MEDICAL DEVICE REGISTRATION WITH SAUDI FDA

Medical Device Marketing Authorization (MDMA)

Prepared by

Bio-Standards®

2025 V.1

www.bio-standards.com

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.

TABLE OF CONTENT

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

Achieving SFDA Compliance for Medical Devices: A Practical Guide

Introduction

Navigating the Saudi Food and Drug Authority (SFDA) regulatory framework is essential for manufacturers and Authorized Representatives (ARs) seeking to market medical devices (MD) and in vitro diagnostics (IVD) in Saudi Arabia. For successful compliance, understanding and addressing key steps such as risk classification, bundling, and the **MDMA-2 (Technical File Assessment)** phase is critical. This white paper provides a structured approach to help you confidently manage the Medical Device Marketing Authorization (MDMA) process.

Step 1
Risk Classification

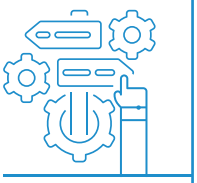
Risk classification is the foundation of the MDMA process. The SFDA uses a risk-based classification system to determine the level of scrutiny required for each device, ranging from Class **A (low risk)** to Class **D (high risk)** according to **MDS-G008 guidelines.** Accurate classification is essential to ensure the appropriate regulatory pathway is followed.

Key Factors in Risk Classification:

1. **Intended Use:** Devices used for diagnostic, therapeutic, or monitoring purposes typically have higher classifications.
2. **Duration of Use:** Devices used for long-term or permanent applications may require a higher classification.
3. **Body Interaction:** Devices that are invasive or interact with critical body systems generally fall into higher risk classes.

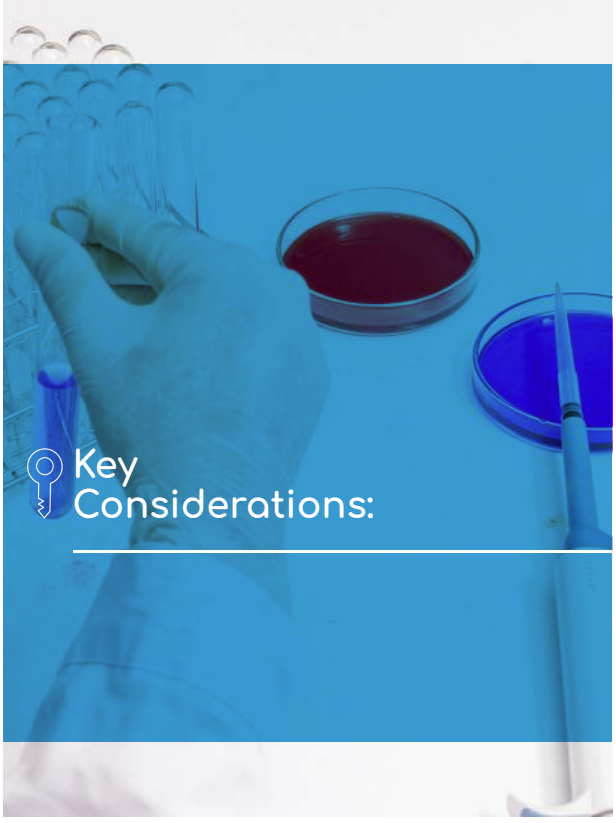
Practical Guidance:

- Carefully evaluate the intended purpose and technical specifications of your device.
- Follow SFDA classification rules to determine the appropriate risk category.
- Ensure your risk classification aligns with the device's design and functionality to avoid reclassification delays.



Step 2
Bundling Strategies

Bundling is a practical approach that allows manufacturers **to group related devices under MDMA applications.** This can save time and reduce administrative efforts while ensuring compliance with SFDA criteria.



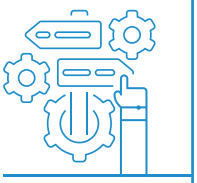
When to Bundle Devices:

- Devices with similar **intended purposes** and **technological characteristics** and **risk classification.**
- Product families or variations that share a common design or functionality.

1. Clearly document the relationship between devices in the bundle.
2. Avoid bundling unrelated devices, as this may lead to application rejection.
3. Ensure all devices within the bundle comply with the same risk classification requirements.

Practical Guidance:

- Review SFDA guidelines to identify bundling opportunities.
- Prepare detailed justifications for bundling to ensure regulatory approval.
- Evaluate all bundled devices to confirm alignment with SFDA's grouping criteria.

