MEDICAL DEVICE REGISTRATION WITH SAUDI FDA

Product Classification System (PCS)

Prepared by

Bio-Standards®

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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.

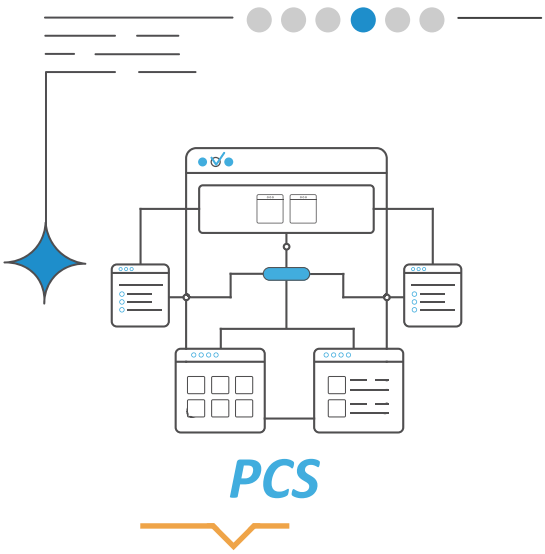
The Authority's mission is protecting the community through regulations and effective controls to ensure the safety of food, drugs, medical devices, cosmetics, pesticides, and feed.

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.

Therefore, if overseas manufacturers, local manufacturers, importers, or distributors wish to market products within these sectors product in Saudi Arabia, they must register it in the SFDA database.

Understanding the SFDA Product Classification System (PCS) for Medical Devices

A Guide by Bio-Standards – Your Regulatory Partner in Saudi Arabia



About This Guide

This e-book is designed to provide manufacturers, importers, and regulatory professionals with a clear understanding of the SFDA Product Classification System (PCS) service specifically as it relates to medical devices. Whether you're unsure if your product falls under the medical device scope or needs a classification decision before proceeding with registration, this guide will help you navigate the process.

What is the Product Classification System (PCS)?

The Product Classification System (PCS) is an official service provided by the **Saudi Food and Drug Authority (SFDA)** that helps determine which regulatory pathway your product must follow — whether it's a **medical device, drug, cosmetic, food,** or otherwise.

PCS is particularly useful when products are on the borderline between two regulatory categories or when their classification is not clear from the outset.

Definition of a Medical Device (as per SFDA)

Any instrument, apparatus, implement, machine, implant, reagent, software, or other article intended by the manufacturer to be used for diagnosis, prevention, monitoring, treatment, or alleviation of disease, and which does not achieve its primary intended action by pharmacological, immunological, or metabolic means.
This includes:

- In-vitro diagnostic devices (IVDs)
- Surgical instruments
- Diagnostic imaging devices
- Assistive/supportive devices (e.g., wheelchairs, hearing aids)

PCS Services We Handle for You

1. Company Account Setup

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

2. Product Classification Application

We prepare and submit your product classification file, including:

- Product description and intended use
- Mode of action
- Catalog, artwork, and quality certificates
- Declaration of Conformity (DoC)
- Manufacturer's classification letter

3. Communication & Follow-up

We follow up with SFDA on your behalf and keep you updated throughout the review process.

4. Classification Decision

You will receive an official SFDA classification decision, which is valid for **1 year.**

Key Outcomes of a PCS Classification Decision

- Official confirmation of your product's classification
- Direction on the required regulatory pathway
- Clarification for products that may fall on the borderline
- A critical first step before submitting for MDMA

Note: The classification decision itself does not guarantee product registration. It only defines the regulatory scope.

When is PCS Required for Medical Devices?

- New or innovative products
- IVD reagents, calibrators, or software with uncertain use
- Accessories or kits with mixed-use components
- Products that may fall under drug or cosmetic categories

Examples of Medical Devices as per SFDA

- Blood glucose meters and strips
- Diagnostic reagents
- Self-pregnancy tests
- Surgical instruments
- Diagnostic imaging agents (e.g., Barium enema kits)
- Assistive devices (e.g., hearing aids, crutches)

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Processing Time

Classification decisions are typically issued within **15 working days**, depending on SFDA workload and submission quality.

Timeline

Fees

02

Fee

A mandatory PCS submission fee is paid via SADAD after application submission.

Appealing a Decision

If you disagree with SFDA's classification, you can submit a formal **appeal** within a specified window, supported by regulatory or scientific justifications.

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 declare that the information provided in this E-Book gathered from the official Saudi Food and Drug Authority (SFDA) website and supported with the issued SFDA's guidelines and regulations. You must not rely on the information in this E-book as an alternative to the Saudi Food and Drug Authority (SFDA) published regulations.

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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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