MDS-REQ 9

Requirements for Licensing of Medical Devices Establishments

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Introduction

Purpose

The purpose of this document is to Specify and Clarify the licensing requirements and obligations for medical devices establishments which subject to the Medical Devices Law and its Executive Regulation.

Scope

This Requirement applies to the following medical devices establishments including electronic activities:

1. Manufacturers
2. Authorized Representatives
3. Importers, Distributors and Optical Establishments
4. Warehouses
5. Establishments of Clinical Trials Verification
6. Service Providers of Conformity assessment and quality management system
7. Service Providers of Testing (Laboratories)
8. Service Providers of Quality Assurance and Radiological Measurements for Health Establishments
9. Service Providers of Medical Maintenance
10. Service Providers of Technical Consultation

This Requirement does not apply to pharmacies, partial sale establishments, and Labs which defined in Annex (1), however obligations from the Medical Devices Law and its Executive Regulation shall be followed, in addition to obtaining the necessary licenses from the competent agencies/authorities.

Background

SFDA has issued this document in reference to Article six of the “Medical Devices Law” 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. An establishment inspection to ensure that all requirements have been met.
3. Notifying the establishment of receiving the information required to license and it has fulfilled the licensing requirements.
4. During the licensing process, confidentiality of information viewed by the employees or those contracted with shall be maintained.
5. A determining the fees for issuing a license for each establishment of medical devices in accordance to Annex (2).
6. Issuing the license for the establishment after fulfill all requirements, valid for one year or similar renewable periods.
7. Reject license request for establishments that does 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 proper actions in case of negligence, violation or manipulation of the SFDA's law, regulations or requirements, and the penalties and fees shall be applied according to Medical Device laws and its executive regulations.
10. Investigate any complaint submitted by establishments or their beneficiaries; and ensure they are objectively evaluated according to the followed procedures.
11. Commitment to publish 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 that wish to engage in any of the activities subject to the law, including electronic activities, shall obtain an establishment license from the SFDA, as well as its branches and warehouses, in accordance with the general and specific requirements contained in this document.

A. General requirements

1. Obligation to all requirement, conditions, and legal procedures before applying for license from the SFDA and provide evidence of compliance.
2. Each establishment shall have a legal entity/or be a part of a legal entity in accordance to the KSA's regulations, to be considered as a legally responsible for its activities and decisions.
3. All medical devices manufacturers, importers and distributors of categories (A) and (B) shall obtain a Quality Management System certificate from a SFDA's accredited Conformity Assessment Bodies (CAB) for medical devices and for quality management system, in accordance to the Saudi Standard (SFDA.MD/GSO ISO 13485) or its equivalent.

   Note: The SFDA's accredited conformity assessment bodies means that those whom carry out their activities inside the Kingdom and have a license from the SFDA, or those located outside the Kingdom and accredited by the International Accreditation Forum (IAF)
4. Authorized representatives, importers and distributors of categories (C) and (D) shall submit evidence of the application of the Quality Management System or an inspection report from the SFDA, that confirms their compliance with the requirements of the Quality Management System in accordance with the Saudi Standard (SFDA.MD/GSO ISO 13485) or its equivalent.
5. Following up all SFDA's issuance related to rules, regulations, conditions, requirements, circulars, guidance and instructions, and any amendment or update published on the SFDA's website and informing beneficiaries and relevant establishments of that.

