices and supplies:

1. The medical device or supply must not be designed for single use.
2. Proficiency and capabilities must be available for those conducting reprocessing of medical devices and supplies.
3. The medical device or supply must be reprocessed according to the manufacturer's instructions, relevant technical specifications, and approved procedures at the facility without affecting its safety, performance, and efficiency.
4. All records of reprocessing operations conducted on the medical device or supply must be kept throughout the use period by the healthcare provider.
5. Compliance with the post-marketing surveillance requirements for medical devices and supplies is necessary.
6. Any other requirements specified by the environment and published on its website.

3/20 Refurbished medical devices must be treated as new medical devices and must comply with the system and regulations' requirements.

4/20 Renewing medical devices under the following conditions:

1. The medical device must have received marketing authorization from the authority before it can be renewed.
2. The manufacturer must bear responsibility for the renewal.
3. The original purpose of using the medical device or its accessories must not change.
4. It is not intended for one-time use.

5. It can't be circulated after renewal unless all technical requirements mentioned in the marketing authorization requirements are met and compliance with the technical regulations and standard specifications approved by the authority is assured.
6. Compliance with providing identifying information, including the renewal date and that it's a refurbished medical device, in a clear and indelible format, in addition to retaining the original identification card.
7. Compliance with the post-marketing surveillance requirements for medical devices and supplies is required.
8. Any other requirements specified by the authority and published on its website.

5/20 Conditions for reselling, loaning, or donating used medical devices:

1. The medical device intended for resale, loan, or donation must have marketing authorization.
2. Resale, loan, or donation of medical devices that could be a source of infection transmission is prohibited.
3. The authority must be notified when reselling, loaning, or donating medical devices according to the post-marketing surveillance requirements for medical devices and supplies.
4. The manufacturer or its accredited representative must be informed of the resale, loan, or donation of the medical device.
5. The recipient of the resold, loaned, or donated medical device must be provided with all technical documents proving that the device meets the authority's requirements, including routine maintenance and performance efficiency reports.
6. Resale, donation, and loan procedures and records for medical devices should be documented and provided to the authority upon request.
7. Compliance with post-marketing surveillance requirements for medical devices and supplies is necessary.
8. Any other requirements specified by the authority and published on its website.

Article 21

The manufacturer must classify medical devices and supplies according to the classification system.

Regulation:

1/21 The authority establishes and publishes hazard classification rules for medical devices and supplies on its website. They are classified into four categories based on their level of risk, as follows:

1. Low risk, symbolized by the letter (A)
2. Low to medium risk, symbolized by the letter (B).
3. Medium to high risk, symbolized by the letter (C).
4. High risk, symbolized by the letter (D).
   The manufacturer must adhere to the above classifications as announced on the authority's website..

2/21 The manufacturer must:

1. Apply the classification rules to each medical device or supply separately when one of the devices or medical supplies is designated for use with another device, whether from the same manufacturer or not.
2. When more than one classification rule applies to the medical supply or device based on the manufacturer's intended use, adopt the highest classification for the item.
3. Separately classify the device or medical supply and its accessories.
4. 4. Document the rationale for classifying its devices or medical supplies, keep the analysis in its technical documents, and provide it to the authority when requested.
5. Adopt the highest device classification in devices assembled in one set, and each device or supply in it individually complies with these regulations, taking into account that the assembly is to achieve the user's requirements and does not change the purpose of using the individual devices that it consists of.

3/21 The system's software is classified as follows:

1. If it affects the use of a separate medical device, it should be classified according to the set's intended use.
2. If it is independent of any medical device, it is classified in itself using the classification rules.

4/21 The authority must review the published classification rules when there is justification through post-marketing monitoring or technology developments.

5/21 The authority may reject the classification provided by the manufacturer if it is not convinced by its justification for adhering to the classification rules announced on the authority's website.

Article Twenty-Two

Establishments wishing to trade medical devices and supplies in the Kingdom must comply with the application of a quality management system.

Regulation

1/22 Manufacturers, importers, distributors, and accredited representatives must obtain a quality management system certificate in accordance with the specification (13485:2017 SFDA.MD/GSO ISO) or the latest version if adopted by the authority from one of the medical devices and supplies and quality management system conformity verification offices accredited by the authority.

