MEDICAL DEVICE REGISTRATION WITH SAUDI FDA

Importation Licenses for Medical Devices and Chemicals in Saudi Arabia

Prepared by

Bio-Standards®

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Bio-Standards®

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 07/01/1424 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.

A marketing guide to fast, compliant market (MDS-G8) entry — MDIL for Demonstrations (MDS-G12) and Chemicals

Introduction: Why This Matters?

In Saudi Arabia, the **Medical Devices Importation License (MDIL)** is the gateway that allows shipments to clear customs and reach users.

For demos, training, or chemicals that enable device operation, having the right MDIL early avoids project delays and protects your brand.

At **Bio-Standards**, we simplify this process by guiding you through SFDA's regulatory pathways, ensuring your products enter the Saudi market smoothly and on time.

Where We Help (Examples)

- **Demonstration & Training Devices (MDS-G8)**
  For exhibitions, proctoring sessions, and hands-on training. These devices are not for clinical use but are essential for market presence and showcasing technology.
- **Chemicals used in Medical Device Applications (MDS-G12)**
  Includes calibration gases, sterilants, chemicals for prosthesis manufacturing, and preservation agents. We also manage coordination with MOI/HCIS if chemicals are controlled.

Benefits of Working with Bio-Standards

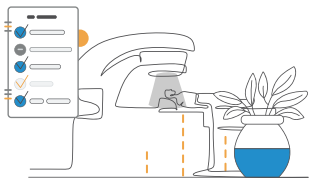
1- Fast Market Access → We prepare your applications & ensure timely license issuance.

2- Risk Reduction → We anticipate common issues that delay shipments and resolve them before submission.

3- Local Credibility → Acting as your Authorized Representative (AR), we ensure full alignment with SFDA.

4- End-to-End Support → From form preparation to customs clearance, including controlled chemical approvals.

→ Simple Processes - Minimal Steps, Maximum Clarity



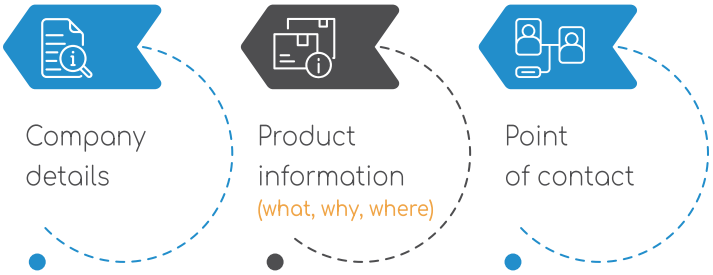
Demonstration & Training Devices (MDS-G8)

1- Quick intake & eligibility check
2- Preparation of MDIL request in SFDA portal
3- Client review/approval
4- Submission & tracking until license is issued
5- Port clearance support

Chemicals in Medical Device Applications (MDS-G12)

1- Define the chemical use case
2- Determine if MOI/HCIS approval is required
3- Prepare forms (attestation, MSDS, supporting docs)
4- Submit & coordinate with SFDA/HCIS
5- Port clearance with proper labeling & storage checks

What We Need From You (Short List)



We'll guide you step by step through the rest.

Trusted by Global Manufacturers

→ 35+ Countries
Manufacturers Supported

→ 120,000+ Products
Registered in Saudi Arabia

Our blend of regulatory precision and business urgency makes Bio-Standards the partner of choice for smooth market entry.

Quick FAQs

1- Are these imports for clinical use? → Demonstration/training MDILs are for non-clinical use. Chemicals support device operations; clinical use depends on classification.

2- Will you handle Arabic attestations? → Yes. We prepare compliant Arabic attestations and manage signatures according to SFDA rules.

3- What if my chemical is controlled? → We coordinate directly with SFDA and HCIS, minimizing back-and-forth & avoiding shipment delays.

4- Do healthcare providers need MDEL? → Healthcare facilities are generally exempt; we confirm case-by-case during intake.

Let Bio-Standards lead the way.

Let's talk

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Note: This guide is a marketing summary and does not replace official SFDA guidance (MDS-G8 & MDS-G12).

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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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