Investor Guideline for Authorized Representative licensing for an Overseas Manufacturer of Medical Devices and Products

Disclaimer: The English version is a translation of the original in Arabic for information purposes only. In case of a discrepancy, the Arabic original will prevail.

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1st Chapter

Introduction:

The board of directors of Saudi Food & Drug Authority (SFDA) states that the legal representative of an external manufacturer shall be licensed by SFDA for the establishment, its branches, and its warehouses, according to Article (15) from the implementing regulations of Medical Device Interim Regulation (1429-8-1) issued on 2008/12/27. This guide indicates the necessary measures and requirements that shall be available for this purpose.

Definitions:

The Investor:

An individual or a group of people (company) that desire to invest in the importation and distribution of a medical device or a product.

The Manufacturer:

Any Individual responsible for designing and manufacturing the medical device/product for the purpose of putting the device to use under the name given, whether the medical device/product was manufactured and designed by the manufacturer or another party.

The Legal Representative:

An individual who is authorized in writing by the manufacturer to represent the manufacturer in Saudi Arabia based on defined tasks including the responsibility of representing the manufacturer at SFDA.

The Establishment:

Any legal status that practices an activity regarding medical devices and products in Saudi Arabia which includes manufacturing and/or launching a medical device/product for marketing purposes and/or distributing the medical device/product or representing the manufacturer.

The Applicant:

A person in Saudi Arabia who is responsible for providing information about the establishment for licensing purposes.

2nd Chapter

Field and Applicability:

The guideline herein applies to investors who desire to obtain a legal representation license to represent an external medical devices/products manufacturer under SFDA, after meeting all the documentations and special requirements of the following government bodies:

- Saudi Food & Drug Authority
- Ministry of Commerce
- Ministry of Investment
- Ministry of Foreign Affairs

ISIC activities that apply for this guideline can be found on the SFDA website www.sfda.gov.sa

