MDS – REQ 9

Requirements for Licensing Medical Device Establishments

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Introduction

Purpose

The purpose of this document is to specify and clarify the licensing requirements and obligations for medical device establishments that are subject to the Law of Medical Devices and its Executive Regulations.

Scope

These requirements apply to every establishment with a legal entity in accordance with KSA regulations and whose main activity is one of the approved economic activities by the SFDA in the field of medical devices, based on the national classification for the economic activities approved by the SFDA, including electronic activities:

1. Local Manufacturers
2. Authorized Representatives
3. Importers and Distributors
4. Warehouses
5. Service Providers of Clinical Trials Verification
6. Service Providers of Testing (Laboratories)
7. Service Providers of Conformity assessment and quality management system
8. Service Providers of Quality Assurance for Radiation Emitting Devices
9. Service Providers of Technical Consultation
10. Service Providers of Medical Device Maintenance

Background

SFDA has issued this document in reference to Article six of the “Law of Medical Devices” issued by Royal Decree No. (M/54) dated 06/07/1442 H which stipulates that “an establishment shall not engage in any of the activities subject to this Law unless registered and a license is obtained” and article ten which stipulates that “The Regulations shall specify the conditions and procedures necessary for registration; issuance of the marketing authorization; and for license issuance, renewal, amendment, transfer, and revocation.” and Articles (2/6) of the Medical Devices Executive Regulation issued by Board Resolution No. (3-29-1443) dated 2/19/1443 H, which state that “Establishments that practice any aspect of the activities subject to the provision of the Law and its Regulation shall obtain a license for the establishment itself, its branches and its warehouses by the SFDA in accordance with the conditions and requirements mentioned in this regulation".

Responsibilities and Authorities of SFDA

1. Study and verify that the applicant's applications and information are sufficient and appropriate and meet all the requirements.
2. Notify the establishment of receiving the information required to license and confirm that it fulfills the licensing requirements.
3. Conduct an inspection of the establishment to ensure that all requirements have been met, and the SFDA has the right to exempt some establishments.
4. During the licensing process, confidentiality of information viewed by the employees or those contracted with shall be maintained.
5. Determine the fees for issuing a license for each establishment of medical devices in accordance with Annex (2).
6. Issue a license to the establishment after fulfilling all requirements, valid for one year or similar renewable periods.
7. Reject the license request for establishments that do not meet all requirements, and notify the applicant of rejection reasons.
8. Periodic supervision and inspection shall be applied to ensure establishment’s compliance with SFDA’s regulations and requirements.
9. Take appropriate actions in case of proven negligence, violations, or manipulation of the SFDA's law, regulations or requirements, and apply penalties and fines according to the Laws of Medical Device and its Executive Regulations.
10. Investigate any complaint submitted by establishments or their beneficiaries; and ensure they are objectively evaluated according to the known procedures.
11. Commit to publishing a list of all licensed establishments on the SFDA's website, along with a statement of their activities.

Requirements for Licensing of Medical Devices Establishments

Establishments wishing to engage in any of the activities subject to the Law of Medical Devices, including electronic activities, shall obtain a license for the establishment, its branches, and warehouses from the SFDA in accordance to the general and specific requirements in this document.

A. General Requirements

1. Adherence to all Conditions, requirements, and regulatory procedures of other competent authorities, and obtaining the necessary licenses before applying for a license from the SFDA, along with providing the evidence thereof.
2. Each establishment shall have a legal entity under the regulations of the KSA, or be part of a legal entity so that it can be considered legally responsible for all its activities in the KSA, including the decisions it takes.
3. Create/open an account in the SFDA Unified Electronic System (GHAD) and obtain an establishment number.
4. Submit a request in the SFDA Unified Electronic System (GHAD) or through the unified platform at the Saudi Business Center for the purpose of obtaining a license to practice the activity, renew, amend, transfer or cancel the license.
5. Submit all required documents through SFDA Unified Electronic System (GHAD) or through the unified platform of the Saudi Business Center.
6. All medical devices manufacturers, importers and distributors in categories (A) and (B) shall obtain a certificate of conformity to the requirements of the quality management system in accordance with the Saudi standard (SFDA.MD/GSO ISO 13485:2017) or its equivalent from one of the providers of medical device Conformity assessment and quality management system which is accredited by the SFDA.

   Note: The SFDA's accredited conformity assessment bodies means that those whom carry out their activities inside the KSA and have a license from the SFDA, or those located outside the KSA and accredited by the International Accreditation Forum (IAF)
7. Authorized representatives, importers and distributors in categories (C) and (D) as well as importers and distributors of optics shall submit documented evidence

or obtain an inspection report issued by the SFDA on compliance with the requirements of the quality management system in accordance with the Saudi standard (SFDA.MD/GSO ISO 13485:2017) or its equivalent.

Note: The Checklist for Quality Manual Form template published on the SFDA's website can be used in preparing for the SFDA's audit visit for the quality management system.

