IMDRF International Medical Device Regulators Forum

Session 5: Implementation and Challenges of UDI

Tracey Duffy
First Assistant Secretary
Therapeutic Goods Administration (TGA)
September 2025

Contents

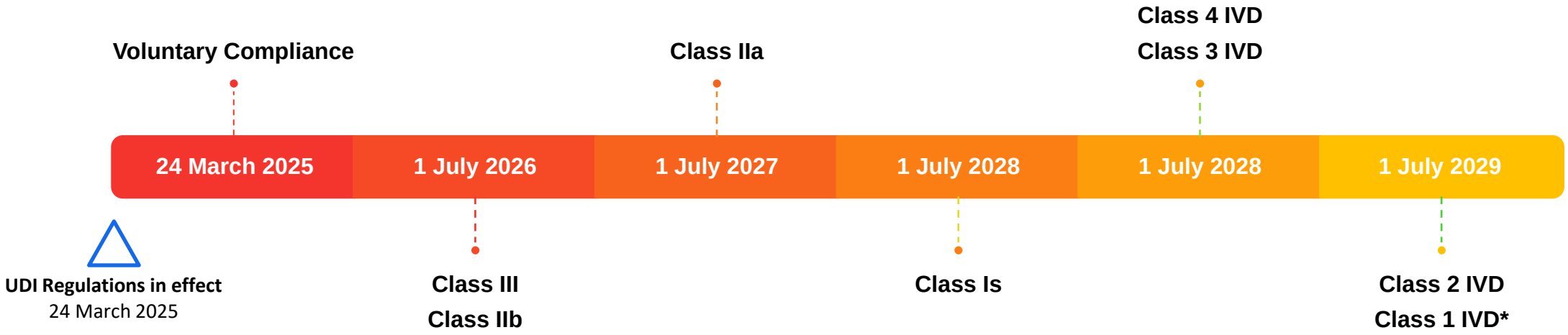
Australia's UDI implementation

- 3 Issuing Agencies – GS1, HIBCC, ICCBBA
- Australia will accept labels with UDI Carriers that meet USA and EU requirements for UDI
- Selected device classes

	Medical devices	Invitro diagnostic devices
UDI ✓	• Class III • Class IIb • Class IIa • Class I – supplied sterile	• Class 4 • Class 3 • Class 2 • Class 1 (Software IVDs or Instrument/Analyser IVDs only)
UDI ✗	• Class I - measuring • Class I • Class 1 IVD (remainder) • In house IVDs	• Devices not included on the ARTG • Patient-matched medical devices with a volume of 5 or less supplied each financial year • Medical devices exempt under Special Access Scheme (SAS) or Authorised Prescriber (AP) Scheme

Australia's UDI implementation

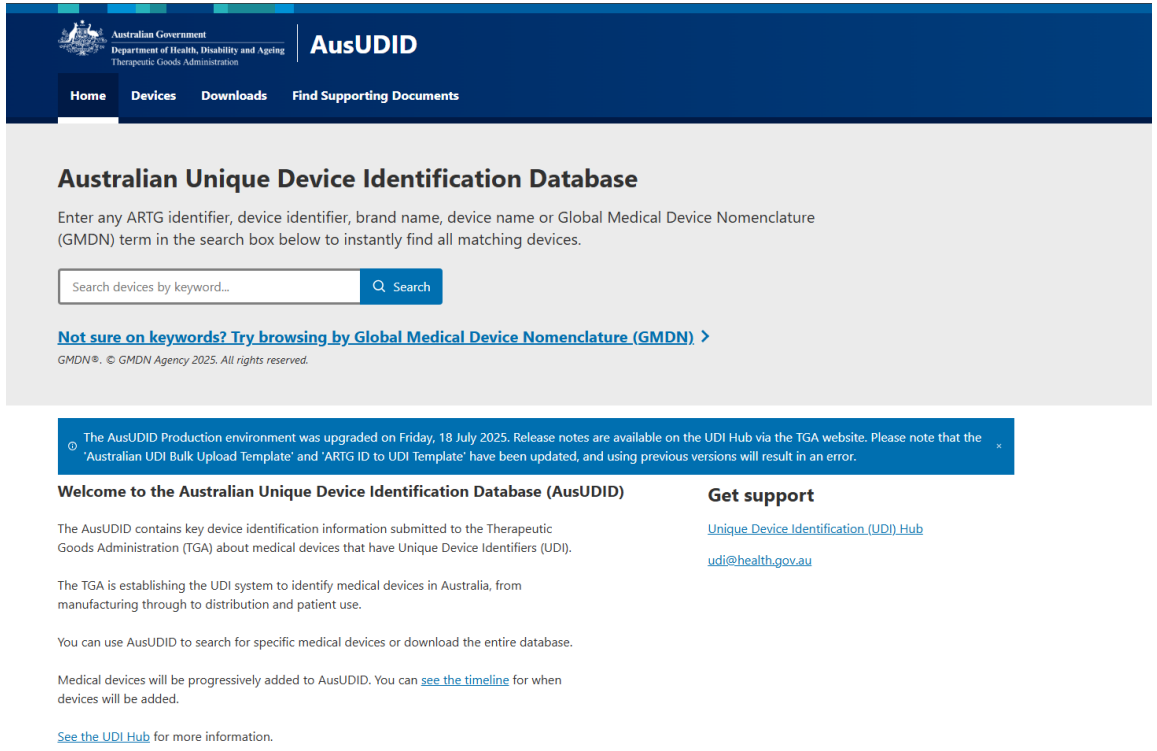
- Regulations updated 24 March 2025 with voluntary compliance until 30 June 2026
- Phased implementation starts with high-risk devices from 1 July 2026



- Additional transition times for:
  - Devices supplied under an MDD or IVDD certificate and transitioning to MDR or IVDR
  - Existing Class III and Class IIb devices manufactured and labelled prior to UDI compliance date

Australia's UDI implementation

- Australian UDI Database (AusUDID) live from 28 March 2025
- Data submission methods include online, Excel spreadsheet, 2 M2M channels
- 1 M2M method follows USFDA messaging format (HL7 SPL)



Implementation challenges

Global impacts

Industry readiness

UDI requirements and existing regulatory environment

Developing the UDI database

Healthcare adoption

Recommendations for new adopters

Stakeholder Engagement

Early and ongoing engagement with industry stakeholders is vital to manage change and mitigate impacts effectively.

Dedicated Support Team

A specialised UDI support team manages enquiries with clear communication and user-friendly educational materials.

Scalable Digital Infrastructure

Design the UDI database with a scalable design, bulk data uploads and modern machine-readable data exchange standards.

Quality Data

The UDI transition will identify issues with existing data and create opportunities for high quality device information.

Healthcare Adoption

Building strong business cases to facilitate healthcare adoption and regulatory alignment.

Thank you / Questions

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Session 5: Implementation and Challenges of UDI

Karen Noffs
Head of Medical Device Premarket Approval Office
Brazilian Health Surveillance Agency (ANVISA)

16 September, 2025

General Office of Medical Devices Premarket Approval

- Analysis of petitions for registration, notification, renewal, changes, and cancellation of Medical Devices.
- Determination of requirements for MD regularization.
- Provision of information on the status of regulated products.
- Guidance to the population and the regulated sector.