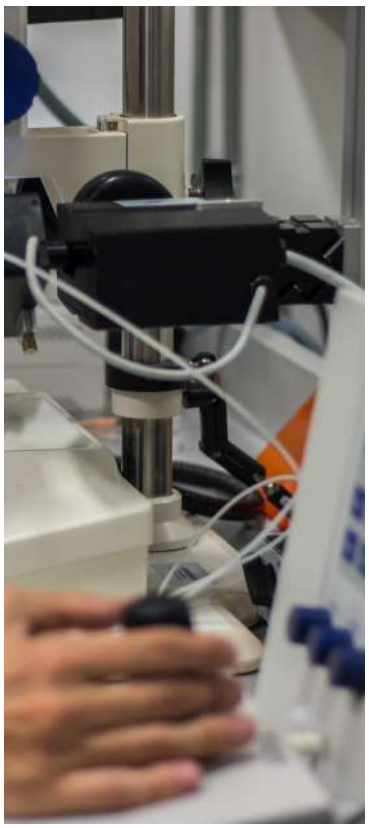


Step 3
MDMA-2 (Technical File Assessment)

The **MDMA-2 stage** is a critical review conducted by the SFDA to ensure that your device's technical file meets regulatory standards.
This process evaluates the safety, performance, and quality of the device before granting market authorization.

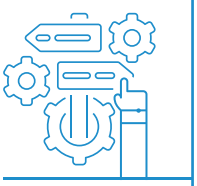
Key Focus Areas in MDMA-2:

1. **Device Description and Intended Use:** Detailed information about the device's design, purpose, and functionality.
2. **Risk Management:** Documentation of risk identification, mitigation, and control measures.
3. **Clinical Evaluation:** Evidence of the device's safety and performance through clinical studies or equivalent data.
4. **Manufacturing Details:** Clear descriptions of manufacturing processes and quality controls.
5. **Post-Market Surveillance Plans:** Strategies for monitoring the device's safety and performance after approval.

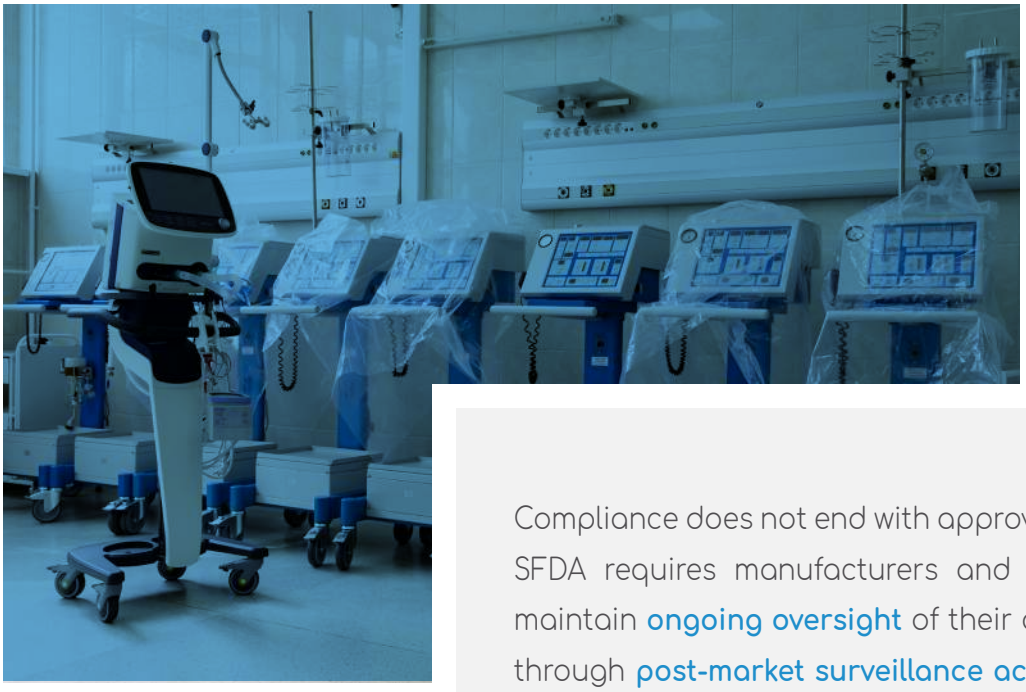


Practical Guidance:

- Compile a complete and accurate technical file that addresses all SFDA requirements.
- Evaluate the technical file for gaps or inconsistencies before submission.
- Engage experts to ensure that your file aligns with SFDA standards and international best practices.



Post-Market Surveillance and Compliance



Compliance does not end with approval. The SFDA requires manufacturers and ARs to maintain **ongoing oversight** of their devices through **post-market surveillance activities.**

Key Post-Market Obligations:

1- Renewals: Submit timely renewal applications to avoid lapses in registration.

2- Variations: Manage and report any changes to the device or its labeling.

3- Market Monitoring: Continuously assess the device's safety and effectiveness in real-world use.

Evaluating for Compliance

While manufacturers are responsible for documentation preparation, regulatory experts can provide valuable evaluations to ensure submissions meet SFDA requirements. Comprehensive reviews can help identify and address gaps, improving the chances of approval.

Benefits of Expert Evaluation:

Reduces the risk of delays or rejection.