8. Pay the licensing fee according to the time periods listed in Annex (2).
9. The establishment shall provide a database to archive all relevant data and documents so it can be easily accessed and retrieved for a period of no less than (5) years.
10. Provide SFDA with documents and information within (10) days of its request.
11. No medical devices shall be circulated in the KSA unless they are registered and have obtained valid marketing authorization from SFDA.
12. Sufficient and appropriate human and other necessary resources shall be provided to preform duties with efficiency, transparency, impartiality, independence and integrity.
13. Medical devices shall not be advertised, promoted or marketed without prior approval from the SFDA's approval in accordance with the Requirements for Advertisement Approval and Launching Awareness and Charity Campaigns for Medical Devices (MDS-REQ8)
14. Provide and implement documented and effective procedures for transportation and storage operations in accordance with the manufacture's requirements, and transporting and storage of medical devices requirements (MDS – REQ 12) which is published on the SFDA's website.
15. Adhere to the instructions provided by the manufacturer in all procedures related to medical devices.
16. Provide in detail all data related to the circulation of the establishment's medical devices, including supply, distribution and customer data, and provide them to the SFDS upon request
17. Adhere to the requirements for inspections and quality management system for medical devices (MDS – REQ10) which is published on SFDA's website.
18. Enable inspectors to review documents, collect information and verify them during inspection visits.

19. Respond to cases of non-conformity observed during inspection visits - if any - by using the form sent with the inspection report, attaching the corrective action plan within the period specified by the SFDA, and notifying the SFDA upon completion of implementing the corrective action.
20. Notify the SFDA of any changes in the information submitted to obtain the license within (10) days of the change occurring.
21. Adhere to the requirements for post-market surveillance of medical devices (MDS – REQ11) which is published on the SFDA's website.
22. Informe the SFDA of any medical devices that violate the Law of Medical Devices and its Executive Regulations, including counterfeit medical devices that do not have a valid marketing authorization (MDMA), and report suspected cases.
23. Request renewal of the license can be submitted (60 days) before the expiration date of the current license. A renewal of the license will be issued from the expiration date of the previous license unless it is canceled.
24. Report to the SFDA in case of a request to amend the license through the Unified Electronic System (GHAD) and submit the required documents.
25. Reporting to SFDA immediately in case the establishment is unable to continue fulfilling the licensing obligations and requirements, and the cancelation of the license is the establishment's responsibility if it does not wish to renew.
26. The establishment wishing to cancel the license or upon its expiration with no desiring for renewal shall be obligated to not practicing the activity and deleting the activity from the commercial registration and submitting the application via the Unified Electronic System (GHAD) to the SFDA/notifying SFDA, and providing evidence that there are no obligations on the establishment.
27. Commit not to share any documents or papers related to the SFDA with any other party, whether inside or outside the KSA, except with prior written approval from the SFDA, and the establishment is fully responsible for maintaining the confidentiality of the information.
28. Follow up on all laws, regulations, requirements, circulars, guidelines and instructions issued by the SFDA, as well as any additional amendments, which are published on the SFDA's website and notify the beneficiaries and relevant parties accordingly.

B. Specific Requirements and Obligations

In addition to what was mentioned in the general requirements section, every establishment shall comply with the specific requirements and obligations listed below depending on the type of each establishment.

1. Local Manufacturers

Specific Requirements

1. A valid industrial license from the Ministry of Industry and Mineral Resources in the event of construction or production that includes one of the industrial economic activities approved by the SFDA in the field of medical devices. This does not apply to the activity of (developing software and medical applications).
2. Submit evidence of implementing clause (2) of the "General Requirements".
3. Submit evidence of implementing clause (6) of the "General Requirements".
4. Pledge to obtain a marketing authorization certificate (MDMA) from the SFDA before trading any medical device in the KSA in accordance with the Requirements for Medical Devices Marketing Authorization which published on the SFDA's website.
5. Pledge that the manufacturer is fully responsible for the quality of all manufactured batches.
6. Appoint a full-time technical manager for the manufacturer who is an engineer, medical device technician, or qualified in one of the related specialties. The technical manager shall be responsible for supervising the technical aspects of developing, producing and distributing medical devices, and ensuring that the medical devices meet design and development requirements and the requirements of related customers. their responsibilities and tasks are specified, but not limited to, the following:
    a. Design and development process supervision: Manage the design and development process, including design inputs, design verification and validation.

b. Product development: Supervise the development of new products, including feasibility studies, design processes, prototypes and tests associated with these processes.
c. Technical requirements for manufacturing: establish and develop technical requirements for the product, design specifications and test protocols for the product.
d. Compliance with industry standards and specifications: Ensure compliance with industry standards and specifications related to the manufacturing process and the product to be manufactured.
e. Manufacturing process development: Develop and implement manufacturing processes, including validation of the manufacturing process, equipment qualification, and production planning.
f. Technical support: Provide technical support to production, quality and customer service teams.
g. Product testing and validation: Supervise product testing, including verification and validation processes.
h. Registration processes: Prepare and submit technical documents and files to obtain marketing authorization for the manufacturer products.
i. Documents and technical files: Develop, follow up and update the technical documents and files of the manufacturer's products.
j. Research and development: Keeping up with modern technologies in the industry, to identify opportunities for innovation and improvement.