6. Create an account in “GHAD “ system to obtain an establishments number.
7. Submitting application request through SFDA's “GHAD “ system the for the purpose of obtaining or renewing a license to practice the activity.
8. Submit all required documents through the SFDA's “GHAD “ system .
9. Pay the License’s fee accordance the periods listed in annex (2).
10. The establishment shall Provide a database to archive all relevant data and documents in order to be easily accessed and retrieved for a period of no less than (5) years.
11. No medical devices shall be circulated in the KSA unless it gets registered and obtain a marketing authorization from SFDA.
12. Provide upon request to SFDA any documents and information within (10) days.
13. A sufficient and appropriate human and other necessary resources shall be provided to do their duties with efficiency, transparency, impartiality, independence and integrity.
14. Documented and effective procedures for storage and transportation shall be available and applied according to the requirements for medical device transportation and storage published on the SFDA’s website.
15. All advertising and promotional materials for medical devices shall not be promoted unless it gets the SFDA approval in accordance with the requirements for approval of advertising published on the SFDA’s website.
16. Empowering inspectors to review documents and verify all information during inspection.
17. Notify SFDA regarding any changes to the information submitted to obtain the license within (10) days of the occurring change.
18. Adhered to post-marketing surveillance requirements of medical devices, which include but not limited to:
    - 18.1. Informing/report to the Center about accidents of medical devices, and provide the center with all the necessary information and documents, including supply and distribution data.
    - 18.2. Informing/report to the Center about safety alerts that affect the kingdom according to the time plan approved by the center.

18.3. Determining risks related to safety alerts that affect the Kingdom, with providing supply and distribution information.

18.4. Providing a corrective action implementation plan that specifies the execution end date.

18.5. Providing proof of safety alarm implementation completion in accordance with the center's approved plan.

19. Inform the SFDA immediately if the establishment cannot continue to meet the provisions and license requirements.
20. SFDA should be Informed immediately if the establishment cannot keep fulfilling the provisions and license requirements.
21. Inform the SFDA about medical devices that violate the provisions and requirements of the Medical Devices Law and its Executive Regulation including falsified medical devices without marketing authorization, and report cases of suspicion.
22. A license renewal application can be submitted before (60 days) from the expiration date of the valid license.
23. SFDA should be notified in case of requesting license amendment through "GHAD " system and submit required documents.
24. If the establishment wishes to cancel its license or upon license expiry date and is not willing to renew, he shall submit the application through "GHAD " system of the SFDA / notify the SFDA and provide proof that there are no obligations on the establishment.
25. To cancel a license, before license expiry date or not willing to renew a license, an establishment shall submit the application through "GHAD " system and notify SFDA, as well as provide proof that there are no obligations on the establishment.
26. Commitment not to share any documents of the SFDA to any other party, whether inside or outside the Kingdom, without a prior written consent from SFDA, and establishment is fully responsible for maintaining the confidentiality of information.

27. Commitment to implement SFDA's recommendations after the inspection visits and provide a corrective plan to address cases of non-conformity - if any - and implement the plan after acceptance by the SFDA within a specified period.
28. Provide a corrective plan to address cases of non-conformity - if any -after SFDA's inspection visit and implement the plan within a specified period after SFDA's approval.

B. Specific Requirements and Obligations

In addition to what is mentioned in the general requirements, each establishment shall comply with the specific requirements Listed below according to the type of each establishment.

1. Manufacturers

Specific Requirements

1. Provide a proof of compliance to what is stated in point (3) of the "General Requirements" section.
2. Hiring a full-time technical Managers who are biomedical engineers, technicians or qualified in one of the related fields.
3. Hiring a full-time quality managers who are biomedical engineers, technicians or qualified in one of the related fields.
4. Specifying the manufacturer's activity and the level of risk for medical devices that are going to be manufactured.

Obligations

1. Compliance with the requirements of medical device Unique Device Identification (UDI) which published on SFDA's website
2. 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 porous.
3. A pledge to obtain a marketing authorization certificate from the SFDA before trading any medical device or supplies in the kingdom according to the requirements for medical devices marketing authorization which published on SFDA's website.
4. A pledge of full responsibility from the manufacturer regarding the quality of all manufactured batches.
5. Conduct all necessary technical tests to prove compliance of their products with regulatory requirements for safety, performance and quality.

6. All technical and reference tests shall be conduct according to technical standards issued by standardization bodies and standards organizations.
7. Commitment to classify medical devices according to the classification system published on the SFDA's website.
8. Comply with the SFDA’s special requirements for home use or implanted medical devices.