Article Twenty-Three

High-risk medical devices or supplies classified according to the classification system may not be dispensed for use outside a healthcare facility without a medical prescription. The authority issues a list of such devices and supplies outside the medical field.

Regulation

1/23 The authority issues a list of high-risk medical devices and supplies, which may not be dispensed for use outside a healthcare facility without a medical prescription. The list published on the authority's website is updated regularly.

2/23 Healthcare providers must provide a medical prescription for the devices and medical supplies listed in Article (1/23).

3/23 Establishments are not permitted to dispense or supply any high-risk medical device to a user unless a medical prescription has been obtained.

Article Twenty-Four

Advertising medical devices and supplies, announcing them, or promoting them is not permitted except after the approval of the authority and in accordance with the conditions specified by the regulations.

Regulation:

1/24 Approval from the authority must be obtained on the format of the promotional or advertising material before publishing it, according to the following requirements and conditions:

1. The medical device or supply has obtained a marketing authorization certificate.
2. The advertisement does not contain any misleading information for the user, contrary to the claims specified by the manufacturer.
3. Avoid misleading the average person in promotional materials, advertisements, and publications directed to the community, including information on the web.
4. Promotional materials, advertisements, and publications directed at individuals using devices and medical supplies must contain information that meets their needs.

5. Those involved in marketing medical devices and supplies have sufficient information about them to provide the correct marketing information.
6. The advertisement does not discredit any other medical device or supply, directly or indirectly.
7. The advertisement does not include anything that violates the provisions of Islamic law and public morals.
8. The language used in the advertisement is Arabic if it is aimed at the general public, and English if it is aimed at health practitioners; other languages may be used as long as they are compatible with the language used in the advertisement.
9. 9. Any additional requirements specified by the authority.

Article Twenty-Five

Awareness or charitable campaigns involving medical devices and supplies are not permitted unless approved by the authority and in accordance with the regulations.

Regulation

1/25 Those wishing to conduct awareness or charitable campaigns related to medical devices and supplies must obtain prior approval from the authority and satisfy the following requirements:

1. The medical device or supply must be registered with the authority and have obtained marketing authorization.
2. Awareness and education must be carried out by specialized and qualified individuals.
3. There should be no commercial marketing signs or advertising materials.
4. Medical devices and supplies should not be used on members of the general public during awareness or charitable campaigns unless the participant's consent is obtained on the declaration form.
5. Distribute no free samples to participants, attendees, or the general public for marketing purposes.
6. The material used in the campaigns should be written in English when its purpose is to address specialists, and Arabic should be added when its purpose is to address regular users.
7. Satisfy all necessary approvals from related entities.
8. Any other requirements requested by the authority and published on its website.

2/25 The authority must ensure that those responsible for the awareness and charitable campaigns related to medical devices and supplies comply with the authority's requirements.

Article Twenty-Six

The authority monitors healthcare providers' compliance with implementing technical regulations within healthcare facilities to ensure the safety, security, and efficacy of medical devices and supplies in diagnosis and treatment.

Regulation

1/26 Healthcare providers must comply with:

1. requirements mentioned in the post-marketing surveillance requirements for medical devices and supplies that pertain to the safe use of medical equipment and supplies.
2. The requirements for radiology departments, nuclear medicine, and radiation therapy are published on the authority's website.
3. Any other requirements imposed by the authority and published on its website.

2/26 Healthcare providers must periodically conduct qualitative quality assurance tests for radiology and medical imaging devices through qualified and trained specialists within the healthcare facility or one of the entities licensed by the authority to provide this service.

3/26 Healthcare providers, in the event of a failure in one of the qualitative quality assurance tests for their radiology and medical imaging devices, must notify the authority and provide a corrective plan

to address the defect within three working days from the date of the test results report, including a copy of the report. The continued use of the device is subject to the recommendations in the report.

Article Twenty-Seven

The establishment and the authorized representative must provide the authority with any document or information requested to carry out its duties stipulated in the system and regulations.

Regulation

1/27 The establishment and the authorized representative must provide the authority with documents and information within ten working days of the request.