7. Appoint a full-time quality manager for the manufacturer who is an engineer, medical device technician, or qualified in one of the related specialties, and is responsible for ensuring the development and implementation of the quality management system in the manufacturer, and reviewing and improving it continuously to ensure compliance with regulatory requirements, industry standards, and customer requirements. His responsibilities and tasks are specified, but not limited to, the following:
   a. Quality system management: Developing, implementing and monitoring the quality management system, including documentation, training and auditing.
   b. Regulatory commitment and compliance: Ensuring compliance with the requirements of the regulatory and legislative body, so that he is a person responsible for regulatory compliance and in addition to his duties, he does the following:

- Verifying the conformity of medical devices during manufacturing according to the ISO 13485 quality management system before the final approval for the device to be circulated in the market (Product release).
- Ensuring the establishment, development and continuous updating of technical documents by the technical manager of the Manufacturer.
- Compliance with post-marketing surveillance requirements
- Commitment to reporting serious incidents, field safety corrective actions, and accident reports.

c. Quality Assurance: Overseeing quality assurance activities, including testing, inspection, and verification.
d. Risk Management: Identifying, assessing, and mitigating risks associated with medical devices.
e. Corrective Actions and Preventive Actions: Managing the process of corrective actions and preventive actions, including investigation, root cause analysis, and implementation of corrective actions.
f. Auditing and Inspection: Conducting internal audits and managing external audits and ensuring compliance with the results of these audits.
g. Supplier Management: Overseeing the selection, evaluation, and monitoring of suppliers to ensure compliance with quality requirements.
h. Training and Development: Developing and implementing training programs to ensure employees are familiar with quality requirements and procedures.
i. Quality and Performance Measures and Goals: Establishing and tracking quality metrics to measure performance and identify areas for improvement.
j. Compliance with Medical Devices Industry Standards and Specifications: Ensuring compliance with industry standards for products and other relevant standards.

8. Determine the manufacturer’s activity and the level of risk of the medical devices to be manufactured.

Obligations

1. Manufacturers with more than one branch shall obtain a separate license for each branch.
2. Commitment from the manufacturer to identified products which manufactured as sample (experimental and will not be sold in the markets) for the purpose of obtaining the ISO 13485 Quality Management System Certificate, and that these devices shall not be traded (provided for free or for a fee, whether for distribution or use), or advertising, and that their identification cards (external label) shall include that they are not intended for trade (sale or use), until they meet the requirements of the law of Medical Devices and obtain marketing authorization from the SFDA.
3. Conduct all necessary technical tests to prove compliance of their products with regulatory requirements for safety, performance and quality.
4. Conduct all technical and reference tests according to technical standards issued by standardization bodies and standards organizations.
5. Commitment to classify medical devices according to the classification system which published on the SFDA's website.
6. Compliance with the requirements of medical device Unique Device Identification (UDI) which published on SFDA's website
7. Commitment to provide after-sales services for their medical devices, including approved spare parts that meet standards and technical requirements of the device to ensure continuity of its function according to its intended purpose throughout device's lifecycle.
8. Notify the national center for medical devices reporting (NCMDR) of any cases of delay or unavailability of medical devices that pose high potential risks for medical services.
9. Comply with the published SFDA's special requirements such as home use medical devices or implanted medical devices.

2. Authorized Representatives

Specific Requirements

1. Provide a proof of compliance with what is stated in point (2) of the "General Requirements" section.
2. Provide a proof of compliance with what is stated in point (6) or point (7) of the "General Requirements" section based on the establishment category.
3. Appointing an authorized person to deal with the SFDA holding an appropriate qualification in one of the related filed.
4. Obtain a separate license form the SFDA for each manufacturer that have been represented within KSA, and in the case there are subsidiary manufacturers affiliated with the main manufacturer, the main manufacturer shall fully own the subsidiary manufacturers.
5. Ensure there is no other authorized representative has been appointed for the same class or general group of the medical devices.
6. Documentation of applying the necessary operations to perform the tasks assigned to him, and attaching the relevant documents.
7. Agreement with the manufacturer shall be documented, approved and subject to the regulations in the KSA.
8. The agreement with the manufacturer shall include the following information - at least: -
    a. Specify the activities which the authorized representative is acting on behalf of the manufacturer in dealings with the SFDA.
    b. Type or group of medical devices subject to the Medical Devices Law and its executive regulation to be market in the KSA.
    c. Authorized Representative shall comply with all requirements for post-marketing surveillance published on the SFDA's website.
    d. Determine the duration of agreement between the parties, as one of them may terminate it in accordance with the following:
        - the manufacturer shall provide written notice to the authorized representative in order to terminate the Agreement,
        - Manufacturer shall appoint a new Authorized Representative and transfer all previous obligations to him immediately upon

termination or non-renewal of the previous authorized representative agreement, and shall notify the SFDA with that.

- the Authorized Representative shall provide written notice to the manufacturer in order to terminate the agreement.

