Kingdom of Saudi Arabia
Saudi Food & Drug Authority

Guidance on the Procedures

for Licensing of Medical Devices and Supplies Establishments

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Introduction

This Guidance covers the services provided by the Saudi Food & Drug Authority (SFDA) for licensing medical device and supplies establishments. Each service within this Guidance describes its content and clarifies its procedures, such as: fees, conditions for obtaining the service, etc. It also explains the channels that can be used for obtaining the service.

Background

The Saudi Food & Drug Authority issued this Guidance based on Article 6 of the Medical Devices and Supplies Law issued by Royal Decree No. (M/54) dated 06/07/1442 AH, which stipulates that “an establishment shall not engage in any of the activities subject to this Law unless registered and a license is obtained”. It is also based on Articles (2/6) of the Implementing Regulation of the Medical Devices and Supplies Law issued by Board Resolution No. (4-29-1443) dated 19/02/1443 H, which stipulates 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".

Field and Scope of Application

This Guidance applies to the investor who wishes to obtain a license for medical devices and supplies establishments for industrial and non-industrial activities (ISIC) that fall under the SFDA's umbrella, after fulfilling all documents and requirements of the relevant government agencies, which include, without limitation, the following:

Ministry of Commerce	Ministry of Municipal, Rural Affairs and Housing	Ministry of Industry and Mineral Resources
Economic Cities and Special Zones Authority	Saudi Authority for Industrial Cities and Technology Zones ”“MODON	Ministry of Investment

You can review the approved economic activities (ISIC) to which this Guidance applies on the SFDA's website.

General Procedures for Licensing of Medical Devices and Supplies Establishments

Account Opening Procedures:

1.Log in the Unified Electronic System “GHAD”.

2.Enter the data required to register as a new user on the system.

3.You can view the steps to open the account by scanning the following QR:

Steps to create a new account (commercial, government, individual, customs broker, Overseas Manufacturer)

1.Log in the Unified Electronic System “GHAD”.

2.Fill in the user data and create a new account through the Unified Electronic System “GHAD”.

3.Choose “Creating New Account” (depending on the type of account required):

Commercial:

- Filling out the commercial registry data and all required fields.
- Comparing the commercial registry activity with the activity specified in the “Fields and Activities” field
- Attaching a letter of authorization for the applicant certified by the Chamber of Commerce.
- In the case of foreign investment in the establishment, an investment license must be attached.

Government

- Filling out the government entity data.
- Attaching a letter of authorization for the applicant.

Individual

- Filling out the national ID/resident ID data and contact information.

Customs Broker

- Filling out the information of the customs clearance license.
- Attaching a letter of authorization for the applicant certified by the Chamber of Commerce.
- Attaching a copy of the customs clearance license.

Overseas Manufacturer

- Filling out the authorized person's data and attaching a copy of the passport.
- Attaching a letter of authorization for the applicant with the required authentications.
- Attaching a copy of the authorized representative agreement, if wished.
- The SFDA studies the application and obtains an account number for the establishment.

Steps to Access an Existing Commercial Account

1.Filling out the user data and create a new account through the Unified Electronic System "GHAD".

2.Request Access on Existing Account.

3.Filling out the account information you want to access using the establishment's account number.

4.Attaching the letter of authorization certified by the Chamber of Commerce and sending the application.

5.After the application is accepted by the SFDA, you can access the establishment's account.

How to apply for a license through the SFDA's Electronic System:

How to obtain (new) license

1.Open an account in the Unified Electronic System (GHAD) and obtain the account number of the establishment.

2.From the control panel of "GHAD" electronic System, choose Licensing Services >> Creating a new license >> Specify the required field and activity.

3.Filling out the application and attaching the required documents.

4.Paying the financial fees for the service.

5.Obtaining a license.

Procedure of Renewing/ Updating and Renewing the License

1.The establishment can apply to renew the license 60 days before its expiry date.

2.An application for renewal or updating and renewal is submitted through the Unified Electronic System (GHAD) through the control panel >> Licensing Services >> Medical Licenses >> Selecting the License >> Choosing Renew/Update and Renew.

3.Filling out the application form and attaching the required documents.

