MEDICAL DEVICE REGISTRATION WITH SAUDI FDA

Medical Device - Unique Device Identification (UDI)

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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Glossary

UDI	Unique Device Identifier.
UDI-DI	Device Identifier.
UDI-PI	Production Identifier.
AIDC	Automatic Identification and Data Capture.
DM UDI	Direct Marked UDI.
Saudi-DI	Saudi Arabia UDI Database.

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 cosmetic product in Saudi Arabia, they must register it in the SFDA database.

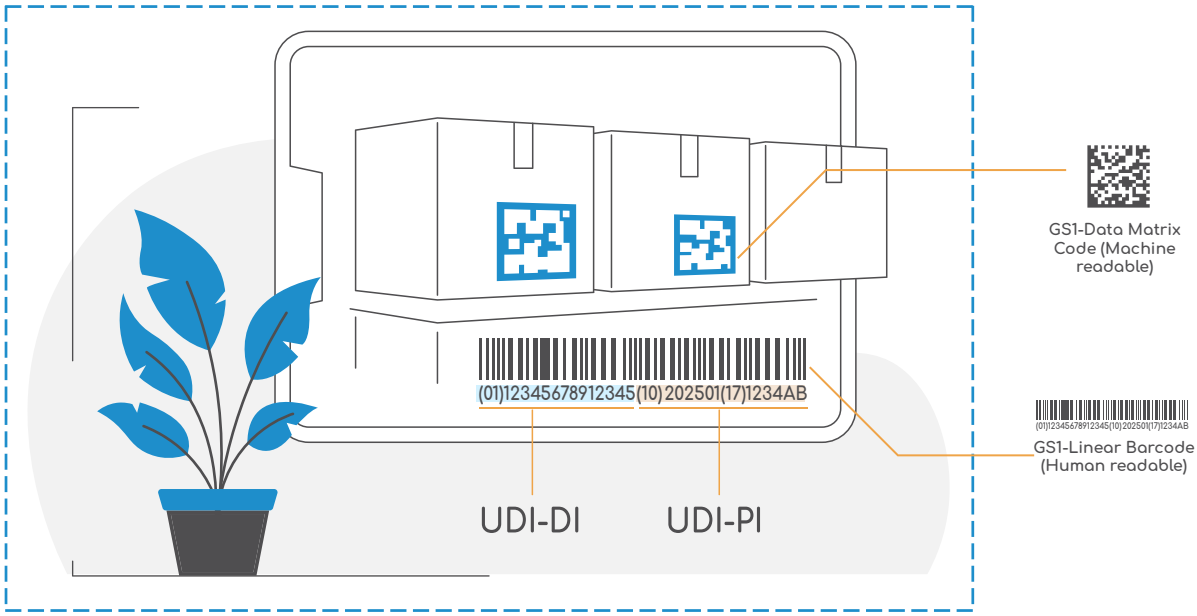
Introduction

The Unique Device Identification (UDI) system is a cornerstone of regulatory efforts aimed at improving the traceability, identification, and management of medical devices. By standardizing device identification, the UDI system supports numerous public health initiatives, including the detection of fraudulent devices, efficient recalls, and enhanced reporting of adverse events. This paper focuses on the requirements outlined in the **SFDA's MDS-REQ-007-V220524/4 guidance document** and highlights the critical steps for manufacturers and Authorized Representatives (ARs) in ensuring compliance.

UDI Requirements Overview

General Requirements

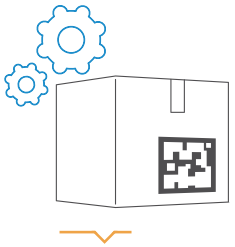
- Manufacturers must adopt standards from recognized issuing agencies (GS1, HIBCC, ICCBBA).
- The UDI consists of two parts: **Device Identifier (UDI-DI)** and **Production Identifier (UDI-PI).**
- The **UDI** must be presented in **two formats:** Human-Readable Interpretation (HRI) and Automatic Identification and Data Capture (AIDC) technology.
- Placement on the **primary label** and **higher-level packaging** is **mandatory.**



Direct Marking (DM)

Devices intended for **multiple uses** with reprocessing between uses **must bear a direct marking (DM) UDI** unless technical or safety constraints make it unfeasible.

UDI-DI Lifecycle Management



A new UDI-DI is required whenever there are **changes** in device attributes, such as model variants or branding, **that may affect traceability or identification.**

Saudi-DI Database

The Saudi-DI database ensures centralized data management. Key requirements include:

- Submission of UDI-DI data before market entry.
- Timely updates to reflect changes.
- Annual validation and periodic data confirmations.

Exceptions and Alternatives

Manufacturers may request **exemptions or propose alternatives to UDI requirements if standard compliance proves infeasible.** These requests must be supported by detailed justifications.

Additional Requirements

Software as a Medical Device (SaMD) UDI must be displayed on physical labels and digitally accessible screens. Major updates to software functionality or safety necessitate a new UDI-DI.

Implantable Devices Implantable devices must include their UDI information on implant cards. For active implantable devices, serial number tracking is required.

Configurable Devices These devices require a configurable UDI that remains accessible either physically or electronically.

Components, Sub-systems, and Accessories Each component or accessory that can be marketed separately must have its own unique UDI.

Single-Use Devices For single-use devices packaged together, the UDI is required only on the package level.

Kits and Procedure Packs Kits must have a unique UDI. Internal components may be exempt based on usage context.

Compliance Deadlines

Compliance with UDI requirements is phased based on device risk classes. Pre-compliance devices may remain on the market for up to one year following the compliance deadline.

Conclusion

The implementation of the UDI system by the SFDA marks a significant step towards strengthening medical device traceability and ensuring patient safety in Saudi Arabia. By adhering to these requirements, manufacturers and Authorized Representatives can enhance operational transparency and contribute to public health initiatives. Understanding and integrating UDI requirements into device design, labeling, and data management processes will not only ensure compliance but also support broader global harmonization efforts in medical device regulation.

References

1. Saudi Food and Drug Authority. (2022). MDS-REQ-007-V220524/4: Requirements for Unique Device Identification (UDI) for Medical Devices.

2. International Medical Device Regulators Forum (IMDRF). (2013). UDI Guidance: Unique Device Identification (UDI) of Medical Devices.

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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

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