Obligations

1. Confirming the continuance accuracy and validity of information which previous submitted on an annual basis, as the SFDA will evaluate any changes to the delegation and take appropriate action if necessary.
2. Notify the manufacturer and confirming there is no more than one authorized representative has been appointed for the same type or general group of medical devices that he wishes to represent within the KSA.
3. Represent the manufacturer in its interactions with the SFDA, and provide any information or documents requested by the SFDA.
4. Cooperating with SFDA in studies and procedures taken during post-marketing surveillance.
5. Inform the SFDA of any incidents occurred outside the KSA related to the medical devices traded in the KSA; an explanation of the circumstances shall be submitted along with the corrective actions taken by the manufacturer or intended to be taken.
6. Identify risks related to safety alarms that affect the KSA and provide the supply and distribution information.
7. Cooperating with establishments that carry out activities subject to the provisions of the medical law and its regulation with regard to medical devices that are traded in the KSA due to the agreement with the manufacturer.
8. The authorized representative's responsibility for the medical devices covered by the agreement shall not expire upon his request to terminate the agreement or its expiration, unless the manufacturer appoints an authorized representative to replace him, or if the medical devices are not available in the market or with users.
9. Notify the national center for medical devices reporting (NCMDR) of any cases of delay or unavailability of medical devices that pose high potential risks for medical services.

10. Ensure the manufacturer’s compliance during the representation period with providing after-sales service, including maintenance for the medical devices throughout their lifecycle. This includes providing approved spare parts that meet the technical specifications and standards of the device to ensure its continued operation according to its intended purpose

3. Importers and Distributors

Establishment is classified according to the electronic questionnaire in GHAD system, which includes type of establishment, activities practiced, number of employees, scope of coverage and type of medical device and the general group of the medical device that will be traded.

Specific Requirements

1. Appoint an authorized person for the establishment to deal with the SFDA, that holds an appropriate qualification in one of the relevant specialties.
2. Provide a proof of compliance with what is stated in point (2) of the "General Requirements" section.
3. Provide a proof of compliance to what is stated in point (6) or point (7) of the "General Requirements" section based on the establishment category.
4. Provide manufacturer's information and data for the medical devices to be imported, along with the authorized representative's information for manufacturer residing outside the KSA.
5. Declaration of conformity indicating the conformity of medical device with the requirements of Law of Medical Devices and its Executive Regulations, signed by the manufacturer.
6. Listing information of the establishment's branches and sales outlets within the main license and supervise the implementation of all requirements and obligations on them on an ongoing basis and update any changes that occur in the information of the branches and sales outlets.
7. Establish a documented procedure for storing and transporting of medical device in accordance with manufacturers requirements, and submitting a pledge to implement and comply with the procedure.
8. The establishment shall have a warehouse license or a storage license by a third party issued by the SFDA in accordance with the requirements for warehouse licensing. As for licensed establishment that have sales centers, it is sufficient to have an internal storage area in the sales centers in accordance with the Requirements for Transporting and Storage of Medical Devices published on the SFDA's website.

9. Provide a documented and an effective tracking procedure to document contacts data of the manufacturer, information related to supply, distribution and use of the medical device, quantities supplied, data of transportation and storage, contact information with users, and information of the medical device in used. Also, provide a pledge to implement and comply with the procedure.

Obligations

1. Importing and/or distributing medical devices that comply with the requirements of the Law of Medical Devices and its Executive Regulations.
2. Ensure that all necessary documents are present with each medical device:
   a. A Valid Marketing Authorization Certificate.
   b. Declaration of conformity indicating the compatibility of the medical device with the requirements of the Medical Devices Law and its executive regulations, 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 published on the SFDA's website.
   d. Identifying information and other relevant documents.
   e. Contact details of the manufacturer, and the authorized representative if the manufacturer is outside the KSA.
3. Notify the National Center for Medical Devices Reporting (NCMDR) of any cases of delay or unavailability of medical devices that pose high potential risks to medical services.
4. If the establishment wishes to provide maintenance services for its medical devices, it shall comply with the manufacturer's instructions and requirements for the after sale and medical devices maintenance according to the Requirements for Post-Market Surveillance of Medical Devices (MDS – REQ11) which published on the SFDA's website. And, if the establishment wishes to provide maintenance services for medical devices that are not its own, a license for medical maintenance service provider shall be obtained in accordance with the Licensing Requirements for Service Provider of Medical Device Maintenance published on the SFDA's website. It is necessary to verify the existence of a medical device maintenance services license issued

by the SFDA when contracting to obtain maintenance services from an external party.

5. Commitments when issuing an importing/distributing license for optics according to the national classification of economic activities published on the SFDA's website not engaging in the activity of importing and distributing other medical devices. In the event of a desire to engage in all activities, including optics products, an importing/distributing license for medical devices shall be issued.

4. Warehouses

Specific Requirements

1. Provide a proof of compliance to what is stated in point (2) of the "General Requirements" section.
2. Appointing a full-time technical Managers who are biomedical engineers, technicians or qualified in one of the related filed.
3. Provide a proof of compliance with transporting and storage of medical devices requirements (MDS – REQ 12) which published on the SFDA's website.
4. Pledge not to store any medical device that violates the SFDA's requirements.