4.Paying the license fees.

5.Obtaining the license.

Procedure of Updating the License:

1.Submit a request to update the license after obtaining the license.

2.The update request is submitted through the Unified Electronic System (GHAD) through the control panel >> Licensing services >> Medical licenses >> Select the license >> Choose to update and attach the required documents.

3.Updating the license.

The SFDA will schedule a visit to the establishment through its inspectors to ensure that the establishment fulfills the requirements.

Requirements to Obtain a License:

The establishment must adhere to the requirements for licensing medical devices and supplies establishments (MDS-REQ).

Special Procedures for Licensing Medical Devices and Supplies Establishments

Licensing a Manufacturer for Medical Devices and Supplies within the Kingdom of Saudi Arabia:

Obtaining a license from the SFDA that enables the establishment to begin in the activity of manufacturing medical devices and supplies within the Kingdom of Saudi Arabia.

Special Procedures:

- Updating the establishment's commercial account and adding
- Manufacturer activity in the "Fields and Activities" field.
- Attaching copy of the Quality Management System Certificate (ISO 13485).
- Attaching copy of the educational qualification of the Manufacturer technical director and an experience certificate (if any).
- Attaching copy of the quality manager's academic qualification and experience certificate (if any).
- Attaching copy of the title deed or lease contract.
- Attaching copy of the industrial license from the competent authority.
- Attaching copy of the municipal license/ MODON contract or economic cities (depending on the establishment's location).

Licensing the Manufacturer's Authorized Representative Located outside Saudi Arabia for Medical Devices and Supplies

Obtaining a license from the SFDA that enables the establishment to practice the authorized representation activity of a manufacturer Located outside Saudi Arabia for medical devices and supplies.

Special Procedures:

- Updating the establishment's commercial account and adding an import/ distribution activity in "Fields and Activities" field.
- Issuing a warehouse license for medical devices and supplies or a license for Space Warehouse (from the SFDA).
- As for sales centers, a storage area within the establishment may be sufficient in accordance with the transportation and storage requirements of medical devices and supplies published on the SFDA's website.
- According to the establishment's classification, a (quality management system certificate, or proof of application of quality management system, or inspection visit report is attached) as follows:

  Establishments (A) and (B): attaching copy of the quality management
- system certificate (ISO 13485).
- Establishments (C) and (D): attaching copy of the quality management system certificate (ISO 13485) or the inspection visit report, or providing proofs of the implementation of the quality management system, where the quality manual attached on the SFDA's website is filled out: https://sfda.gov.sa/ar/forms/88751

Licensing Optical Establishments

Obtaining a license from the SFDA that enables the establishment to begin in the activity of importing and distributing optics.

Special Procedures:

- Issuing a commercial register for one of the economic activities in the field of optics activity (from the Ministry of Commerce).
- Updating the establishment's commercial account and adding an optics activity in the "Fields and Activities" field.
- Issuing a medical devices warehouse license or a Space Warehouse (from the SFDA).
- As for sales centers, a storage area within the establishment may be sufficient in accordance with the transportation and storage requirements of medical devices and supplies published on the SFDA's website.
- Attaching copy of the quality management system certificate (ISO 13485) or the inspection visit report, or providing proofs of the implementation of the quality management system, where the quality manual attached on the SFDA's website is filled out: https://sfda.gov.sa/ar/forms/88751.

License for a Warehouse and Space Warehouse for Medical Devices and Supplies

Obtaining a license from the SFDA that enables the establishment to begin in the activity of storing medical devices and supplies.

Special Procedures:

A. Medical Devices and Supplies Warehouse

- Updating the establishment's commercial account and adding a warehouse activity in the "Fields and Activities" field.
- Attaching copy of the municipal license/ MODON contract or economic cities (depending on the establishment's location).
- Determining the space allocated for storing medical devices and supplies.
- Attaching copy of the academic qualification of the warehouse technical director.
- Attaching copy of the title deed or lease contract.

