MEDICAL DEVICE REGISTRATION WITH SAUDI FDA

Medical Device Establishment License

Prepared by

Bio-Standards®

2025 V.1

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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.

Therefore, if foreign manufacturers, local manufacturers, importers, or distributors wish to market cosmetic product in Saudi Arabia, they must register it in the SFDA database.

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.

Why This Matters?

Operate legally. Win trust. Avoid delays.

MDS REQ 009 sets the licensing rules for medical device establishments in KSA. A valid license signals to regulators, hospitals, and partners that you're operating safely and compliantly.

If you're starting or scaling in KSA, this is your first green light.

Outcomes when you do this right:

- Smoother imports and market access (no last minute surprises)
- Stronger customer confidence and sales velocity

Who Needs a License
(at a glance)

If you are any of the following in KSA, you likely need an SFDA Establishment License:

We help you register your account on the SFDA PCS system to enable submissions.

01- Manufacturers
(including local assembly/packaging/labelling)

02- Authorized Representatives (ARs)

03- Importers & Distributors, and Optical establishments

04- Warehouses
(including third party storage arrangements)

05- Clinical Trials Verification entities

06- Conformity Assessment & QMS service providers (CABs)

07- Testing Laboratories

08- Quality Assurance & Radiological Measurements providers for health facilities

09- Medical Maintenance providers

10- Technical Consultation providers

> Not sure where you fit? Our quick scoping call maps your activities to the **correct establishment type(s)** in minutes.

What SFDA Typically Looks For

Keep it simple. Be ready to evidence these fundamentals:

1. **Legal presence** and the right commercial activities.
2. **GHAD account** and establishment number.
3. **Quality Management System (ISO 13485)** suitability for your role (manufacturer / importer / distributor / AR...)
4. **SOPs**, aligned to SFDA requirements.
5. **Traceability & PMS** (NCMDR reporting, safety alerts, CAPA discipline).
6. **Qualified personnel** (e.g., Technical/Quality Managers, Radiation Protection Officer where applicable).

We package these into a "licensing evidence pack" to accelerate review & inspections.

4 STEPS How Bio Standards Gets You Licensed

01.Assess

We confirm your establishment **type(s)**, gaps vs. MDS REQ 009, and your **QMS** fit.

02.Prepare

We develop/refresh essential artifacts: GHAD profile, role specific SOPs, traceability & PMS matrices, job descriptions, training logs.

03.Apply

We assemble and submit your **GHAD application** (establishment / branches / warehouses), coordinate with SFDA.

04.Approve & Maintain

We guide post approval obligations (renewals, amendments, advertising approvals, PMS cadence) so you **stay** compliant.

What You Get Working With Us

- **Clear roadmap:** exact establishment type(s), documents, and next steps
- **Regulator-ready document pack:** SOPs, templates, and checklists tailored to your activity
- **After license care:** renewals, amendments, PMS & advertising support

Optional add-ons

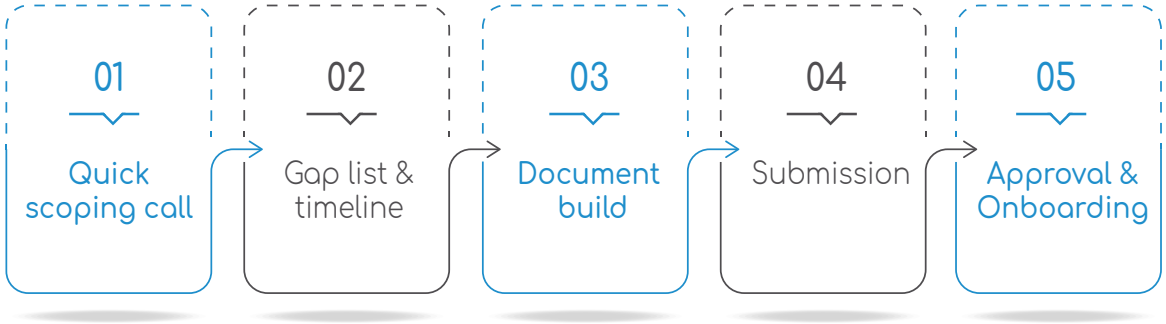
Marketing Authorization (MDMA) strategy, UDI readiness, distributor onboarding, third party storage contracts, and maintenance licensing.

Common Pitfalls (and how we avoid them)

- **QMS evidence not aligned with the declared role** → We tailor scope and show practical implementation.
- **Missing warehouse or third party storage coverage** → We arrange the right licensing/contract route.
- **Late renewals & unapproved advertising** → We set a compliance calendar and pre clear promotional materials.

Fees & Next Steps
(kept light)

SFDA fees depend on establishment type Ready to move?



About Bio-Standards

Riyadh based regulatory partner dedicated to medical devices in Saudi Arabia. We serve manufacturers, ARs, importers/distributors, and healthcare providers with:

- **Establishment Licensing (MDS REQ 009)**
- **Authorized Representative (AR)** services
- **MDMA** strategy and submissions
- **PMS / NCMDR** systems and reporting support
- **Warehouse & third party storage** licensing
- **Quality & compliance**

Why Clients Choose Us

- **SFDA focused** team with hands on GHAD experience
- **Bilingual** (Arabic/English) communication and documentation
- **Templates that work:** we keep it organized, and inspection ready
- **Dedicated account lead** and clear timelines

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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