Obligations

1. Comply with manufacturer's requirements in addition to compliance with transporting and storage of medical devices requirements (MDS – REQ 12) which published on the SFDA's website.
2. If the establishment carries out storage activities for others, the following shall be adhered to:
    a. The renter shall have a storage license with others.
    b. A contract between the main renter and the renter shall be signed contains the information and obligations of both parties in accordance with the requirements of the SFDA, including data on the areas and spaces allocated for storage. The contracts shall specify the responsible party for transporting and delivery of the storage medical devices to the client.
    c. Documenting and keeping all record related to procedure or trade related to renters.
    d. Commitment not to cancel the warehouse license if there are valid licenses for renters within the warehouse.
3. Commitment to issue a third-party storage license for each space rented within a medical devices warehouse with a separate license that cannot be used or transferred to another warehouse.

4. In case the establishment wishes to rent space inside a warehouse, the renter shall have a valid medical device warehouse license.
5. The renter shall do the following:
    a. Adhere to the manufacturer's instructions and comply with the requirements for transporting and storage of medical devices (MDS-REQ12) published on the SFDA's website.
    b. Provide the lessor with a copy of the documented procedure for transporting and storing medical devices.
    c. Providing the lessor (warehouse) with a copy of the receipt and delivery data when withdrawing and transporting (delivering) a medical device/supply from the warehouse to the customer.
    d. Not carrying out of any medical device/supply in the event that a decision is issued by the SFDA to close the warehouse in which it was stored until receiving a notice from the SFDA permitting the disposal.
    e. Not to sublet the allocated areas and spaces to any other party under any circumstances.
    f. Obtaining a separate third-party storage license when renting additional areas or spaces in the warehouse later.
    g. Not to use the third-party storage license to store medical devices in a warehouse other than the warehouse stipulated in the third-party storage license issued by the SFDA.
    h. Upon cancellation, termination or expiration of the lease contract and one of the parties does not wish to renew it while the third-party storage license remains valid, the renter shall do the following within a period not exceeding (10 days):
        - Submit a request to the SFDA to cancel the third-party storage license and withdraw the medical devices from the warehouse.
        - Conclude a contract with an alternative licensed warehouse and submit a request to the SFDA to obtain a storage license at the alternative warehouse.
6. Adhere to any special requirements issued by the SFDA, such as those for storing medical devices that contain chemical substances.
7. Document all transactions and procedures carried out inside the warehouse.

5. Service Providers of Clinical Trials Verification

Specific Requirements

1. Registered and completed the electronic application on the SFDA's website (GHAD's system) for license a clinical studies verification' establishment (Clinical Study Monitoring Center).
2. The manager of Clinical Trials Verification Establishments shall be a full-time Saudi national holding at least a bachelor's degree in a related health or scientific field.
3. Appoint a full-time Saudi clinical study officer with a suitable academic qualification of no less than a bachelor's degree and at least three years of experience in the field of clinical studies.
4. Attach CV, certificates and experiences for clinical trials responsible person.

Obligations

1. Not to initiate any clinical trials without obtaining approval from the SFDA.
2. Adhere to the requirements outlined in the Requirements for Clinical Trials of Medical Devices (MDS-REQ 2) published on the SFDA website.
3. Notify the SFDA within a maximum of five days upon completion of clinical trials, occurrence of major deviations from the study protocol, or any event that affects the safety and rights of study subjects.
4. Comply with the standard of Clinical investigation of medical devices (SFDA.MD/ISO 14155) or an equivalent version.
5. Comply with the standard of Clinical investigation of medical devices (SFDA.MD/ISO 20916) or an equivalent version.
6. Archive all documents and correspondence related to the functions and tasks assigned to the center in accordance with written work procedures, and maintain the confidentiality and privacy of information.
7. Appointing a trained and qualified employee and organize a continuous training programs to develop their skills.
8. Document the duties and tasks of the center in writing in each clinical study with the study sponsor.

9. Providing training programs for employees of the entity executing clinical trials that suitable to the conducted clinical trials.
10. Adhere to the research ethics system for living organisms.

6. Service Providers of Testing (Laboratories)

Establishments conducting tests and measurements in the field of medical devices under standard conditions, Whether the private lab is independent or part of a conformity assessment body, shall meet the requirements and conditions accordance to The Requirements for Licensing Private Laboratories published on the SFDA's website.

7. Service Providers of Conformity assessment and quality management system

Specific Requirements

1. Obtaining accreditation from the Saudi Accreditation Center in the relevant fields.
2. Providing the SFDA with a conformity assessment program, including specific requirements and procedures for each field applied for.
3. Providing the SFDA with organizational structure, a list of technical and administrative staff, and a certified copy of their qualifications, training courses, and job descriptions.
4. Providing an electronic system to document all procedures for granting conformity certificates, issuance of technical and financial reports, and all related procedures for issuing the certificate (for fields that are required). Also, the SFDA shall granted a full authority to access and electronically link the system. Furthermore, the system shall include, at a minimum, the following:
    a. The number of applications received in detailed by country of origin or source.
    b. Number of applications for which conformity certificates were granted, and the SFDA may verify the certificates.
    c. Number of rejected applications.
    d. Number of applications for which corrective action was requested.
    e. Corrective actions completed and documented.
    f. Number of objections submitted by customers on verification results.
    g. Any special reports or statistics requested by the SFDA.