- **Participation in international regulatory forums – Promotion of Regulatory Convergence.**

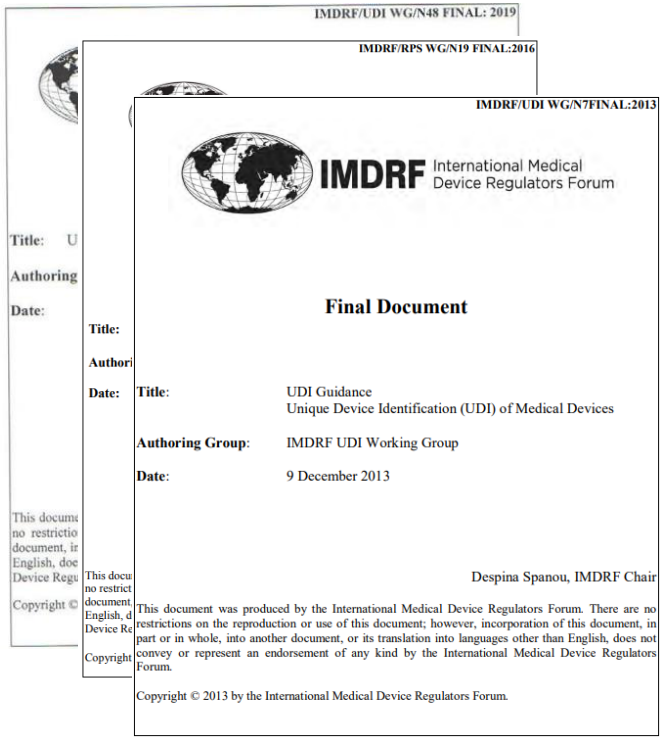
How the Brazilian UDI Regulation was built

- IMDRF documents were studied in detail;
- UDI Regulation of other jurisdictions were also studied;
- Brazilian regulation was inspired by what were already published by other jurisdictions;
- A **phased implementation** was determined as a must, since the beginning;
- All steps were carried out in accordance with Brazilian Good Regulatory Practices (GRP).

UDI Regulation in Brazil

☑ Resolution RDC n. 591/2021 identification of medical devices registered with Anvisa, through the Unique Identification of Medical Devices (UDI) system, based on International Medical Device Regulators Forum - IMDRF/RPS WG/N7, IMDRF/RPS WG/N19, IMDRF/RPS WG/N48.

- ✓ Included in **Anvisa's Regulatory Agenda** 2021-2023;
- ✓ Regulation process started in 2021;
- ✓ **Public consultation** carried in 2021;
- ✓ Published december 2021;
- ✓ In force to a subset of implantable devices since the start, fully in force for all devices 2031~;
- ❑ Normative act to officially launch the Brazilian UDI database, resulting from the Public Consultation nº 1.313/2025



UDI System Summary

- It is a system for assigning "identifier codes" to devices, which takes advantage of the logic and processes of generating codes for product identification in the general logistics scope, which:
  - identifies a device with a set of characters, functioning, roughly speaking, as a “pre-market authorization number” for each device model/presentation (UDI-DI);
  - to which is added the device's production data (UDI-PI), with a complementary set of coded characters.
- The components are represented by letters or numbers, for reading by human eyes (HRI); and by barcode, 2D matrix or RFID, for machine reading (AIDC).

UDI timeline in Brazil - a phased implementation

In force
10/01/22

1

Labeling requirements

- Class IV — 10/07/25
- Class III — 10/01/26
- Class II — 10/01/27
- Class I — 10/01/28

2

Permanent mark for reusable devices

- Class IV — 10/07/27
- Class III — 10/01/28
- Class II — 10/01/29
- Class I — 10/01/30

3

SIUD data submission

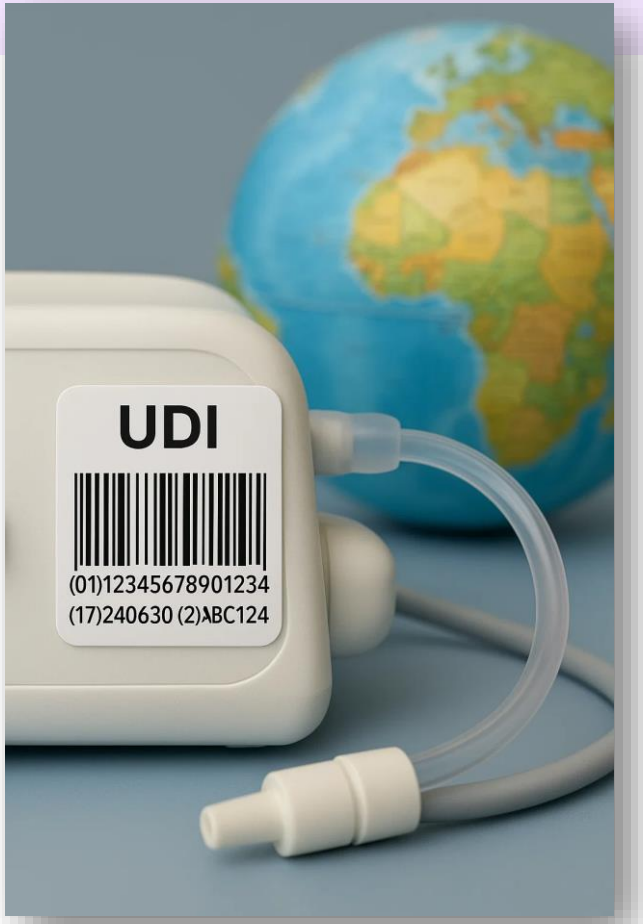
- SIUD official release expected — Oct/25
- Classe IV — Apr/29
- Classe III — Oct/29
- Classe II — Oct/30
- Classe I — Oct/31

Challenges and lessons learned - UDI regulation

- **Public consultations of regulation** drafts (and Good Regulatory Practices in general) are **very important** in our view (not only for UDI).
- Public webinars, Q&As, and other **knowledge sharing** methods are also essential.
- Contact channels must be available, so industry and other stakeholders can clarify their doubts.
- A **deep understanding of issuing entities rules for DI emission**; this is a topic that we now realize requires significant attention.
- A phased implementation is a must; but long deadlines require frequent reminders (for all stakeholders).

ANVISA UDI database development

- A senior GGTPS collaborator was assigned as Product Owner, supported by representatives from each MD field (Materials, IVD, etc.);
- Lean inception were adopted to define the MVP, and Scrum method for development;
- 10 industry representatives were invited to test the database in “pilot tests” as development progressed (4 tests, 1 still ongoing);
- “**Pilot tests”** proved very important!
- Brazilian regulations, prior to the UDI, made it impossible to fully match fields with other existing databases.



SIUD overview

datavisa

Anvisa's main system, which handles pre-mkt authorization and pre-UDI associated data

UDI-DI

47964357965424

DI obtained from Issuing Agency

Web form submission
One at a time

Batch submission (XML/JSON)
UI upload or API

HL7 FHIR

SIUD

ANVISA

Consultas
ANVISA - AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA
https://consultas.anvisa.gov.br/#/

WEB

Open data

API

HL7 FHIR

RNDS
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dados.gov.br

Challenges and lessons learned - Database development

- **Product Owner** or someone on its **side must understand data modeling** and how MD data should be organized.
- **From the start** have your development team and Product Owner **study the documentation of databases deployed by other jurisdictions -** ask them for tips and demos.
- In our view, **batch transactions** feature is a requirement for a UDI database, so a standard for such transactions must be chosen; **study the standards available** and already deployed by other jurisdictions **before** writing any line of code or **performing any data modelling**; applying this order should significantly reduce the difficulty of developing.
- We strongly recommend some sort of **externally available sandbox environment** at the database. Unfortunately, it's something we don't have (yet) on SIUD.
- **“Pilot tests”! We highly recommend it**. Numerous bug fixes, improvements, and much praise for enabling social participation during development process.