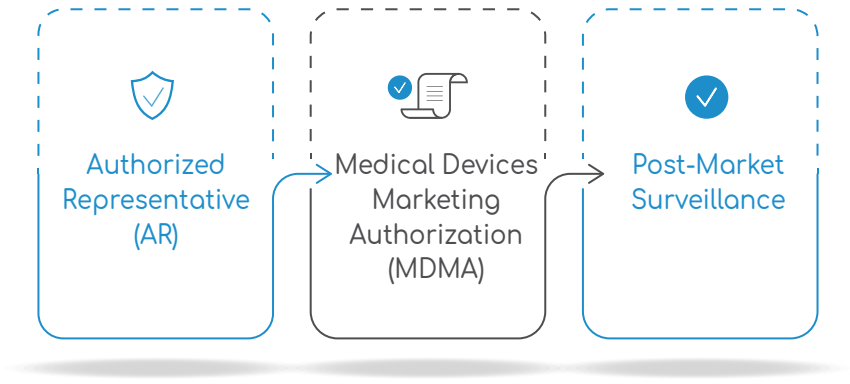
Confirms alignment with SFDA guidelines and international standards, such as ISO

Simplifies the MDMA process by providing targeted guidance.

Conclusion

Risk classification and bundling form the foundation of a successful MDMA submission, while accurate documentation and preparation for MDMA-2 ensure regulatory compliance. By following these structured steps and engaging expert evaluators, manufacturers and ARs can confidently navigate the SFDA process, ensuring swift market access and ongoing compliance.

> For further guidance or evaluation of your submission, consider partnering with regulatory specialists to streamline your compliance journey and achieve your market goals.



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

info@bio-standards.com
www.bio-standards.com
Bio-Standards
Riyadh, Saudi Arabia

Disclaimer

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.

1. Licence to use this E-Book

Subject to your compliance with the restrictions below and the other terms of this disclaimer, we grant to you a worldwide non-exclusive non-transferable licence to download a copy of this E-Book. You must not in any circumstances:

(a) Sell, license, sub-license, rent, transfer, distribute or redistribute this E-book or any part of it.

(b) Edit, modify, adapt, or alter the E-book or any part of it.

(c) Use of this E-Book or any part of it in any way that is unlawful or in breach of any person's legal rights under any applicable law, or in any way that is offensive, indecent, discriminatory, or otherwise objectionable.

(d) Use of the E-book or any part of the E-book to compete with us, whether directly or indirectly.

(e) Use the E-book or any part of the E-book for a commercial purpose.

You must retain, and must not delete, obscure, or remove, all or any copyright notices and other proprietary notices in this E-Book.

The rights granted to you by this disclaimer are personal to you, and you must not permit any third party to exercise these rights.

2. Limited Warranties

Whilst we endeavour to ensure that the information in this E-Book is correct, we do not warrant or represent its completeness or accuracy.

We do not warrant or represent that the use of this E-Book will lead to any particular outcome or result.

To the maximum extent permitted by applicable law and subject to Section 3 below, we exclude all representations, warranties, and conditions relating to this E-Book and the use of this E-Book.

3. Limitations and exclusions of liability

Nothing in this disclaimer will:

a) limit or exclude our or your liability for fraud or fraudulent misrepresentation.

b) limit any of our or your liabilities in any way that is not permitted under applicable law.

c) exclude any of our or your liabilities that may not be excluded under applicable law.

d) The limitations and exclusions of liability set out in this Section and elsewhere in this disclaimer.

e) We will not be liable to you in respect of any losses arising out of any event or events beyond our reasonable control.

f) We will not be liable to you in respect of any loss or corruption of any data, database, or software.

4. Trademarks

a) Bio-Standards, our logo, and tagline are trademarks belonging to Bio-Standards LLC. We give no permission for the use of these trademarks, and such use may constitute an infringement of our rights.

b) The other registered and unregistered trademarks or service marks in the E-book are the property of their respective owners. Unless stated otherwise, we do not endorse and are not affiliated with any of the holders of any such rights and as such we cannot grant any license to exercise such rights.

5. Digital rights management

You acknowledge that this E-Book is protected by digital rights management technology, and that we may use this technology to enforce the terms of this disclaimer.

6. Pirate copies

If you have received a copy of this E-book from any source other than us or, then that copy is a pirate copy. If this has happened to you, please let us know by email to **info@bio-standards.com**

7. Governing law

This disclaimer shall be governed by and construed in accordance with Saudi law.

Bio-Standards®

Partners in Compliance

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).

Kingdom of Saudi Arabia

+966 558 100 990

info@bio-standards.com

www.bio-standards.com

4578 Al Imam Abdullah Ibn Saud Ibn Abdul Aziz Branch Road Al Shohda District | Unit No 17, Riyadh 6862-13241 Kingdom of Saudi Arabia