Obligations

1. Bearing professional responsibility for any claims or lawsuits arising from its activities against third parties.
2. Performing services through any of its branches, and in case it delegates a third party to perform some of its tasks, the third party shall be subject to all the requirements stipulated in this document and obtain SFDA's approval to delegated tasks and provide SFDA with a copy of the concluded authorization

contracts. The service provider shall bear full legal and financial responsibility for those services provided by a third party.

3. Conformity assessment shall be completed according to the following mechanism:
    a. Inform the establishment of any non-conformities and required corrective actions, if any.
    b. Provide the SFDA with a conformity assessment report in accordance with the approved forms by the SFDA, within a maximum period of (15) days from the completion of the conformity assessment activity.
    c. Conformity shall be checked periodically according to the risk assessment.
4. Access to the main company resources shall be available for people in KSA.
5. Keeping a record of people participating in each conformity assessment activity, including those outside the KSA, and to submit it to SFDA upon request or during audit visit.
6. Applying and following the procedures to guarantee impartiality and integrity, such as:
    a. Employees shall not be involved in design, manufacture, marketing, installation, maintenance or supply of medical device.
    b. Employees shall not have any previously participated in providing consulting services related to medical device.
    c. There shall be no financial interest with the manufacturer, importer or distributor of the medical device.
7. Apply and maintain a documented policy that guarantees safety and confidentiality of all documents and information obtained during the conformity assessment in quality management system. Such documents or information shall not be disclosed to any person or entity other than the SFDA without explicit approval from relevant external establishment or manufacturer.
8. Commitment to provide a service level agreement with clients.

8. Service Providers of Quality Assurance for Radiation-Emitting Devices

Specific Requirements

1. Appoint a Saudi radiation protection officer licensed by the Nuclear and Radiological Regulatory Authority, and provide the SFDA with a copy of the radiation protection officer's practice license.
2. Provide the SFDA with a copy of practice license for radioactive materials in the case that the establishment uses radioactive materials.
3. Provide the SFDA with a copy of engineering plan for the radioactive sources storage area in case that the establishment uses radioactive materials.
4. Saudi specialists/technicians and experts with a minimum of a bachelor's degree qualification are required in one of the following disciplines biomedical engineering, medical physics, or any related specialty. from an accredited scientific institution. The submitted scientific qualifications for providing this service will be evaluated.
5. A qualified Saudi expert to approve test results. The required qualifications are a Ph.D., or a Master's degree with at least three (3) years of practical experience, or a Bachelor's degree with at least five (5) years of practical experience in medical engineering, medical physics, or any related field from an accredited scientific institution. The submitted scientific qualifications for providing this service will be evaluated.
6. Providing measuring devices and simulators compatible with international standards and recording their data in the licensing form. Provide SFDA with a list of all assistive devices for measuring and calibration devices.
7. Provide SFDA with organizational structure, a list of technical and administrative staff, certified copies of their qualifications, training courses and job descriptions.
8. Provide SFDA with a copy of procedures and steps followed to implement each requested service to obtain a license, along with an explanation of the approved scientific reference for conducting tests method.

9. Provide a certified copy of the radiation protection and safety program at the establishment in both Arabic and English, which describes the radiation protection system used and proposed emergency response plan in case of an accidental radiation hazard, and radiation technical consultancy service providers are excluded.

Obligations

1. In compliance with what is mentioned in protection against ionizing radiation general instructions in the KSA and safe transportation of radioactive materials instructions in the KSA or any other documents issued by specialized authorities.
2. Refer to the approved scientific references for all technical reports issued by the establishment, in addition to clarifying the baseline values and permissible tolerance ranges (Baseline Tolerance) according to the scientific reference used in each test.
3. Add a related activity to quality assurance services and radiological measurements provision in the commercial registration after obtaining the SFDA's license.
4. It is not permitted to use unlicensed radioactive sources in terms of number, type and radioactivity.
5. It is not permitted to sell, rent, lend or donate radioactive sources to another establishment without obtaining approval from competent authorities.
6. It is not permitted to transfer fixed radioactive sources to any other location within the establishment without obtaining approval from competent authorities.
7. Dispose of radioactive sources when they are no longer needed shall be done in accordance to the general instructions for radioactive waste management and the general instructions for protection against ionizing radiation in KSA.
8. Notify the SFDA in case of a failure in one of radiology and medical imaging devices quality assurance tests, or in case of a defect in radiology rooms shielding within (3) days of test results report issuance with attaching a copy of the report. The report shall include a recommendation whether to continue using the device or not.

9. Provide personal radiation dose measurement cards for all employees while maintain records for 5 years.
10. Obtaining valid calibration certificates for all measurement devices from accredited laboratories.
11. It is not permitted to change work sites or violate the license without obtaining the prior approval from the SFDA.
12. Provide the SFDA with the schedules of delivering the services to healthcare providers before beginning the service, if requested.

9. Service Providers of Technical Consultation

Establishments engaging in consulting activities in the field of medical devices shall meet the requirements and conditions in accordance to Guide for Licensing Consulting Services Establishment published on the SFDA's website.