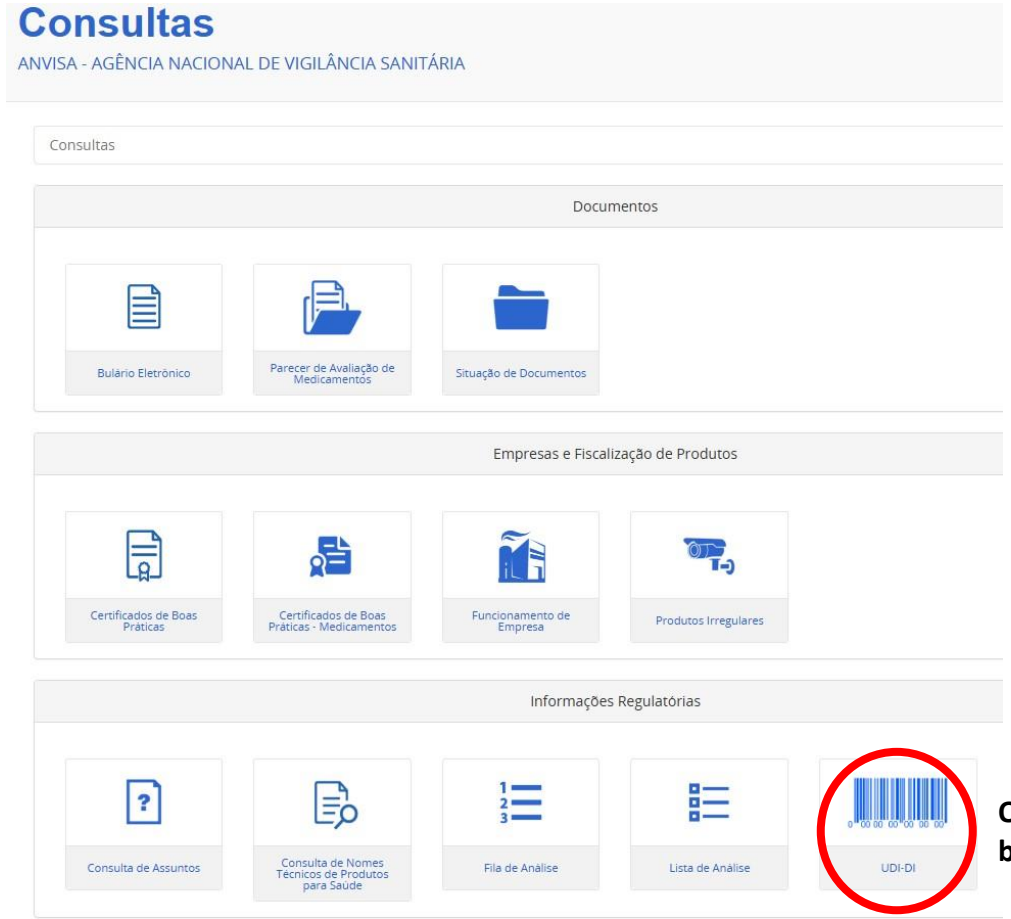
SIUD documentation

SIUD is not available yet, but its documentation repository is:

- System operation manual (release candidate, pt-br only for now);
- Machine to machine documentation (main features, pre-release, pt-br only for now);
- Batch submission examples.

https://www.gov.br/anvisa/pt-br/assuntos/produtosparasaude/udi/siud

Public data in ANVISA



https://www.consultas.anvisa.gov.br/#/

Once available UDI data will be here!

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Thank you!

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UDI Implementation in Japan

Marika DOI
Pharmaceutical Safety Division, Pharmaceutical Safety Bureau
Ministry of Health, Labour and Welfare (MHLW)

15 September 2025

Timeline for UDI Implementation

2000s
MHLW began medical device code standardization efforts

2006
Notification regarding barcode labeling for prescription pharmaceuticals

2008
Notification regarding barcode labeling for medical devices

2019
Legal revision

2022
Legal enforcement of mandatory barcode labeling

Article 68-2-5 of the PMD Act*

2025
Legal revision

*Related notification: https://www.pmda.go.jp/files/000248333.pdf

Products and Data to Be Labeled

Type of medical devices	Individual packaging		Packaging to be sold		Original packaging	
	Product code	Manufacturing identifier	Product code	Manufacturing identifier	Product code	Manufacturing identifier
(1) Medical devices that fall under special treatment materials	◎	◎	●	●	◎	◎
(2) Medical devices that fall under specially controlled medical devices or specially designated maintenance-and-management-required medical devices other than (1)	○	○	●	●	◎	◎
(3) Medical devices other than (1) and (2)	○	○	●	●	◎	◎
(4) *In vitro* diagnostics	○	○	●	●	◎	◎
(5) Consumable materials used repeatedly for medical care exclusively at medical institutions, which are other than (1) - (4).	○	○	◎	○	◎	○

●: Information that shall always be labeled in accordance with Article 68-2-5 of the Act
◎: Information that shall always be labeled in accordance with this notification
○: Optional labeling

Compliance Rate

	Database registration rate	Barcode labeling rate	
		Individual packaging	Packaging to be sold
(1)Medical devices that fall under special treatment materials	**98.1%**	**99.5%**	**99.1%**
(2)-1 Specially designated maintenance-and-management-required medical devices	**93.2%**	**92.3%**	**97.9%**
(2)-2 Specially controlled medical devices	**82.7%**	**92.3%**	**97.9%**
(3) Other medical devices	**91.0%**	**84.8%**	**98.8%**
(4) *In vitro* diagnostics	**76.1%**	**99.1%**	**99.7%**
(5) Consumable materials	**60.5%**	**-**	**89.4%**

Results of the “Survey on the Progress of Digitalization in Medical Devices, etc.” conducted by MHLW (as of September 2023)
https://www.mhlw.go.jp/content/10807000/001442481.pdf

Upcoming Regulatory Changes

< Basic purpose of UDI labeling >

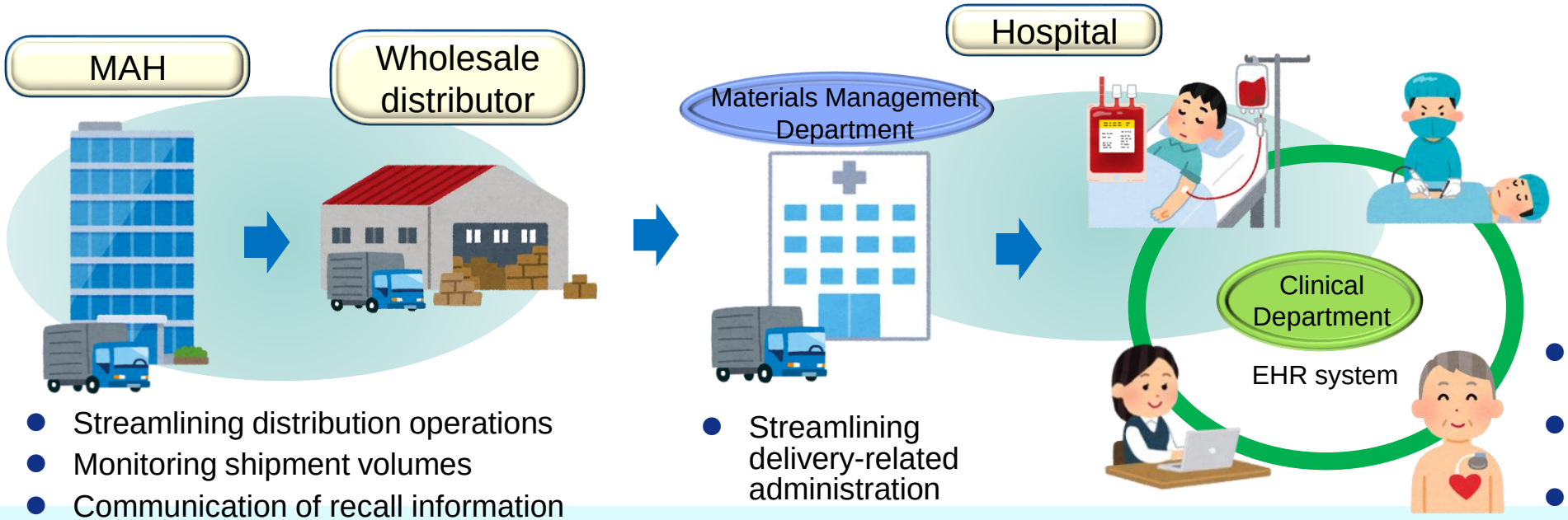
- Prevention of medical device mix-ups
- Ensuring traceability
- Promoting distribution efficiency