2. Authorized Representatives

Specific Requirements

1. Provide a proof of compliance to what is stated in point (4) of the “General Requirements” section.
2. To be present in the Kingdom.
3. Obtain a separate license for each establishment that have been represented within the Kingdom,
4. Ensure there is no other authorized representative has been appointed for the same class or general group of medical devices.
5. Documentation of the necessary processes for performing the tasks assigned to him with attachment of relevant documents.
6. Agreement with the manufacturer shall be documented, approved and subject to the regulations in the Kingdom.
7. The agreement with the manufacturer shall include the following information -at least: -
   7.1. Specify the activities in which the authorized representative acts on behalf of the manufacturer in its dealings with the SFDA.
   7.2. Type or group of medical devices subject to the Medical Devices Law and Executive Regulation to be marketed in the Kingdom.
   7.3. Authorized Representative shall comply with all requirements for post-marketing surveillance published on the SFDA's website.
   7.4. Determine the duration of agreement between the parties, as one of them may terminate it in accordance with the following:
      7.4.1. In order to terminate the Agreement, the manufacturer shall provide written notice to the authorized representative.
      7.4.2. 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.

7.4.3. In order to terminate the Agreement, the Authorized Representative shall provide written notice to the manufacturer.

Obligations

1. Confirming the continuance accuracy and validity of information which previous submitted on an annual basis, as SFDA shall evaluate any changes to the delegation and take appropriate action if necessary.
2. Notify the manufacturer and confirm that 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 Kingdom related to the medical devices traded in the Kingdom; an explanation of the circumstances shall be submitted along with the corrective actions taken by the manufacturer or intended to be taken.
6. Inform the SFDA of all corrective actions results from post-marketing follow-up investigations conducted by the manufacturer for medical devices that are traded in the Kingdom, explaining the reasons for the corrective actions and providing information on the measures taken or intends to be taken.
7. Provide a proof of complete implementation of the corrective action for the safety alarm in accordance to the plan approved by the center.
8. Identify risks related to safety alarms that affect the Kingdom and provide the supply and distribution information.
9. Cooperating with persons engaged in activities subject to the provisions of the Medical Devices Law and its Executive Regulation regarding medical devices traded in the Kingdom under the agreement concluded between him and the manufacturer.
10. The responsibility of authorized representative towards medical devices covered in the agreement shall not elapse upon their request to terminate the agreement, unless the manufacturer appoints another authorized representative to replacement him, or if medical devices are not available on the market and among the users.

3. Importers, Distributors and Optical Establishments

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 / requirement and the general group of the medical device / requirement 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. Submit evidence of compliance either with points number (3) or number (4) of the "General Requirements" section according to the category of distributors and importers.
3. Provide manufacturer information and data for the medical devices to be imported, along with the authorized representative information for manufacturer residing outside the Kingdom.
4. Existence of documented procedure for storing and transporting medical device in accordance with manufacturers requirements, and submitting a pledge to implement and comply with the procedure.
5. Existence of warehouse license at the establishment or a storage license with third parties issued by the SFDA in accordance with "warehouse licensing requirements", as for the sales centers, it is possible to suffice with a storage area within the establishment in accordance with "transportation and storage for medical devices requirements" published on the SFDA's website.
6. Provide a documented and an effective tracking procedure to document contact 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.
7. Declaration of conformity indicating the conformity of medical device with the requirements of Medical Devices Law and its Executive regulations, signed by the manufacturer.

Obligations

1. Importing and/or distributing medical devices that comply with the requirements of the Medical Devices Law and its executive regulations.
2. Ensure that all necessary documents are present with each medical device:
   a. 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 Kingdom.
3. A pledge is the manufacturer has been informed, through their authorized representative regarding applicant's intention to import their medical devices to the Kingdom.
4. Comply with the manufacturer's instructions and the requirements of medical devices maintenance which stated in the post-marketing control requirements and published on the SFDA's website in case of providing maintenance services.
5. If the establishment wishes to provide maintenance services for its medical devices, it shall comply with the manufacturer's instructions and requirements of medical devices maintenance stated in the post-marketing control requirements and published on the SFDA's website. And if the Establishment wishes to provide maintenance services for medical devices that are not affiliated to it, a medical maintenance service provider license shall be obtained in accordance with the Medical Maintenance Service Provider Licensing Requirements.