Article Twenty-Eight

The manufacturer, the authorized representative, and the healthcare provider must comply with reporting incidents related to their medical devices and supplies to the center.

Regulation

1/28 Healthcare providers must appoint a liaison officer with the center in accordance with post-marketing surveillance requirements.

2/28 The manufacturer, the authorized representative, and the healthcare provider must comply with the post-marketing surveillance requirements for medical devices and supplies and report incidents related to their medical devices and supplies to the center. They must also provide the center with all necessary information and documents, including supply and distribution data.

Article Twenty-Nine

The center issues safety alerts to warn the user and healthcare provider of the risks resulting from the use of medical devices and supplies.

Regulation

1/29 The center issues safety alerts for medical devices and supplies after evaluating the risks and confirming the Kingdom's impact.

2/29 The center publishes safety alerts on the authority's website or other communication means, according to the procedures followed.

Article Thirty

The manufacturer and the authorized representative must report to the center about their medical devices and supplies regarding the following:

1. Safety alerts issued by similar regulatory bodies outside the Kingdom.
2. Risks that affect the safety of the medical device or supply.
3. Completion of the corrective action safety alert.

Regulation

1/30 The manufacturer and the authorized representative must comply with the following:

1. Inform the center of any safety alerts that affect the Kingdom, according to the center's approved timeline.
2. Identify the risks related to the safety alerts that affect the Kingdom, providing supply and distribution information.
3. Submit a corrective action implementation plan, including a completion date.
4. Provide proof of completing the corrective action for the safety alert, in accordance with the plan approved by the center.

2/30 After fulfilling all the post-marketing surveillance requirements, the center issues a completion notice for the corrective action to the manufacturer and the authorized representative.

Article Thirty-One

In the event of a safety alert, the establishment and the healthcare provider must stop trading in medical devices and supplies until the center issues a notice indicating the completion of the corrective action for the safety alert.

Regulation

1/31 The establishment and healthcare providers are required to do the following:

1. Use the medical device or supply according to the recommendations in the safety alert.
2. Do not import or distribute any device or medical supply that has had a recall or usage suspension issued.
3. Stop trading in the medical device / supply if the corrective action stipulates this.
4. Provide the necessary information and reports for the safety alert.

Article Thirty-Two

The establishment and the authorized representative must respond to the authority's request to trace the medical devices and supplies, and the regulation defines the procedures related to this.

Regulation

1/32 The establishment and the authorized representative must provide the authority with information on the supply and distribution of its medical devices and supplies that are in circulation in the Kingdom.

2/32 The establishment and the authorized representative are required to track the medical device and supply in the Kingdom, as well as to provide the authority with the following information:

1. Contact data for factories of medical devices and supplies.
2. Supply and distribution data and locations of display or sale.
3. Quantities supplied and data on their transport and storage.
4. Lists of names and contact information of the users.
5. Information about the circulated medical device, including its name, brand, identification number, serial numbers, supplied batches, and other necessary information to identify and track it.
6. Any other information required by the authority and published on its website.

3/32 The authority has the right to ensure that the establishment or authorized representative has put in place and implemented effective tracking procedures for medical devices and supplies during their circulation in the Kingdom.

Article Thirty-Three

The authority inspects establishments as well as medical devices and supplies to ensure that the system's provisions, regulations, and technical rules are followed. Inspectors who are deemed to be criminal law enforcement officers are appointed by the council's leader. Their responsibilities include the following:

1. Seize medical devices and supplies that violate the system's provisions.
2. Handle the seized violations as follows:
   a) Retain them and the relevant documents, when necessary.
   b) Take samples for analysis.
   c) Recommend the destruction of proven fraudulent or harmful items.
   Destruction is carried out after a decision from the authority, in accordance with recognized technical standards. The implementation is managed by a committee—or more—appointed for this purpose by a decision from the council's president. The violator bears the cost of the destruction process.

Regulations

1/33 The authority inspects the manufacturer's quality management system in the pre-marketing stage when necessary. The inspection report issued by the environment or one of the medical device and supply conformity verification offices, as well as the approved quality management system, is one of the required documents to obtain a marketing authorization certificate.