10. Service Providers of Medical Device Maintenance

Specific Requirements

1. Providing technical staff of engineers and medical maintenance technicians according to the following conditions:
   a. With academic or technical qualifications in biomedical engineering/technology or a related field.
   b. They shall receive specialized training from the manufacturer or from a trained person by the manufacturer on their medical devices.
2. Provide appropriate testing equipment to examine medical device function, its calibration, efficiency of performance and safety, which shall comply with the measurement and calibration system issued by Royal Decree No. (M/51) dated 13/11/1434 AH, and its executive regulations and related instructions.
3. Provide the SFDA with organizational structure, a list of technical and administrative staff, a certified copy of their qualifications, training courses and their job descriptions.

Obligations

1. Provide a maintenance management system and an inventory management system for collecting, storing, organizing, analyzing and recording data of the medical device in addition to the necessary spare parts, and a list of all spare parts suppliers approved by the manufacturer.
2. Providing approved spare parts according to the standards and specification of the medical device/supply immediately, and delay is not accepted except with justification in the case of corrective maintenance.
3. Comply with the manufacturer's instructions for corrective maintenance and calibration. If such instructions are unavailable, refer to the technical standards approved by the SFDA.
4. Preserve all data and agreements concluded with healthcare providers.
5. Providing a suitable storage spaces for medical devices, products and spare parts as recommended by the manufacturer and in accordance with the requirements for transportation and storage of medical devices.

6. Providing a designated and equipped place for the medical device’s maintenance.
7. Ensure that test equipment has been calibrated by the manufacturer or an accredited entity, in accordance with the measurement and calibration system issued by Royal Decree No. (M/51) dated 11/13/1434 AH, its executive regulations and related instructions, and maintain calibration certificates.
8. comply with maintenance requirements contained in post-marketing Surveillance requirements for medical devices, which are published on SFDA's website.
9. Implement documented work procedures.

Final Provisions

1. Adhere to the Law of Medical Devices, its Executive Regulations, and requirements contained in this document; if non-compliance occur, penalties and violations will be applied to the violating establishments according to the approved schedule of violations and penalties published on the SFDA's website.
2. Establishment wishes to cancel their license shall submit a request to the SFDA, and noting that the expiration or cancellation of the license does not exempt the establishment from legal liability.
3. Establishments have the right to object to the SFDAs decision regarding establishment's licensing and provide justifications for that. The objection shall be made in accordance with applicable legal procedures.
4. Commit not to use the SFDA's name or logo for advertising purposes or placing them on any products or on establishments.
5. Establishment shall commit the principles of independence, impartiality, and integrity, and ensure where there is no conflict of interests in the services provided in the case that there is more than one activity at the establishment. and ensure independency.

Annexes

Annex (1): Definitions and Abbreviations

KSA	Kingdom of Saudi Arabia
SFDA	Saudi Food and Drug Authority
LAW	Medical Devices Law
Executive Regulation	Implementing Regulation of the Law of Medical Devices.
NCMDR	National Center for Medical Devices Reporting
Establishment	A legal entity involved in an activity related to medical devices.
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 Supply	A medical material or product used in diagnosis, treatment, prosthetics, or orthotics; or in disability cases or other medical uses for humans, including medical gases.
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.
Healthcare Provider	Any government or private establishment that provides healthcare services.
User	A professional, lay person, or a patient who uses a medical device.
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 • labelling

Authorized Representative (AR)	A legal person based in the Kingdom who has written authorization from a manufacturer located outside the Kingdom to represent it in the Kingdom with regard to the implementation of the “Medical Devices Law and its Regulations.
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.
Warehouse	A building or part thereof, licensed by the SFDA and designated for storing the medical device.
Clinical Study verification Establishment	Entities responsible for monitoring and verifying clinical studies, conducting all activities related to clinical study verification.
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.
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.
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.
Classification System	A system adopted by the SFDA that assesses the level of risk related to the medical device and its safety.
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.
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.
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 for Radiation Emitting Devices	A set of technical tests, measurements, and calibrations adopted by the SFDA to ensure the safety and accuracy of medical radiation devices, ensuring the effectiveness of diagnosis and treatment.

Radioactive Medical Materials	A material from which ionizing radiation is emitted, whether by itself, or in other medical devices used for diagnosis and treatment.
Medical Imaging Materials	Any contrast media used in humans to enhance images obtained using medical imaging techniques.
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.
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.
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.
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.
Applicant	A natural or legal person who meets the necessary conditions and has authorization from the establishment.
Calibration	The required corrective adjustments to medical devices or testing equipment to maintain its performance accuracy according to a reference standard.
Test Equipment	The devices or tools used to perform functional tests or calibrations of medical devices.
Spare Parts	Spare parts compatible with the medical device in accordance with technical reports proving safety.
Maintenance Management System	A Computer-based software system that is used to automate processes related to technical support of medical devices, corrective maintenance, periodic preventive maintenance (PPM) and contracts management; and provides a wide range of data reports related to the medical device lifecycle.