4. Warehouses

Specific Requirements

1. Appointing a full-time technical Managers who are biomedical engineers, technicians or qualified in one of the related filed.
2. Apply storage and transportation requirements for medical devices which published on the SFDA's website.

Obligations

1. Comply with manufacturer’s requirements in addition to compliance with transportation and storage of medical devices requirements published on the SFDA's website.
2. In the event that establishment storage with third parties, the following shall be adhered to:
   a. The renter shall have a storage license with others.
   b. A contract shall be signed between the main owner and the renter containing 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.

5. Establishments of Clinical Trials Verification

Specific Requirements

1. Completed the electronic application on the SFDA's website for license the verifies clinical studies' establishment.
2. Clinical Trials Verification Establishments manager shall be a full-time Saudi national with a bachelor's degree as a minimum in health or science related majors.
3. Attach CV, certificates and experiences for clinical trials responsible person.
4. Appointing a full-time Saudi responsible for clinical trials holds an appropriate academic qualification of not less than a bachelor's degree, and who has experience in the field of clinical studies for not less than three years.

Obligations

1. No clinical trials without SFDA approval shall be verified.
2. Compliance with the requirements for clinical trials of medical devices published on SFDA's website.
3. Proof of compliance to standard of Clinical investigation of medical devices (SFDA.MD/ISO 14155 Clinical investigation of medical devices for human subjects — Good clinical practice) or a similar version.
4. Proof of compliance to standard of In vitro diagnostic medical devices (SFDA.MD/ISO 20916 In Vitro Diagnostic Medical Devices - Clinical Performance Studies Using Specimens from Human Subjects - Good Study Practice) or a similar version
5. Appointing a trained and qualified employee and organize a continuous training programs to develop their skills.
6. Implementation of documented work procedures for the establishment.
7. Providing training programs for employees of the agency executing clinical trials that suitable to the conducted clinical trials.

6. Service Providers of Conformity assessment and quality management system

Specific Requirements

1. Obtaining accreditation from the Saudi Accreditation Center, provided that the Designation scope is included in accreditation activity. Provisions, requirements and required documents can be found in designation regulation of conformity assessment bodies (CAB) and private laboratories and guideline requirements of designation conformity assessment bodies and private laboratories.
2. Providing the SFDA with a conformity assessment program, including specific requirements and procedures for each field has been 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, as a minimum, the following:
   4.1. The number of applications received and must be detailed by country of origin or source.
   4.2. Number of applications for which conformity certificates were granted, and SFDA may verify the certificates.
   4.3. Number of rejected applications.
   4.4. Number of applications for which corrective action was requested.
   4.5. Corrective actions completed and documented.
   4.6. Number of objections submitted by customers on verification results.
   4.7. 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, it shall be subject to all the requirements stipulated in this document and obtain SFDA's approval to delegate tasks and provide it with a copy of the concluded authorization contracts, while bearing 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 the approved forms by the SFDA, within a maximum period of (15) days from the completion of the conformity assessment action.
    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 Kingdom, 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. Conformity assessment bodies are obligated to provide a service level agreement with customers in appropriate manner to their designated fields.

7. Service Providers of Testing (Laboratories)

Specific Requirements

1. Establishment’s manager shall be a full-time with a minimum of bachelor's degree in one of the relevant fields.
2. Providing quality manual to the laboratory.
3. Submitting a detailed statement of approved tests, products covered by tests scope, and prices, for consideration by the SFDA.
4. Applying an inclusive laboratory electronic system.

Obligations

1. Obligation to obtain an accreditation from the Saudi Center for Accreditation, the range of tests and products that were licensed shall be included in the accreditation certificate within one and a half years from the date of obtaining the license, but not more than that.
2. Providing the SFDA with organizational structure, a list of technical and administrative staff, a certified copy of their qualifications, training courses, their job descriptions, and identification of the devices and equipment needed to operate the laboratory within one and a half years from the date of obtaining the license, but not more than that.
3. A licensed establishment may increase the number of tests during the validity period of the license, as long as the SFDA receives a detailed statement of tests to be added and products covered by the test scope. After obtaining the license from SFDA, the accreditation certificate shall include the added tests within one and a half years after obtaining the license, but not more than that from the date of obtaining the license.
4. Performing services through any of its subsidiaries, and in the case, it is delegated to a third party to perform some of its tasks, it shall be subject to all requirements stipulated in this document and obtain the SFDA's approval to delegate tasks and

provide it with a copy of the concluded authorization contracts, while bearing full legal and financial responsibility for those services provided by a third party.