2/33 The authority conducts inspection visits to factories in the post-marketing stage and has the right to appoint conformity verification and auditing establishments to carry out this role on its behalf.

3/33 The authority establishes the inspection requirements and the quality management system for medical devices and supplies, as well as the inspector's duties, powers, and rights.

4/33 Inspections are conducted on establishments according to the quality management system and work procedures outlined in the inspection requirements and the quality management system for medical devices and supplies.

5/33 If the inspector detects a medical device or supply that violates the system, regulations, provisions, requirements, or technical rules approved by the authority, it is obligatory for him to seize and hold the medical device or supply in accordance with the procedures stipulated in the inspection requirements.

6/33 The inspector, upon presenting proof of his status, is entitled to do the following:
1- Enter the establishment and inspect it along with its warehouses, storage spaces, transport means, etc.
2- Request to open any locked site within the establishment.
3- Seek help from the security authorities to enable him to perform his duties if necessary.
4- Recommend any of the precautionary measures listed in Article 1/39 of the regulations.

7/33 When taking samples, the inspector is obligated to follow the procedures as stated in the inspection requirements and the quality management system for medical devices and supplies.

Article Thirty-Four

Everyone subject to the provisions of the system is obligated to maintain the confidentiality of the information they may obtain due to their duties.

Article Thirty-Five

The inspector must present his job card when conducting inspection and seizure work. The establishment should enable him to perform his duties without hindrance.

Article Thirty-Six

The chief has decided that financial rewards for the authority's inspectors are permissible.

Article Thirty-Seven

By chief decision, it is possible to award an incentive reward of up to 25% of the amount of the due penalty to anyone who assists the authority's non-inspectors in uncovering a violation of the system and regulations.

Article Thirty-Eight

The authority, in agreement with the Ministry of Finance, establishes the rules governing the granting of rewards referred to in Articles Thirty-Six and Thirty-Seven of the system.

Article Thirty-Nine

The authority has the authority to take the necessary precautionary measures in the event of a belief in the existence of harm, a misleading claim, or an impact on the safety, security, and efficiency of medical devices and supplies in accordance with the regulations.

Regulations

1/39 The authority has the authority to take the following precautionary and protective measures in the event of a belief in the existence of harm, a misleading claim, or an impact on the safety and security of medical devices and supplies:

1. Seize the medical device or supply until its safety and security are verified.
2. Temporarily close the establishment or part of it according to the procedures outlined by the regulations as follows:

a) Document the incident with a record that includes a description of the potential harm and its location.
b) Recommend the type of closure suitable for the potential harm.
c) The closure remains in effect until the potential harm is removed, corrective action is completed and the risks are evaluated.
d) The closed establishment may not be reopened without the environment's approval.

3. Suspend the establishment's license until the potential harm is removed.
4. Take a sample for laboratory examination and perform the necessary tests at the expense of the establishment.
5. Any other measures taken by the authority to protect public health or the user of the medical device or supply, as required by the nature of the incident and potential harm.

2/39 If the authority determines that the device or medical supply is in violation of the system, regulations, or technical regulations, it may take one or more of the following actions:

1. Issue and publish a safety warning.
2. Continue to seize the device or medical supply if it has been previously seized until the corrective action is completed if it is correctable.
3. Ban the circulation of the device or medical supply.
4. Stop the production lines that are proven to cause harm.
5. Order destruction at the expense of the violating establishment according to the decision of the committee provided for in Article 33 of the system.
6. Any other steps taken by the authority to ensure the safety of medical devices and supplies as required by the circumstances.
7. Apply any of the penalties provided for in Article 42 of the system.

3/39 The manufacturer, the authorized representative, and the establishment are obligated to implement the environment's decisions related to precautionary measures until the safety and security of the affected medical devices and supplies are confirmed.

Article Forty

It is not allowed to circulate medical devices and supplies if the authority decides to withdraw them from the market or ban their circulation.

Article Forty-One

In accordance with the provisions of the system, the following actions are violations:

1- Deceiving or attempting to deceive any medical device or supply.

2- Selling, dispensing, or possessing for the purpose of trade in counterfeit medical devices or supplies, knowing they are counterfeit.

3- Bringing into the Kingdom a medical device or supply that is not registered, counterfeit, or does not have marketing permission, or attempting to do so.