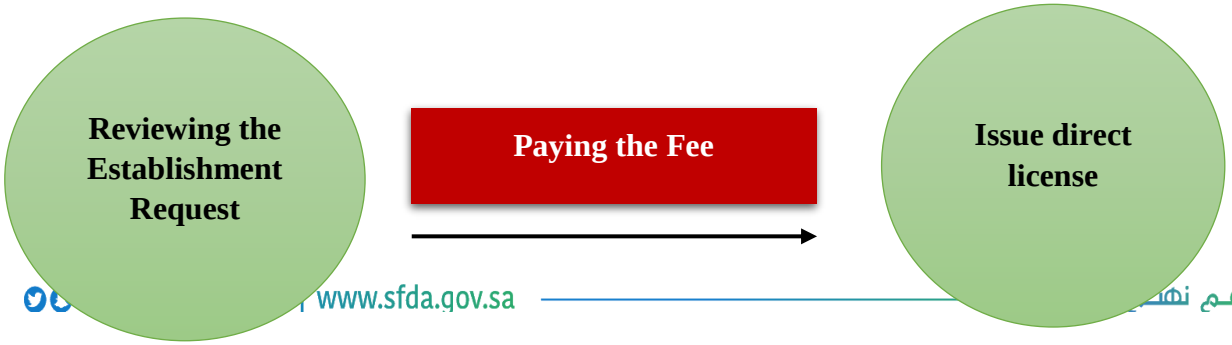
3rd Chapter

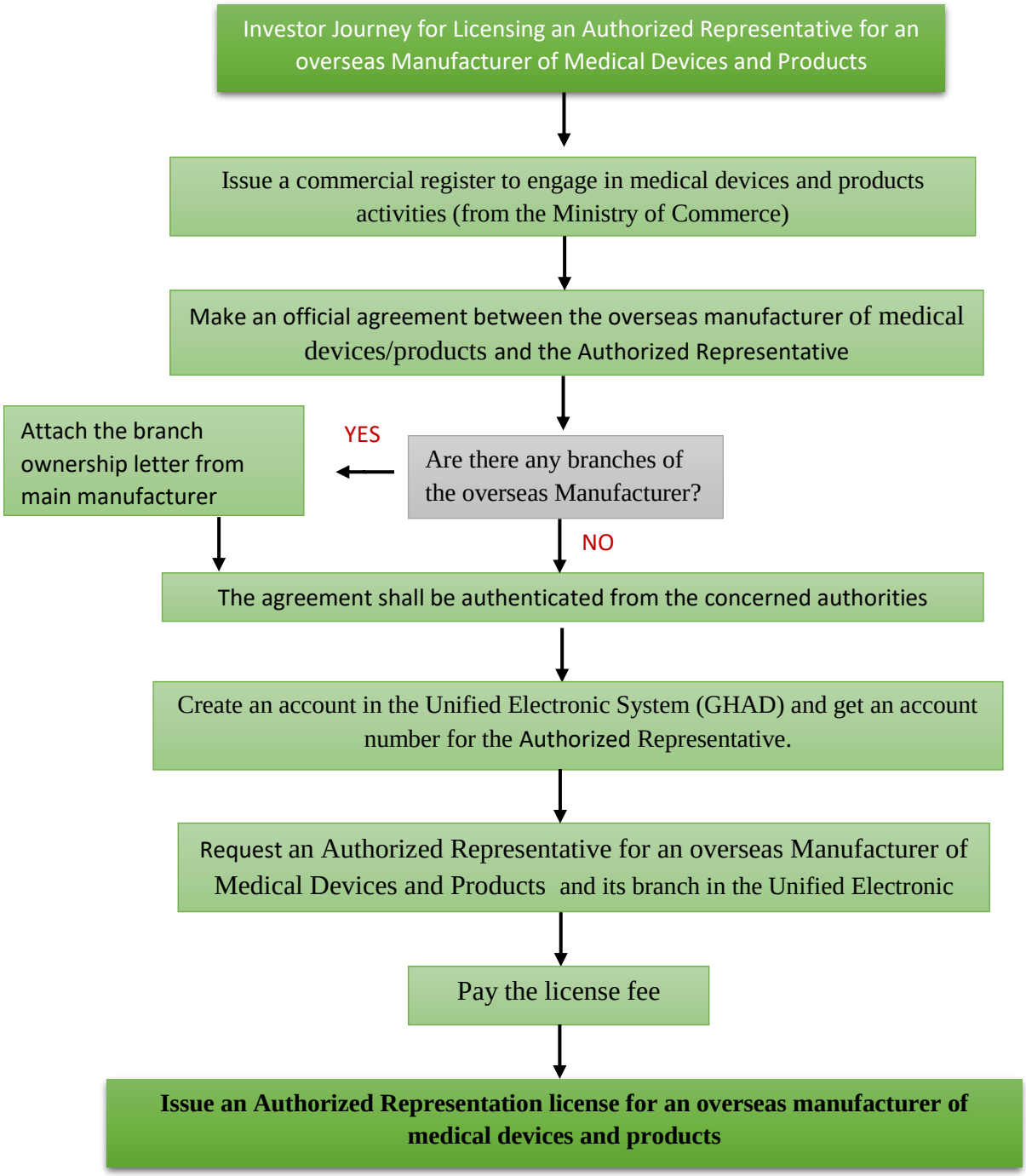
A Guideline for Issuing a License for an Authorized Representative for an overseas Manufacturer of Medical Devices and Products

1. Make an official agreement between the overseas manufacturer of medical devices/products and the Authorized Representative. In case the main manufacturer has a multiple sub site manufacturer, the main manufacturer must provide a letter stating that all sub site manufacturer is wholly owned.
2. The agreement shall be authenticated from the concerned authorities
3. Create an account in the Unified Electronic System (GHAD) and get an account number for the establishment.
4. Apply to request an Authorized Representative for an overseas Manufacturer of Medical Devices and Products and its branches through the Unified Electronic System (GHAD)
5. Pay the license fee, if the request was accepted.
6. Issue the license from SFDA. The establishment shall not engage in activities unless a Quality Management System is applied and documented according to the Saudi Standard (ISO GSO/MD.SFDA 13485: 2016) or any equivalent standard. The site inspection will be conducted by the SFDA.
7. Visiting the establishment will be done by SFDA inspectors.

Estimated Time for Licensing a Legal Representation for an External Manufacturer of Medical Devices:

A direct license will be issued for low-risk activities after reviewing the establishment request and issuing the license shortly after paying the fee. The site inspection will take place after issuing the license, the establishment can engage in activities afterward.




Investor Journey for Licensing an Authorized Representative for an overseas Manufacturer of Medical Devices and Products
Issue a commercial register to engage in medical devices and products activities (from the Ministry of Commerce)
Make an official agreement between the overseas manufacturer of medical devices/products and the Authorized Representative
Are there any branches of the overseas Manufacturer?
YES
Attach the branch ownership letter from main manufacturer
NO
The agreement shall be authenticated from the concerned authorities
Create an account in the Unified Electronic System (GHAD) and get an account number for the Authorized Representative.
Request an Authorized Representative for an overseas Manufacturer of Medical Devices and Products and its branch in the Unified Electronic
Pay the license fee
Issue an Authorized Representation license for an overseas manufacturer of medical devices and products

4th Chapter

Requirements and Documentations for Issuing a License

Requirements:

1. The applicant shall submit the following:

- An account number given by SFDA to the establishment of the investor.
- A list that includes medical devices/products classes that are planned to be imported to Saudi Arabia, along with detailed contact information of the manufacturers of these devices.
- The establishment shall be obliged to obtain the documentation needed to affirm their adherence to the responsibilities mentioned in Article (16) of the Medical Device Interim Regulation as follows:

A. If the establishment desires to launch any of the marketing restricted devices in Saudi Arabia, notify either the manufacturer of the medical device/product or the legal representative.

