MEDICAL DEVICE REGISTRATION WITH SAUDI FDA

Authorized Representative Licensing

Prepared by

Bio-Standards®

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Partners in Compliance®

Bio-Standards was established in 2010 as a regulatory consultant specialized in product registration with the Saudi Food & Drug Authority (SFDA) and Saudi Standards Organization (SASO), and local market access for international manufacturers of Medical Devices, Pharmaceuticals, Cosmetics, Food, Feeds, and Pesticides. Bio-Standards also provides matchmaking services between international manufacturers and local distributors. We are proudly serving more than 700 clients and has registered more than 120,000 products.

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Overview

The Saudi Food and Drug Authority (SFDA) was established under the Council of Ministers resolution no (1) dated 1424/01/07 H, as an independent body corporate that directly reports to The President of Council of Ministers.

The Authority's mission is protecting the community through regulations and effective controls to ensure the safety of food, drugs, medical devices, cosmetics, pesticides, and feed.

The main purpose of the SFDA is to regulate, oversee, and control food, drug, and medical devices, as well as to set mandatory standard specifications thereof, whether they are imported or locally manufactured. Moreover, the SFDA is in charge of consumers awareness on all matters related to food, drug, and medical devices and all other products and supplies.

Introduction

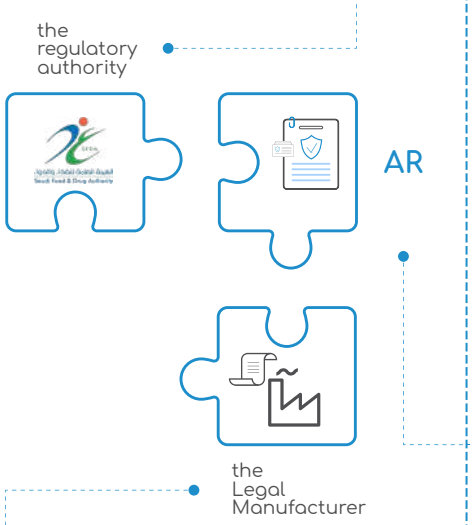
The relationship between an Authorized Representative (AR) and the Legal Manufacturer (LM) is the cornerstone of medical device compliance, particularly in regions like middle east and Saudi Arabia. This guide offers a concise overview of the AR appointment process and its interaction with the LM, focusing on roles, responsibilities, and regulatory requirements.

What is an Authorized Representative (AR)?

An **Authorized Representative** acts as a local point of contact between **the regulatory authority** and **the Legal Manufacturer.** This is especially crucial for overseas manufacturers aiming to market medical devices in countries where local representation is mandated.

Key Functions of the AR:

- Facilitating regulatory submissions.
- Maintaining compliance with local regulations.
- Addressing inquiries or audits from regulatory bodies.



The Role of the Legal Manufacturer (LM)

The Legal Manufacturer is the entity responsible for **designing, manufacturing, and ensuring the safety and performance of a medical device.** Collaborating with an AR ensures that their products meet regulatory requirements in the Saudi market.

Key Responsibilities of the Legal Manufacturer:

Providing accurate technical documentation.

Ensuring compliance with applicable standards & regulations.

Supporting the AR with information for registration.

The AR and LM Partnership

The AR-LM relationship is defined by transparency, collaboration, and adherence to regulatory standards. A clear division of responsibilities and effective communication is essential.

Steps in the Authorized Representative License Process:

1. **Agreement Establishment:**
   Drafting a written agreement defining roles, responsibilities, and confidentiality clauses.
2. **Registration:**
   The AR submits applications to the local regulatory authority, ensuring all documents comply with national requirements.
3. **Ongoing Compliance:**
   The AR monitors the device's market performance and coordinates post-market surveillance activities with the LM.

The Apostille Process and Non-Hague Convention Countries

The apostille process is used to authenticate documents for use in countries that are part of the Hague Apostille Convention. It simplifies international document validation by certifying their authenticity without requiring further legalization by consulates.

Steps in the Apostille Process:

1- Obtain the original document or certified copy.

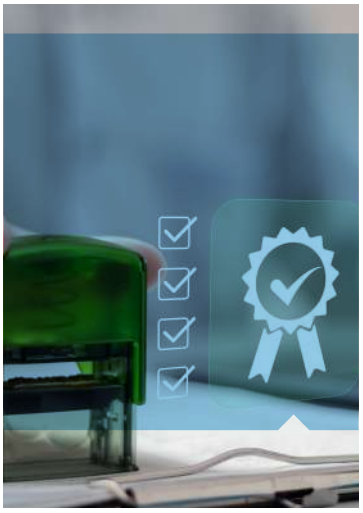
2- Have the document notarized if required.

3- Submit the document to the designated authority for apostille certification.

When the LM is in a Non-Hague Convention Country: If the LM is based in a country that is not a member of the Hague Convention, an alternative legalization process is required. This typically involves:

1. Authentication by the issuing country's relevant authority (e.g., Ministry of Foreign Affairs).
2. Legalization by the embassy or consulate of the target country.
3. Translation of the document into the required language if necessary.

This additional process ensures the documents are legally recognized in the target market, albeit with more steps and time required.



A successful Authorized Representative and Legal manufacturer collaboration ensures smooth market entry, sustained compliance, and regulatory peace of mind. For Legal manufacturers, selecting a reliable Authorized Representative in Saudi Arabia is a critical decision, while Authorized Representatives must maintain robust processes to meet regulatory obligations.

Let Bio-Standards Help You

Our regulatory experts at Bio-Standards are equipped to:

- Assess your product's classification potential
- Prepare complete and compliant PCS files
- Communicate directly with SFDA on your behalf
- Save you time, avoid rejections, and reduce risk

Let's talk

Bio-Standards – Medical Device Regulatory Experts

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Bio-Standards® has the right skillset and technical knowledge to support you with your regulatory and registration needs with the Saudi Food & Drug Authority (SFDA).

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