4- Manufacturing a medical device or supply in violation of any system, regulatory, or technical provision.

5- Using false information to promote medical devices and supplies, either on them or in their advertising.

6- Transporting or storing a medical device or supply in violation of the transport and storage

conditions set by the authority.
7- Bringing into the Kingdom packages or covers for a medical device or supply for the purpose of deception, or attempting to do so.
8- Manufacturing, printing, possessing, selling, or displaying packages or covers for a medical device or supply for the purpose of deception.
9- Committing any other violation of the provisions of the system.

Article Forty-Two

1- Without prejudice to any stricter penalty imposed by another system, anyone who violates any of the system's or regulations' provisions shall face one or more of the following penalties:

a) A fine not exceeding (five million) riyals.
b) Temporary closure of the establishment for a period not exceeding (one hundred and eighty) days.
c) For a period of no more than one year, the marketing permission for the medical devices and supplies involved in the violation will be suspended.
d) Cancellation of marketing permission for the medical devices and supplies involved in the violation.
e) Prohibition of the violator from practicing any activity related to medical devices and supplies for a period not exceeding (one hundred and eighty) days,
f) cancellation of the license.

In the case of repeated violations, the penalty imposed under subparagraphs (a), (b), (c), and (e) of this paragraph may be doubled. If the violation is committed within one year of the first violation, it is considered repeated.

2- If the violation involves any of the actions specified in paragraphs (1), (2), (3), (7), and (8) of Article Forty-One of the system, the penalty is imprisonment for a period not exceeding (ten) years or a fine not exceeding (ten million) riyals, or both. In addition, any of the penalties specified in subparagraphs (b), (c), (d), (e), and (f) of paragraph (1) of this article may be imposed, and the penalty is doubled in the event of a recurrence.

Article Forty-Three

The authority is responsible for imposing the penalties stipulated in paragraph (1) of Article Forty-Two of the system, in accordance with a table issued by the council, which includes a classification of violations and the specified penalties for each, taking into account the nature of the activity and the committed violation, its seriousness in each individual case, and the aggravating and mitigating circumstances.

The chief or his delegate decides on these penalties. In all cases, the authority has the authority to take precautionary measures if deemed necessary.

Regulation

1/43 The violator is notified of the penalty decision in one of the following ways:

1. Delivering the penalty decision to the violator by hand with an acknowledgement of receipt or proof of refusal.
2. Delivering the penalty decision to the offending establishment at its location with proof of delivery from any member of the establishment and documenting that.
3. Sending the approved decision to the national address of the violator registered with the authority.
4. Sending the approved decision to the email of the offending establishment or owner registered with the authority.

Article Forty-Four

1. A committee(s) shall be formed by a decision of the council, with no fewer than (three) members, at least one of whom is a legal consultant, to consider grievances submitted to the authority from

decisions to impose penalties issued in accordance with paragraph (1) of Article Forty-Two of the system.

2. The rules and procedures of the committee's work, as well as the remuneration of its members, are determined by a council decision.
3. It is permissible to appeal the committee's decisions before the administrative court.

Article Forty-Five

If the violation is covered by the ruling of paragraph (2) of Article Forty-Two of the system, it shall be referred to the public prosecutor for investigation and referral to the competent court in accordance with the procedural rules.

Article Forty-Six

The judgment or decision issuing the penalty may, depending on the circumstances, include a provision for publication at the violator's expense in a local newspaper published in his place of residence. If there isn't a newspaper in his area, look for one in the next one. Alternatively, it may be published in any other suitable medium, depending on the type of violation committed, its gravity, and its impact, provided that the publication occurs after the judgment has acquired finality, or the decision is secured by the expiration of the period of grievance, or the issuance of a final judgment rejecting the grievance against it.

Article Forty-Seven

Any person harmed by a violation of the system's provisions has the right to seek compensation from the competent court for the damages caused by that violation.

Article Forty-Eight

The council shall issue the regulation within (one hundred and eighty days) from the date of publication of the system in the official gazette, and it shall be effective from the date of its entry into force.

Article Forty-Nine

The system will go into effect 180 days after its publication in the official gazette.