5. A licensed establishment may increase the number of tests during the validity period of the license, as long as it submits a request that includes details of new Tests and their accreditation certificate issued by the Saudi Accreditation Center (SAAC).
6. Committing that all tests are conducted according to the SFDA license and by the approved price.
7. Tests results shall be issued according to laws and technical regulations, conditions and requirements, and the establishment is legally responsible for any resulting damage.
8. Presenting the license, accreditation certificate, organizational structure, technical departments, and test prices in a visible place at the laboratory entrance, and not making any modification without SFDA approval. In addition to publishing them on the laboratory's website.
9. Committing to conduct competency tests organized by SFDA.
10. Preserving intellectual ownership of the standard used, maintaining the confidentiality of information accessed by him or by his employees or those who have been contracted with throughout the license period, even after the expiration of the license and not disclosing any information related to the services without a prior written consent from the SFDA.
11. Renewing license at least (3) months before its expiry date. The affective of the renewal will start from the expiry date of the license

8. Service Providers of Quality Assurance and Radiological Measurements for Health Establishments

Specific Requirements

1. Appointing a Saudi radiation protection officer licensed by the Nuclear and Radiological Control Commission, and providing the SFDA with a copy of the radiation protection officer's practice license.
2. Provide the SFDA with a copy of the license to practice radioactive materials in the case that the establishment uses radioactive materials.
3. Provide the SFDA with a copy of engineering plan for radioactive sources storage area in the 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.
5. 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.
6. Provide SFDA with organizational structure, a list of technical and administrative staff, a certified copy of their qualifications, training courses and job descriptions.
7. Provide SFDA with a copy of procedures and steps followed to implement each requested service to obtain a license, with an explanation of approved scientific reference for conducting tests method.
8. Provide a certified copy from 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 the 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 Kingdom and safe transportation of radioactive materials instructions in the Kingdom or any other documents issued by competent authorities.
2. Referring to approved scientific references for all technical reports issued by the establishments.
3. Adding related activity to quality assurance services and radiological measurements provision in the commercial registration after obtaining the SFDA's license.
4. It is not allowed to use unlicensed radioactive sources in terms of number, type and radioactivity.
5. It is not allowed to sell, rent, lend or donate radioactive sources to another establishment without obtaining approval from competent authorities.
6. It is not allowed to transfer fixed radioactive sources to any other place within the establishment without obtaining approval from competent authorities.
7. Disposal of radioactive sources when they are not needed anymore shall be done in accordance to the general instructions for radioactive waste management and the general instructions for protection against ionizing radiation in the Kingdom.
8. Inform the SFDA in the case of a failure in one of radiology and medical imaging devices quality assurance tests, or in the 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 keeping records for 5 years.
10. Obtaining valid calibration certificates for all measurement devices from accredited laboratories.
11. It is not allowed to change work sites or violate the license without obtaining the prior approval from the SFDA.

9. Service Providers of Medical Maintenance

Specific Requirements

1. Providing technical staff of engineers and medical maintenance technicians according to the following conditions:
   1.1. With academic or technical qualifications in biomedical engineering/technology or a related field.
   1.2. 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 must 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. Providing 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. Providing 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 original spare parts to the department/person requesting maintenance service at health care establishment immediately, as delays are not acceptable except with justification in case of corrective maintenance.
3. Instructions application issued by the manufacturer regarding corrective maintenance and calibration. In case the instructions are not available, it shall be referred to the technical specifications approved by the SFDA.

4. 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.
5. Providing a designated and equipped place for the medical device’s maintenance.
6. 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.
7. compliance with maintenance requirements contained in post-marketing control requirements for medical devices, which are published on SFDA's website.
8. Implementation of the documented work procedures.