< New Challenge >

- Currently, product data registration is requested at shipment stage
  - at the notification level (using private databases)
- Legal revision in 2025 will mandate registration by manufacturers
- Public database under development; specifications under review

Key Points for Effective UDI Utilization

- Barcodes are only useful when both labeling and database registration are in place
- Limited use by few stakeholders reduces overall impact
- Active participation from all stakeholders is essential



- Streamlining distribution operations
- Monitoring shipment volumes
- Communication of recall information

- Streamlining delivery-related administration

- Storage of implantation records
- Streamlining insurance claim processes
- Response to recall

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Session 5:

Saudi FDA
Unique Device Identification (UDI)

Eng. Abdullah Alghuraibi
Executive Director of Medical Devices Evaluation

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AGENDA

- ❑ Introduction.
- ❑ SFDA -UDI Requirements & Submission steps.
- ❑ Summary of the experience and the most important considerations for the future

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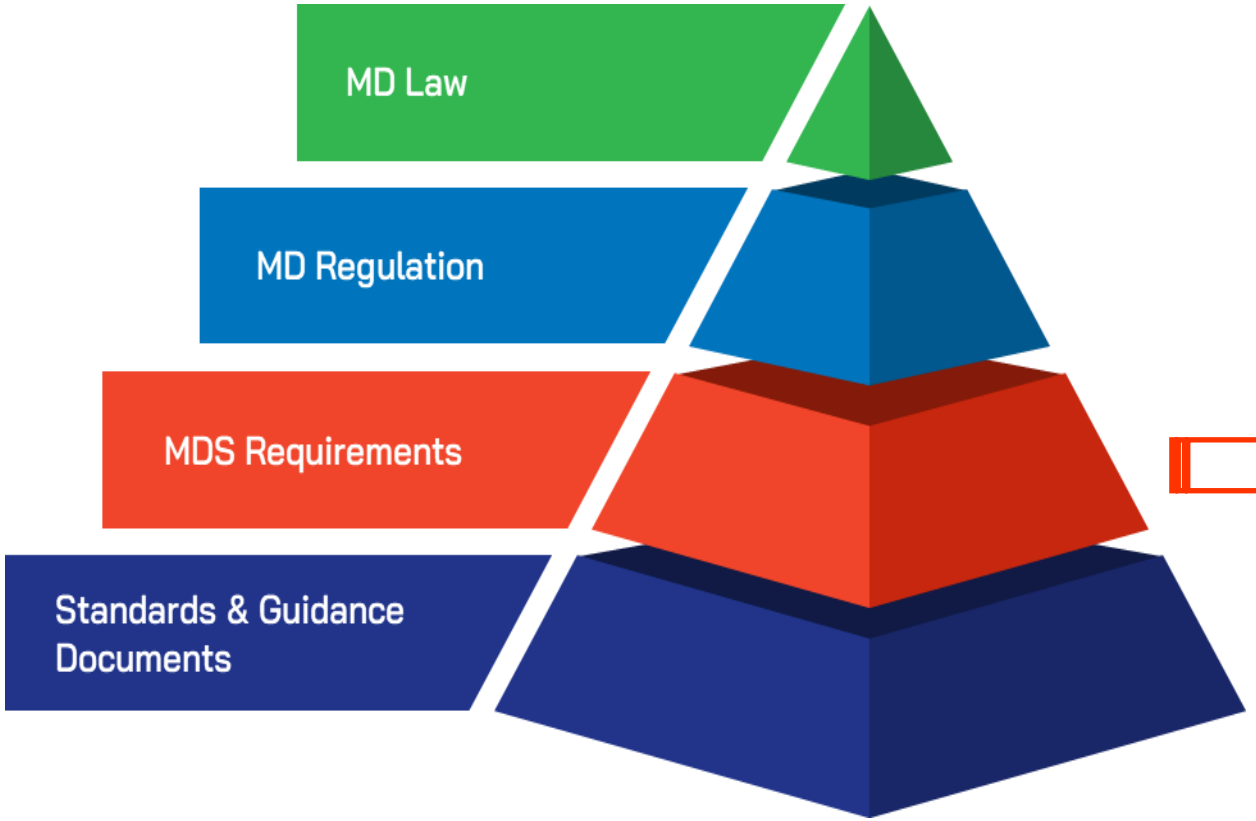
SFDA MD Regulation Framework



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Compliance Dates and The current progress

Compliance Timeframe	
Launching the UDI database and starting optional registration for all type of devices	1st October 2020
Risk Class	**Compliance date**
Class B & C (Medium risk) Class D (High risk)	1st September 2023
Class A (Low risk)	1st September 2024

Submitted UDI Records (Aug. 2025)

#of Devices	446703
#of Manufacturers	1797

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Saudi Food & Drug Authority

Scope

- ✓ **All medical devices & accessories**,
- ✓ The **manufacturer**, or its **authorized representative**, shall submit and maintain the appropriate data in UDI database

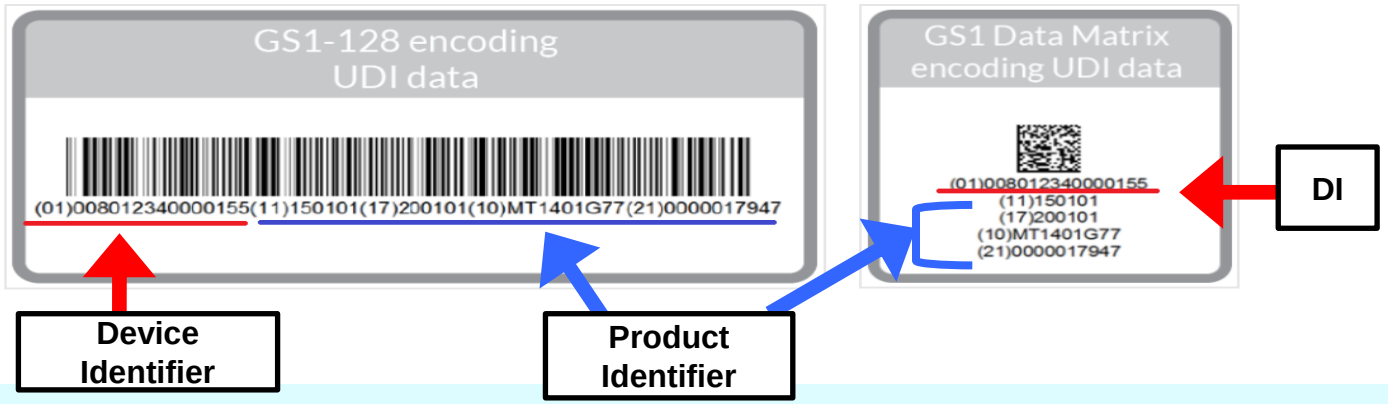
General UDI Requirements include:

- ✓ Recognized issuing Agencies: GS1, HIBCC and ICCBBA
- ✓ The UDI label shall contain two parts: the UDI-DI and the UDI-PI(s).
- ✓ UDI-PI shall include: lot number, serial number, software identification, or expiration (use by) date
- ✓ The UDI shall be readable during normal use and throughout the intended life of the device

UDI in Label

✓ The UDI **must be presented in two forms** on the device label and higher levels of packaging:

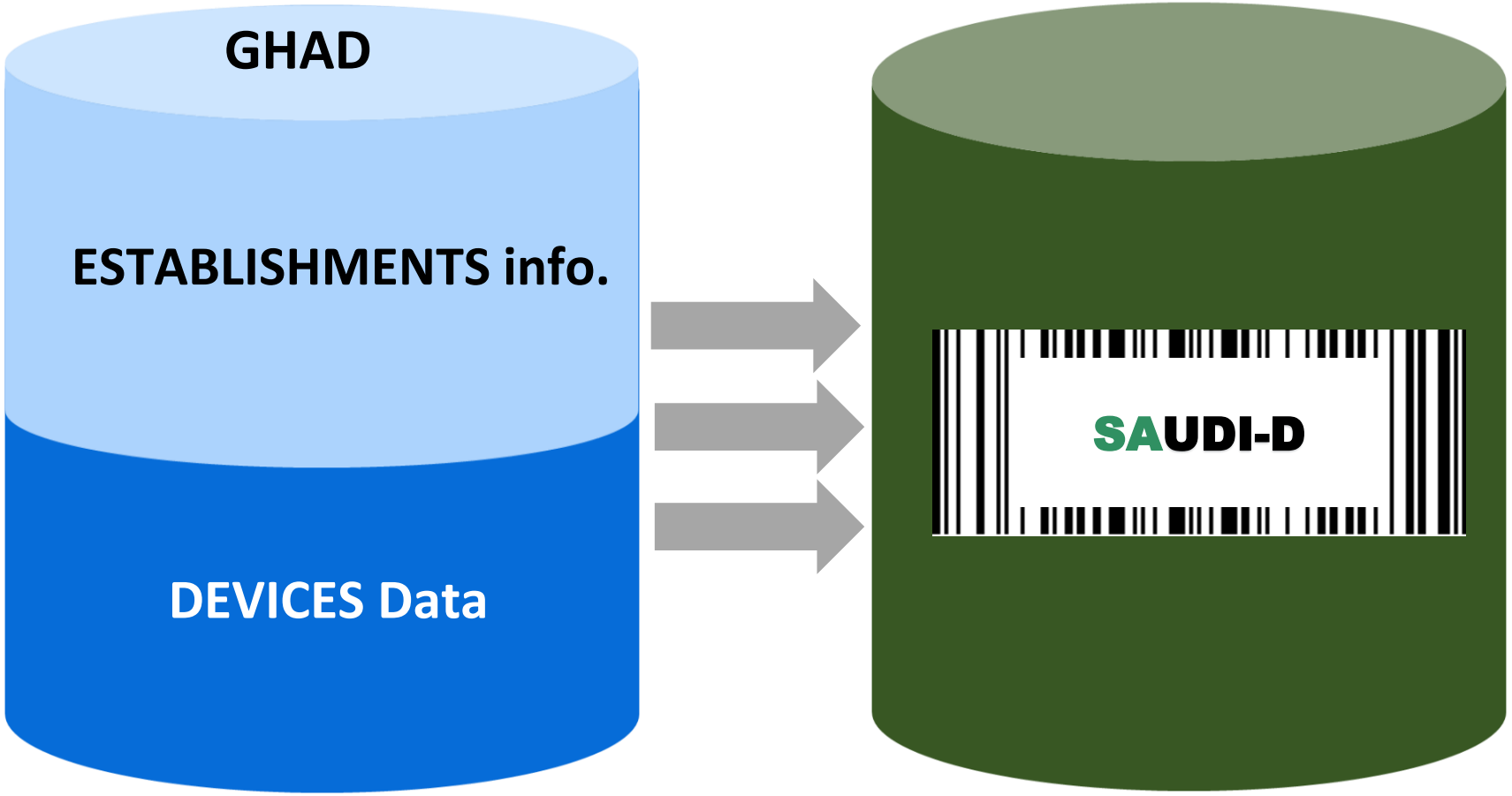
1. **Human Readable Interpretation (HRI):** Easily readable plain-text format.
2. **Automatic Identification and Data Capture (AIDC) Technology**: Such as barcodes (linear or 2D) or RFID, enabling automated scanning and data capture.

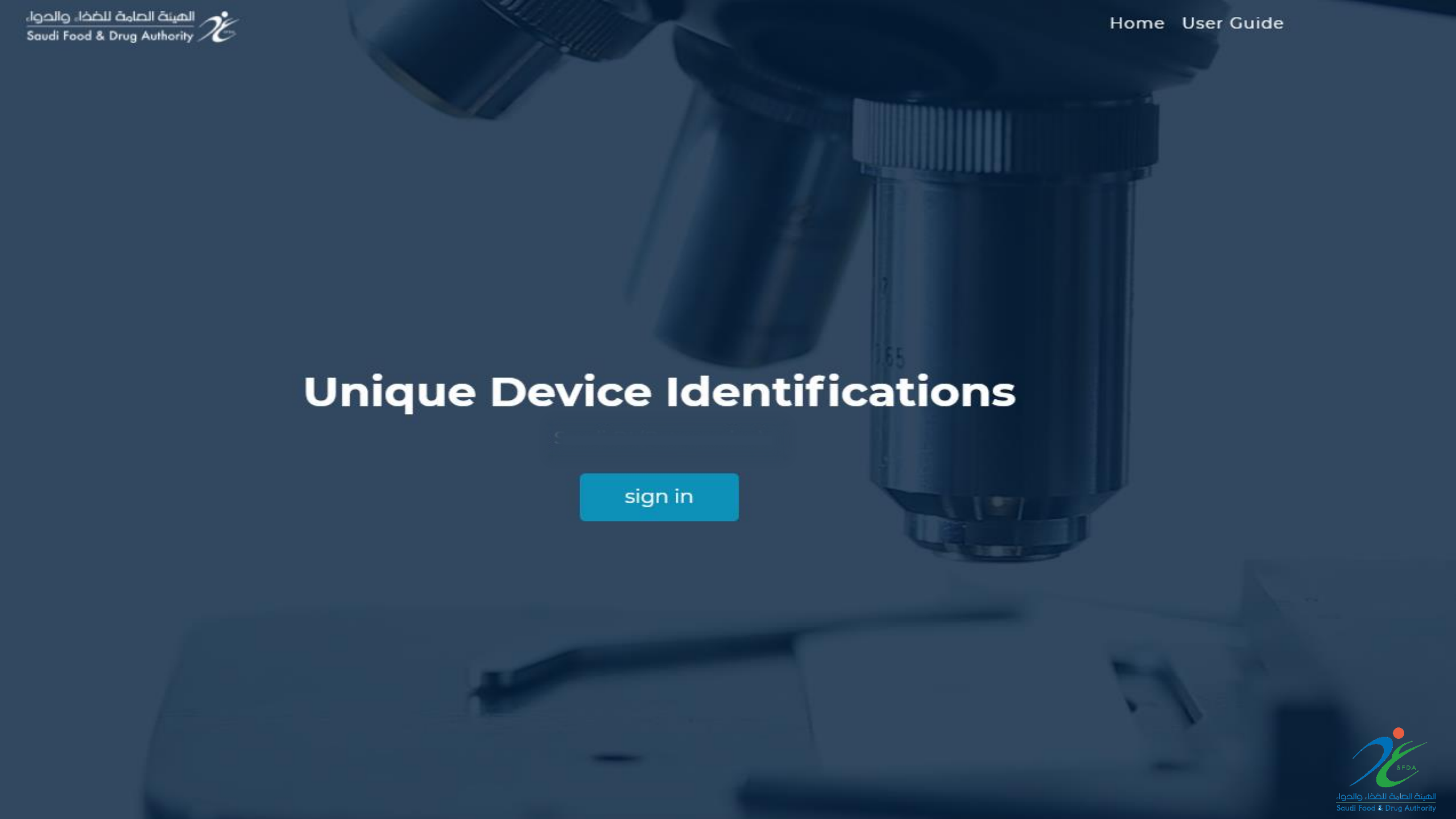


SAUDI-DI Database

- The data shall be available in SAUDI-DI database at the time the device is placed on the market.
- Device Records need to be checked and maintained periodically (at least annually) by the manufacturer or its authorized representative
  - ✓ Revisions shall be made within 10 days when the data changes
  - ✓ ensure the data is accurate and consistent with data submitted to GHAD system modules