B. Ensure storing and/or transporting the medical device/product shall be met the instructions in the recommendations given by the manufacturer.

C. Documenting the selling process of the medical device/product to ensure tracking the product in the market. The establishment is responsible for controlling and tracking the medical device/product.

D. Ensure to attach the label and marketing permission and notify SFDA if the establishment was unable to launch the medical device/product in the market.

- Notify SFDA within 10 days if there are any changes in the information provided.

2. Issue a commercial register for medical devices/product activities (from the Ministry of Commerce)
3. Make an official agreement between the overseas manufacturer of medical devices/products and the Authorized Representative. In case the main manufacturer has a multiple sub site manufacturer, the main manufacturer must provide a litter stating that all sub site manufacturer is wholly owned.

4. The agreement shall be authenticated from the concerned authorities
5. After issuing the bill from the Operating Sector Billing System, pay the license fee of 2600 SAR annually for each contract, via SADAD system (SFDA billing number: 109)
6. Establish, Document, and apply the Quality Management System according to the Saudi Standard "Medical devices - Quality Management System - Regulatory Requirements (SFDA.MD/GSO ISO 13485:2016)"

Documents:

1. Make an official agreement between the overseas manufacturer of medical devices/products and the Authorized Representative.
2. The main manufacturer must provide a letter stating that all sub site manufacturer is wholly owned. In case the main manufacturer has a multiple sub site manufacturer
3. A clear computer-made sketch of the establishment location that indicates the city name, neighbourhood name, street names, and names of the location surrounding establishments. It shall include the contact details of the applicant and GPS coordinates.

5th Chapter

Application Procedures for Issuing a License for an authorized Representative for an overseas Manufacturer of Medical Devices and Products

1. Create an account in the Unified Electronic System (GHAD) and get an account number for the establishment.
2. In the Unified Electronic System of SFDA (GHAD), select (Authorized Representative License)
3. Fill out the application form and attach the required documentation.
4. Pay the license fee.

6th Chapter

License Renewal

1. The establishment may apply for license renewal 60 days before the expiry date of the current license.
2. The renewing application shall be done through the Unified Electronic System (GHAD), with attaching the required documentation.
3. Pay the fee to license engaging in activities in the absence of any violations by the establishment.
4. Obtain a license issued by SFDA to engage in Authorized Representation activities for overseas manufacturers of medical devices/products.

7th Chapter

License Duration and Fees

License Duration:

According to the annually updated regulation.

Fees:

Pay the license fee of 2600 SAR annually for every contract.

8th Chapter

Violations and Penalties:

Medical devices/products activities have no violations and penalties regulation.

(The regulation will be attached later)

9th Chapter

Common Questions

1. Why is registering medical devices/products establishments in the registration and licensing system considered crucial?

Registering medical devices/products establishments in the registration and licensing system is considered crucial owing to the following:

- Issuance of a license to conduct the establishment activities.
- Building a database for all medical devices/products establishments in Saudi Arabia.
- Enhancing communications between SFDA and medical devices and products establishments.
- Enabling medical devices and products establishments to update their data consistently, besides easing the communication process with SFDA as a regulatory body of these establishments.
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2. *Who is registering in the Establishments Registration system?*

An official and an authorized individual by the establishment who has access to adequate technical information to complete the registering technical and administrative process.

3. When to apply for a license from SFDA to engage in activities?

Apply for a license through the Unified Electronic System, after obtaining a commercial register and finalizing the establishment preparations by 100%.

5.When the establishment is entitled to engage in activities?

The establishment can engage in activities after obtaining the license from SFDA and apply and document the Quality Management System according to the Saudi Standard (SFDA.MD/GSO ISO 13485:2016), any activities before issuing the license are prohibited.

6. How long does the licensing issued by SFDA in medical devices/products activities last?

According to the annually updated regulation.

7. When shall the investor apply for license renewal?

The establishment shall apply for a license renewal before 60 days of the expiry date of the current license.

8. If the investor has multiple medical devices/products establishments, is it registered as a single establishment in SFDA registration and licensing system?

Each establishment shall be registered by the investor separately (two independent applications)

9. Is it necessary to update the file of the registered establishment?

Yes, information shall be updated if needed such as the commercial register or contact details.

10. What contact details do I reach when I need help?

Applicants may reach out to us if needed by contacting through the unified number 19999 or our email: md.mdel@sfda.gov.sa

Contact Details

Unified Number	19999
Email	md.mdel@sfda.gov.sa