10. Service Providers of Technical Consultation

Specific Requirements

1. Establishment manager shall be a full-time, with a minimum of bachelor's degree.
2. Providing SFDA with organizational structure, a list of technical and administrative staff, and a certified copy of their qualifications, training courses, and job descriptions.
3. A qualified technical officer shall be appointed for each activity, with a bachelor's degree as a minimum, according to the requirements contained in the Guide for Licensing Consulting Services Establishment.
4. A copy Saudi Commission for Health Specialties certificates for establishment's employees.
5. Providing a quality system within the establishment that clarifies approved work procedures and methods of keeping customer's technical reports.

Obligations

1. Maintaining confidentiality of information viewed the establishment, their employees or those contracted with during the license period and also after the license expiry and not revealing any information related to provided services.
2. Experience and full knowledge in the SFDA's field of work and its regulations; and the principles of independence, impartiality and integrity, with ensuring that there is no conflict of interest in the provided services in case there is more than one activity at the establishment, and ensuring the independence of the technical staff participating in the consultations from any activity of supplying or distributing products in the same field of consultations.
3. Committing that the provided consulting services is approved by technical staff and technical officer in the consulting establishment.
4. Providing a training plan to development establishment's employees in the licensed fields, and committing to provide technical staff with training courses.

Final Provisions

1- Adhere to Medical Devices Law, 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- Establishments have the right to object to the SFDAs decision regarding establishment's licensing and provide justifications for that. The objection shall be in accordance with the applicable legal procedures.
3- Establishment wishes to cancel its license or when finish submitting application request through SFDA electronic system shall notify SFDA as well providing a proof there are no obligations on the establishment.

4- Obligating not to use the SFDA name or logo for the purposes of advertisement or place them on any products or on establishments.
5- Establishment shall commit the principle of independence, impartiality, and integrity, and ensure that there is no conflict of interests in the services provided in the case that there is more than one activity at the establishment. and guarantee independency.

Annexes

Annex (1): Definitions & Abbreviations

KSA	Kingdom of Saudi Arabia
SFDA	Saudi Food and Drug Authority
Law	Medical Devices Law
Regulation	Executive Regulations of the Law
NCMDR	The National Center for Medical Devices Reporting
Medical Devices	Any instrument, apparatus or implement or implant or in vitro reagent or calibrator or software, or material used for operating medical devices, or any other similar or related article, intended to be used alone or in combination with other devices for diagnosis or prevention or monitoring or controlling or treatment, or alleviation of disease or injury, or for compensation for an injury; investigation, replacement, modification, or support of the anatomy or of 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, but which may be assisted in its intended function by such means.
Medical Supply	A medical material or product used in diagnosis, treatment, replacement, or correction/ straightening; or in disability cases or other medical uses for humans, including medical gases.
Medical Radioactive Material	A material that emits ionizing radiation either by itself or when used with other medical devices or supplies for the purpose of diagnosis and treatment.
Establishment	A legal entity engaged in an activity related to medical devices and supplies.
Manufacturer	Any national or foreign establishment the purposes of which include designing or manufacturing medical devices or supplies for use under its name within the Kingdom or abroad. Manufacturing shall include refurbishing, assembling, packaging, and labelling.
Health Care Provider	Any government or private establishment that provides health care services.
Authorized Representative	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 this Law and its Regulations.
Consultation Services Establishments	Establishments that provide technical consultation services related to regulatory affairs to the establishments engaged in the field of medical devices in the Kingdom market.