SFDA Systems





Unique Device Identifications

sign in

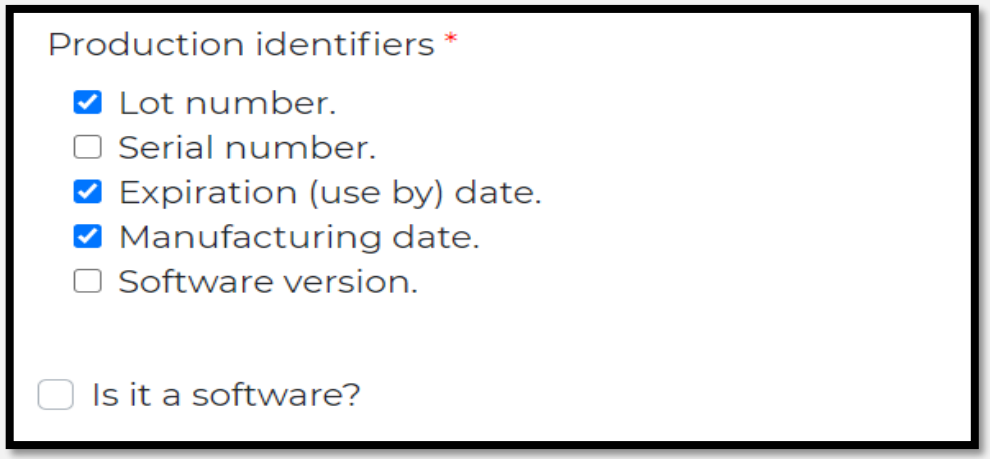
By interring a valid listing number, **all relevant information will be retrieved from Marketing Authorization database.**

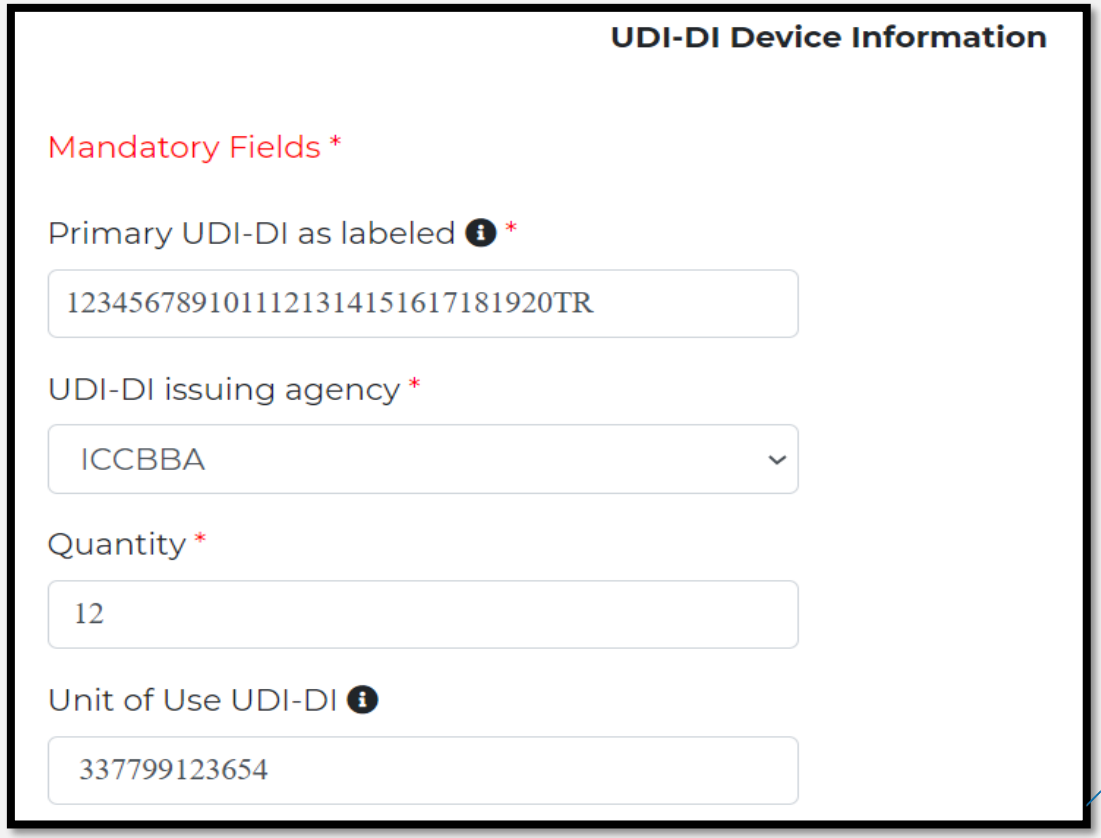
Listing Number	**Authorization Number**
ME00000000091SFDAA00008	MDMA-1-2021-0053
Brand Name	**Device Type**
test Product by Belal	Medical Device
Manufacturer Name	**Device Classification**
Test Manufacturer by Belal	Class III
Manufacturer Number	**Device Description**
ME0000000091	12345678900
Product Name	**sterile Device**
test Product by Belal	-
	Home Use
	No

Primary UDI-DI on the device's primary label, which consider a primary key in the database and to which other DIs are linked to it

UDI-DI issuing agency is selected from drop-down .

Quantity is number of units in this device or package





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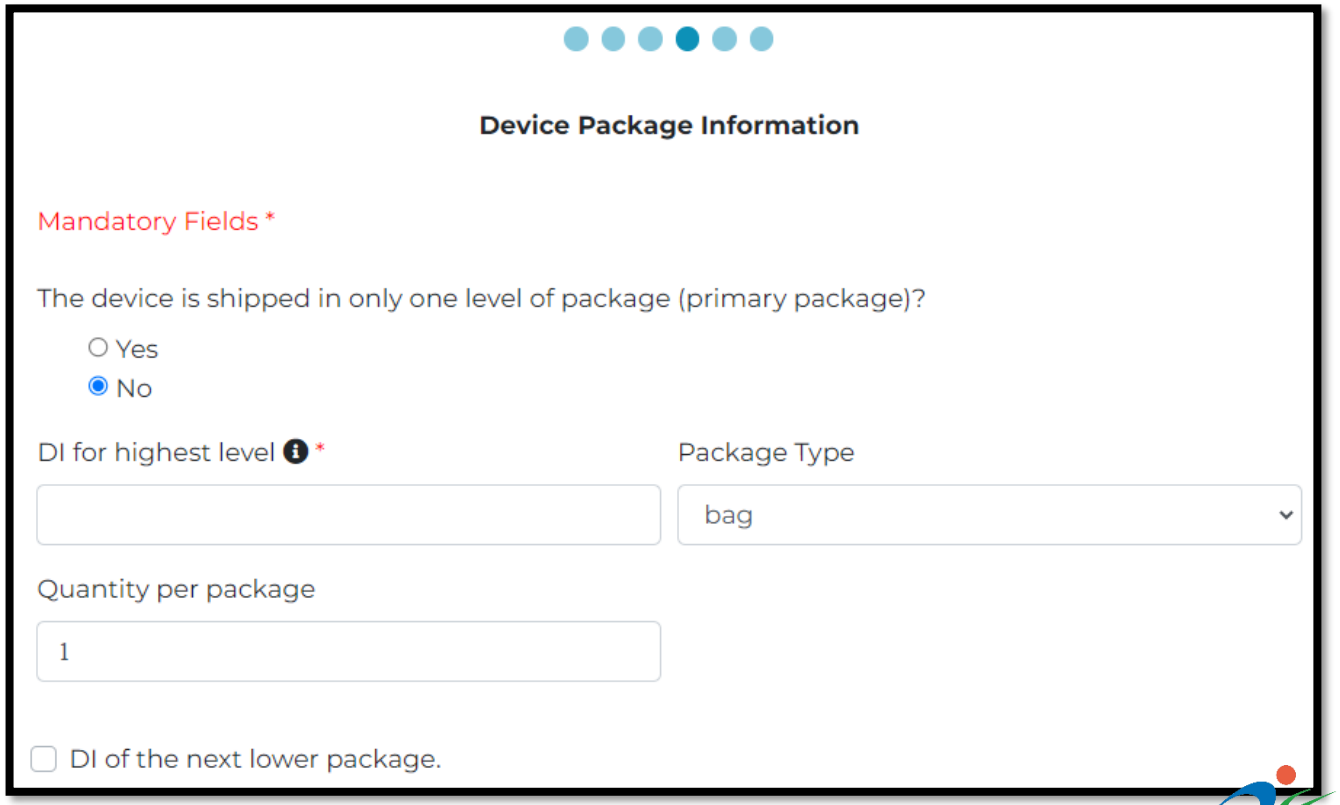
Package UDI-DI