B. Space Warehouse License

- Updating the establishment's commercial account and adding a warehouse activity in the "Fields and Activities" field.
- The main lessor must have a medical devices warehouse license from the SFDA, permitting him to practice the "storage for others" activity and specifying the storage space.
- Choosing the leased warehouse from the list of licensed warehouses available on "GHAD" Electronic System.
- Attaching a contract between the main lessor and the lessee that includes the information of both parties and their obligations in accordance with the SFDA's requirements, including data on the areas and spaces allocated for storage.

Quality Assurance and Radiation Measurements Service Providers License

Obtaining a license from the SFDA that enables the establishment to begin in the activity of quality assurance and radiological measurements.

Special Procedures:

- Updating the establishment's commercial account and adding the quality assurance and radiological measurements activity in the "Fields and Activities" field.
- Attaching copy of the radiation protection officer's license.
- Attaching copy of the academic qualification certificate for the technicians and specialists.
- Attaching copy of the calibration certificate.
- Submitting an authenticated and approved copy of the establishment's protection and safety program of radiation, in both Arabic and English.
- Justification or a contract invoice to read radiation operation cards from the personal radiation dose readings record for all employees, while keeping the records for 5 years.

License to provide Maintenance Services for Medical Devices and Supplies

Obtaining a license from the SFDA that enables the establishment to begin in the activity of maintenance services for medical devices and supplies.

Special Procedures:

- Updating the establishment's commercial account and adding the activity of a medical maintenance provider in the "Fields and Activities" field.
- Attaching copy of the maintenance contracts with the hospital (attach each contract separately).
- Attaching copy of the list of employees registered with the Ministry of Human Resources and Social Development.
- Attaching copy of the CVs of all field medical maintenance engineers.
- Attaching copy of the training certificates for maintenance engineers.

Regarding clinical trial verification establishments, providers of conformity verification services and quality management system, providers of testing services (laboratories), providers of consulting services:

To know the licensing procedures for these establishments, you can view the Guidance on the SFDA's website.

Period Expected for Obtaining the License

A. Establishments: Importer and distributor / optics / authorized representative / warehouse and Space Warehouse / maintenance service provider

Studying the establishment application >> pay the fees >> issuing the direct license

The establishment's application is studied and the license is issued immediately after paying the financial fees, provided that an inspection takes place later after the license is issued, and the establishment can practice the activity after obtaining the license.

The license is issued within 2 working days a maximum.

B. Establishments: Medical device Manufacturer / quality assurance and radiological measurements

Studying the establishment application >> Preparing for the joint field inspection >> Conducting the inspection and preparing the final report >>issuing the license

The license is issued within 7 working days a maximum.

License Fees and Periods

Establishments type	License period	Financial compensation	Note
Medical devices manufacturers	5 years	SAR 5000	
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

Violations and Penalties

Penalties and violations are applied to violating establishments according to the classification table of violations and the penalties prescribed, in accordance with the Medical Devices and Supplies Law and its Implementing Regulations.

Frequently Asked Questions (FAQ)

Q/ Why is registration in the Unified System for Registering and Licensing Medical Device and Supplies Establishments important?

Registration in the Medical Device and Supplies Establishments Registration and Licensing System is important for several reasons:

1. Issuing a license to practice the activity of medical devices and supplies establishments.
2. Building a database for all medical devices and supplies establishments and their products in the Kingdom of Saudi Arabia.
3. Improving means of communication between the Saudi Food & Drug Authority and medical device and supplies establishments.
4. Enabling medical device and supplies establishments to update their data on an ongoing basis, and facilitating the process of communicating with the SFDA as a control entity for these establishments.

Q/ Who does register in the unified system?

The process of registering medical device and supplies establishments is carried out by a person responsible and authorized by the establishment, who have sufficient technical information to complete the technical and administrative registration steps.

Q/ Is it necessary to update the file of the registered establishment?

Yes, the data must be updated when necessary, such as the commercial register, or the industrial license or contact information

Q/ If the investor has more than one medical devices and supplies establishment, is it registered as one establishment in the SFDA's unified system?

The investor must register each medical equipment and supplies establishment separately

Q/ Is it necessary to obtain an importer's license if the establishment's activity is a health care provider?

The establishment is not required to obtain an importer's license, noting that the medical device or supply must have a marketing permit from the SFDA.

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