Corrective Maintenance (Repair)	An unscheduled procedure to correct or repair malfunctions of medical device or its components, including repair, restore or replace used components or systems to restore safety and performance of a medical device.
Branches	A legal entity affiliated with a main establishment registered in the KSA and licensed by the SFDA to practice an activity related to medical devices and performs the same activity or part of the activity.
Point of Sale	The place where medical devices are sold, including shops, exhibitions, commercial markets, kiosks, electronic stores, and similar sales outlets belonging to an importing and distributing establishment for medical devices.
After-Sales Services	The services and procedures provided after the device is delivered to customers, including, but not limited to: warranty obligations, maintenance, spare parts, training, technical support, and software.
software	A set of applications, protocols, and computations used to operate a device.

Annex (2): License Periods and Fees

Establishments type	License period	Financial compensation	Note
Medical devices manufacturers	5 Years	5000 SAR	
Authorized Representative	From one to 10 years	2600 SAR Per year	According to customer's choice and period of the contract
Distributors and importers of medical devices *		- When the establishment updates its license and changes its class to a higher one, a financial fee will be charged (the difference between the two class). *Establishment is classified according to the electronic questionnaire (Survey of import/distribution establishments, importer/distributor establishments of optics) in the GHAD system, which includes type of establishment, activities that are practiced, number of employees, scope of coverage, and categories of devices.	
Class A	Yearly	25000 SAR	
Class B	Yearly	15000 SAR	
Class C	Yearly	8000 SAR	
Class D	Yearly	5000 SAR	
Class A	Yearly	7500 SAR	
Class B	Yearly	5000 SAR	
Class C	Yearly	2500 SAR	
Medical devices warehouses	1-5 Years	800 SAR	Storage license with others (800 SAR) each year
Clinical Trials Verification Establishments	5 Years	5000 SAR	
Conformity assessment establishments and quality management system	3 Years	Depends on the domain and adding countries	Domain is from (20,000 / or 40,000) SAR, in addition to each country / 1000 SAR
Medical device testing services providers	5 Years	5000 for the main lab 2500 for each branch	1000/ Designation 3 Years
Quality assurance and radiological measurements services providers for health establishments	3 Years	5000 SAR	Activity: Ensuring quality of medical x-ray equipment.
Maintenance services for medical devices providers	From one to 5 years	1000 SAR For each year	According to the customer's choice
Service providers of Technical advisory services for medical devices	5 Years	1000/ Scope	Including Providers of consulting services for radiation in health field

Annex (3): List of Changes on the Previous Version

Number & Date of the Previous Version	Changes Description
MDS – REQ 9 Version number: 1,0 2022/07/31	• Adding the following New Items to Requirements and Obligations for the establishments of: 1. **Local Manufacturers:** - Special Requirements: 1, 2. - Obligations: 1, 3, 9. 2. **Authorized Representatives:** - Special Requirements: 1, 3. - Obligations: 9, 10. 3. **Importers and Distributors:** - Special Requirements: 5. - Obligations: 3, 5. 4. **Warehouses:** - Special Requirements: 1. - Obligations: 2-A, 2-B, 2-D, 3, 4, 6. 5. **Clinical Study Verification Facilities:** - Obligations: 3, 6, 10. 6. **Inspection Service Providers (Laboratories):** - Refer to The Requirements for Licensing Private Laboratories 8. **Service Providers of Quality Assurance for Radiation Emitting Devices:** - Special Requirements: 5. 9. **Service Providers of Technical Consultation:** - Reference: See the Licensing Guide for Consulting Service Establishments. 10. **Service Providers of Medical Maintenance:** - Obligations: 4. • Change the name of (Manufacturers) to (Local Manufacturers). • Change the name of (Importers, Distributors, and Optics Establishments) to (Importers and Distributors). • Change the name of (Service Providers of Quality Assurance and Radiological Measurements for Health Establishments) to (Service Providers of Quality Assurance for Radiation Emitting Devices)

	• Quality Assurance and Radiation Measurement Service Providers for Health Facilities: Renamed to Quality Assurance Service Providers for Radiation-Emitting Devices. • Optics importers and distributors are added to the establishments required to submit proof of applying a quality management system or an inspection report from the SFDA. • Adding to the final Provision: Establishments wishing to cancel their licenses shall submit a request to the SFDA. The expiration or cancellation of the license does not exempt the establishment from legal liability. • Update the License extensions and fees schedule: - The license duration for Warehouses has been amended to be annual. • Examples have been added for the responsibilities: - The Technical Manager of the manufacture. - The Quality Manager of the manufacture. • Adding the following definitions: - Adulterated Medical Devices - User. - Spare Parts - Branches. - Point of Sale. - After-Sales Services. • General wording updates.
A new document issued based on the issuance of the Law of Medical Devices and there is no previous version for it.	• The following documents have been replaced and the requirements contained in the old document has been included in this document: - Rule of Procedure for Establishment Registration (IR2) - Rule of Procedure for Establishment Licensing (IR4) - Procedural Rule for Licensing Legal Representatives (IR5) - Guidelines for distributors and importers of medical devices (G1) - Domestic Manufacturers' Guide (G2) - Guidelines for legal representatives of medical devices (G3) - Guidelines for Overseas Manufacturers (G4) - Guidelines for licensing requirements for providers of quality assurance and ionizing radiological measurements services for health establishments (G51) • Guidance on the requirements of the Saudi Food and Drug Authority to license service providers of quality assurance and radiological measurements.