- **Package Information**
- **Add levels of the package hierarchy starting from the bigger level.**

bigger level

Lower level



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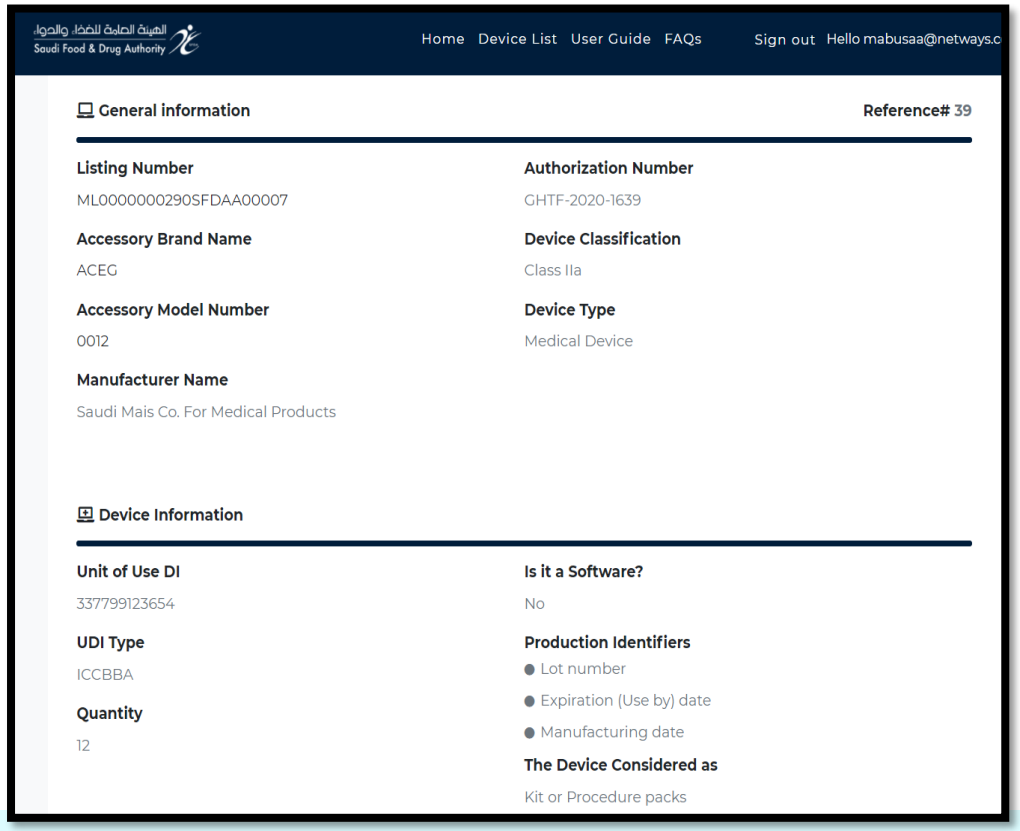
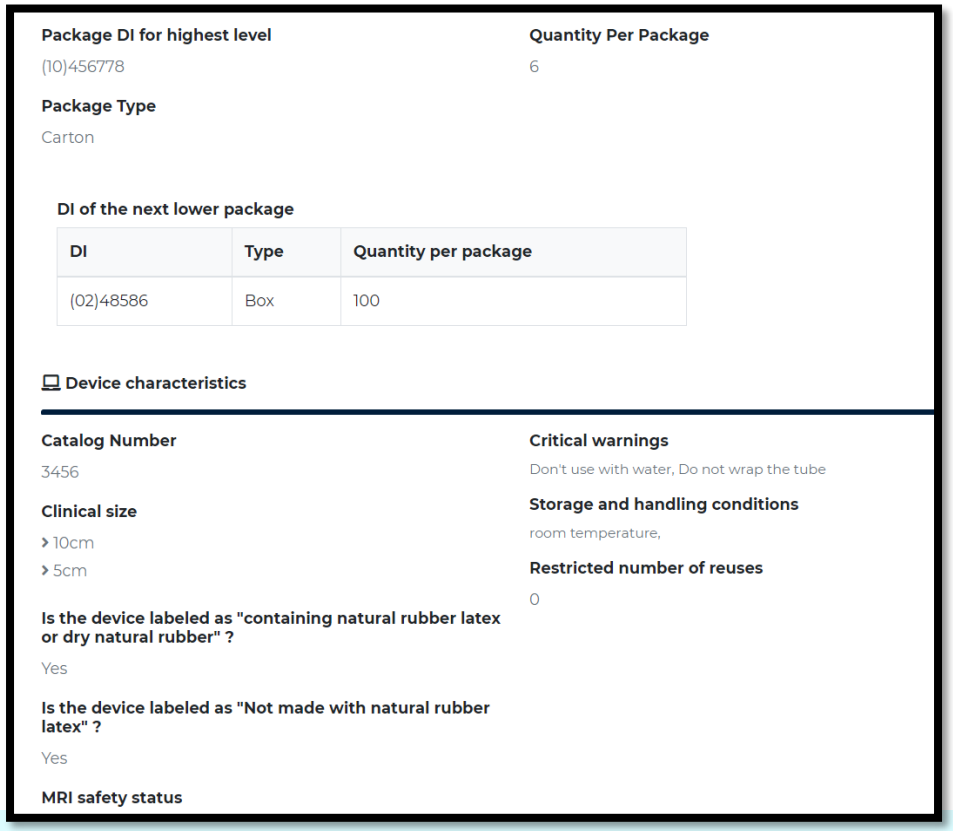
Summary View of Submission

Upon submission, the summary of the record is displayed.