Clinical Trials Verification Establishments	Establishments that take charge of follow up clinical trials and conduct all activities related to clinical trials verification.
Circulation of Medical Devices and Supplies	The provision of medical devices and supplies at no cost or for a fee, whether for distribution or use.
Registration	A procedure for listing in the MDNR any medical device or supply and any establishment that engages in any activity governed by this Law.
Marketing Authorization	A document issued by the SFDA permitting the circulation of a medical device or supply in the market.
Classification System	A system approved by the SFDA to assess the safety and the level of risk of a medical device or supply.
Quality Management System	A system approved by the SFDA to verify the quality, effectiveness, and safety of a medical device or supply in accordance with the latest edition of the Technical Standard (ISO 13485) or its equivalent, as provided in the Regulations.
Quality Assurance	A set of technical tests, measurements, and calibrations approved by the SFDA to verify the safety, accuracy, and quality of medical radiological devices, in order to ensure the efficacy of diagnosis and treatment.
Technical Regulations	Mandatory documents issued by the SFDA for medical devices and supplies which specify the basic standards of safety, performance, and manufacturing and provide relevant instructions, including terms and symbols as well as packaging and labelling requirements.
Standards	Non-mandatory documents approved by the SFDA, including rules, guidelines, specifications of medical devices and supplies, or production processes and methods related thereto as well as terms and symbols, and packaging and labelling requirements.
Label	Any statement, information, or illustration printed on a medical device or supply, including identifying information, technical description, method of use, and manner of storage and transportation.
Safety Alert	A notice issued by the National Center for Medical Devices Reporting indicating the risk associated with a medical device or supply and the corrective action required to avoid such risk.
Field Safety Corrective Action	An action taken by the manufacturer to limit or reduce the risks compromising the safety of a medical device or supply.
Medical Imaging Materials	Any material used to improve contrast that can be obtained by using medical imaging techniques.
Importer	An establishment in the supply chain that supplies a medical device to the Kingdom.
Distributor	An establishment in the supply chain that supplies a medical device to another distributor or its end user.

Traceability	Procedures and measures that enable the tracing of medical devices, at any stage of the supply chain.
Advertising	Any statement, whether written, audible, visual, or otherwise matters intended to promote a medical device or its technology, or direct or indirect sale.
Inspection	A systematic and documented procedure carried out by the SFDA to verify establishment or manufacturer's obligation with the particular conditions and requirements for establishments and medical devices determined by the Law and its Regulation.
Applicant	A natural or legal person who meets the necessary conditions and has an authorization from the establishment.
Warehouse	A building or part of it licensed by the SFDA and designated for medical device storage.
Unique Device Identification (UDI)	A series of numbers and letters created through approved specifications in order to identify a medical device specifically and clearly throughout all stages of its circulation.
Calibration	The required correction adjustments to medical devices to maintain its performance accuracy according to standard.
Suitable test equipment	Devices or instruments used to perform functional or calibration tests of medical devices.
Maintenance management system	It is used to automate processes related to technical support for medical devices, provide support for the inventory management system for the medical device, corrective maintenance, periodic preventive maintenance (PPM) and contract management, and provide a wide range of different data reports related to the life cycle of the device or medical device.
Corrective maintenance (CM)	Unscheduled process used to restore the physical integrity, safety and/or performance of a device after a failure. it includes the repair, restoration, or replacement of used components or systems with the intent of restoring the safety and performance of the medical device or supply.
Partial sale establishments	Establishments that carry out the process of selling medical devices for home use to the end user through retail markets such as canters, exhibitions, points of sale and electronic stores, but are not primarily involved in importing and distributing medical devices.
Laboratories	Prosthetics, audio-visual, dental and similar services laboratories.

Annex (2): License extensions 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 *		*Establishment is classified according to the electronic questionnaire 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	
Optics Establishments**		**Establishment is classified according to the electronic questionnaire 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	7500 SAR	
Class B	Yearly	5000 SAR	
Class c	Yearly	2500 SAR	
Medical devices warehouses	5 Years	4000 SAR	Storage license with third parties (800 SAR) each year
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
Clinical Trials Verification Establishments	5 Years	5000 SAR	
Service providers of Technical advisory services for medical devices	5 Years	1000/ Scope	
Medical device testing services providers	3 Years	1000/ Designation	License is valid for five years. License fee is 5,000 riyals for the main laboratory and 2,500 SAR for each branch
Maintenance services for medical devices providers	From one to 5 years	1000 SAR For each year	According to the customer's choice
Quality assurance and radiological measurements services providers for health establishments	3 Years	5000 SAR	Activity: Ensuring quality of medical x-ray equipment.

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

Changes Description
• 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) - Guide to the Saudi Food and Drug Authority requirements for licensing providers of quality assurance and radiological measurements services