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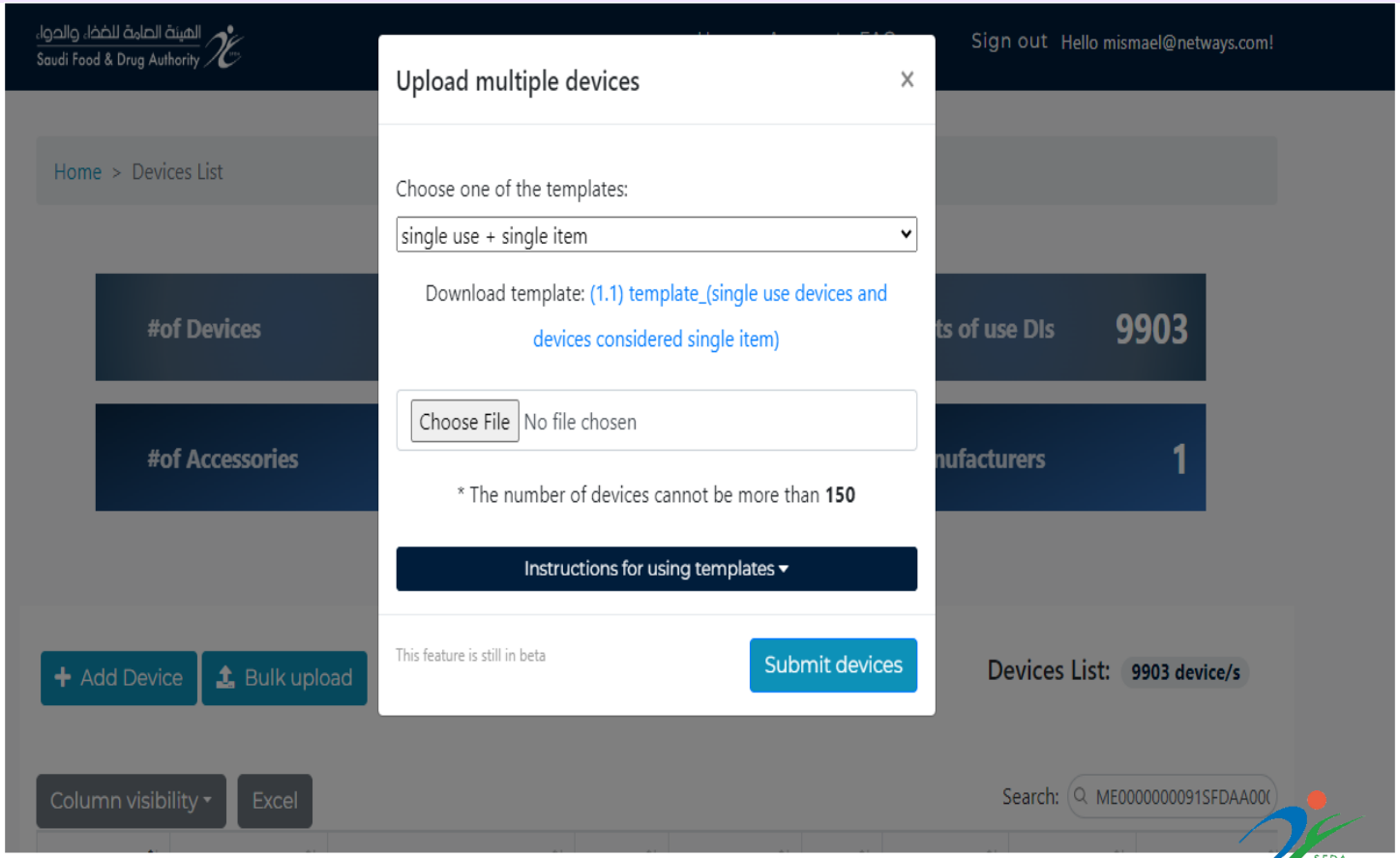
Bulk upload

- Bulk upload for submitting many records in a single Excel sheet
- All data will be automatically saved and displayed within the Devices records list.
- Any wrong data should be corrected individually through the update action.

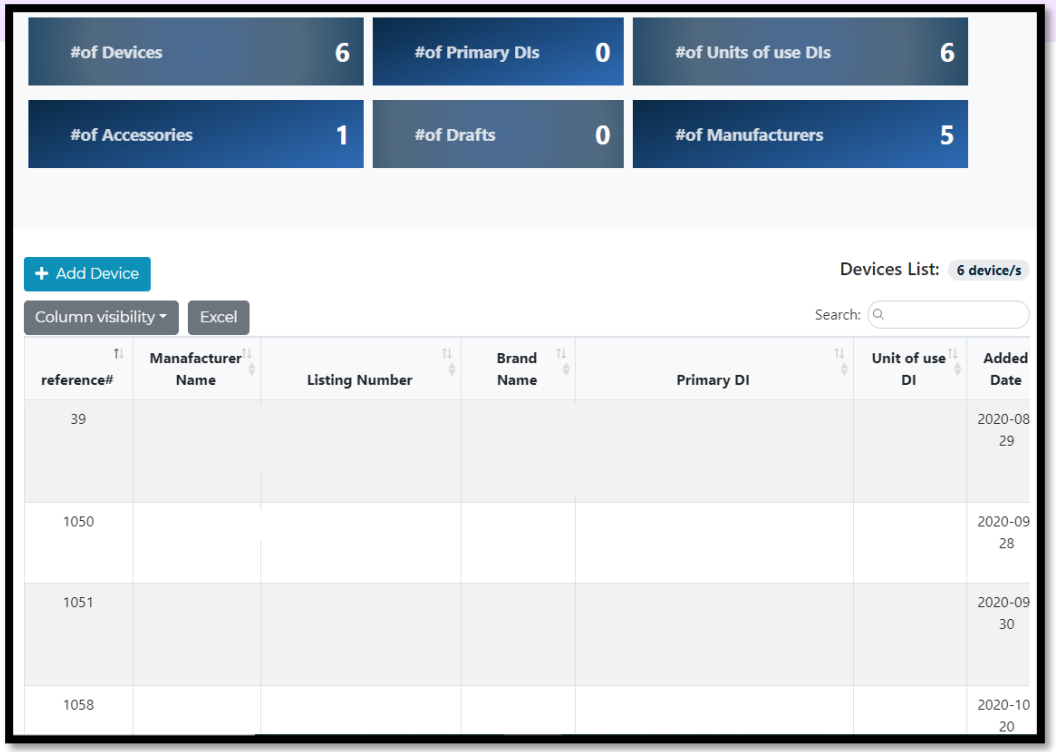


Device List page

Icon Actions

- **Add Device** –to start a new record
- **Column Visibility** – to select the columns displayed
- **Excel** – to export a spreadsheet of records

Search Field



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Summary of the experience and the most important considerations for the future

- The implementation of UDI is a crucial initiative that highlights the **commitment to a safe, transparent, and efficient** medical device ecosystem.
- By establishing clear regulatory requirements ,providing a central database, and implementing a phased compliance approach, the SFDA is actively **enhancing patient safety, improving product traceability**, and bolstering the integrity of the medical device supply chain.
- The Saudi UDI framework is **aligned** with global guidelines and initiatives.
- The **continued collaboration** among manufacturers, healthcare providers, and the SFDA will be crucial in realizing the full potential of UDI, ultimately contributing to a healthier future for the people of Saudi Arabia.

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Summary of the experience and future considerations

- **Ongoing efforts** are crucial to address potential challenges:

  - Awareness and Education
  - Systems Integration
  - Data Quality and Accuracy
  - Technological Adoption
  - Global Harmonization and Continued collaboration.

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Thank You

Contact us at:

md.rs@sfda.gov.sa

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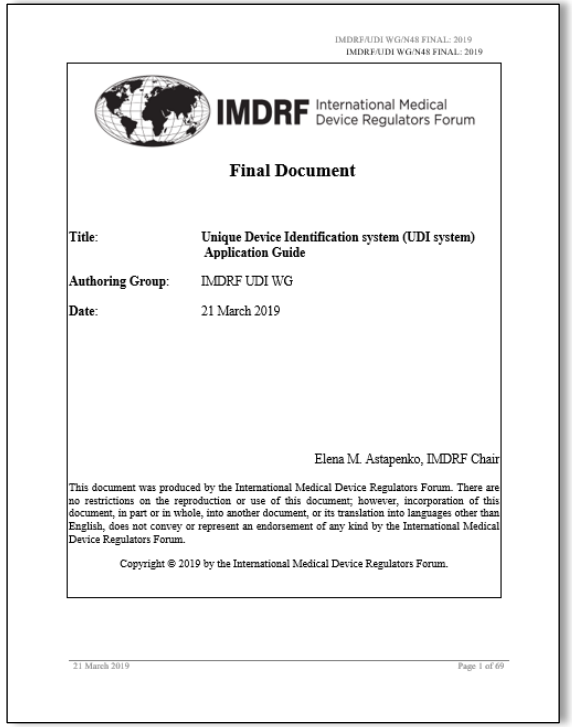
Session 5: Implementation and Challenges of UDI

Dennis Black
UDI Program Director, BD
(Representing Industry)

September 16, 2025

We are succeeding with the implementation of UDI

- **Device Labels:** Millions of labels modified to include UDI requirements
- **UDI Data:** is being created, published, and maintained in multiple countries
- **Process Modifications:** Including Regulatory, Quality, Supply Chain, Manufacturing, Sales, etc., continue to be implemented


IMDRF/UDI WG/N48 FINAL: 2019

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Final Document

Title:	**Unique Device Identification system (UDI system) Application Guide**
Authoring Group:	IMDRF UDI WG
Date:	21 March 2019

Elena M. Astapenko, IMDRF Chair

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Much has been accomplished in the past 12 years!

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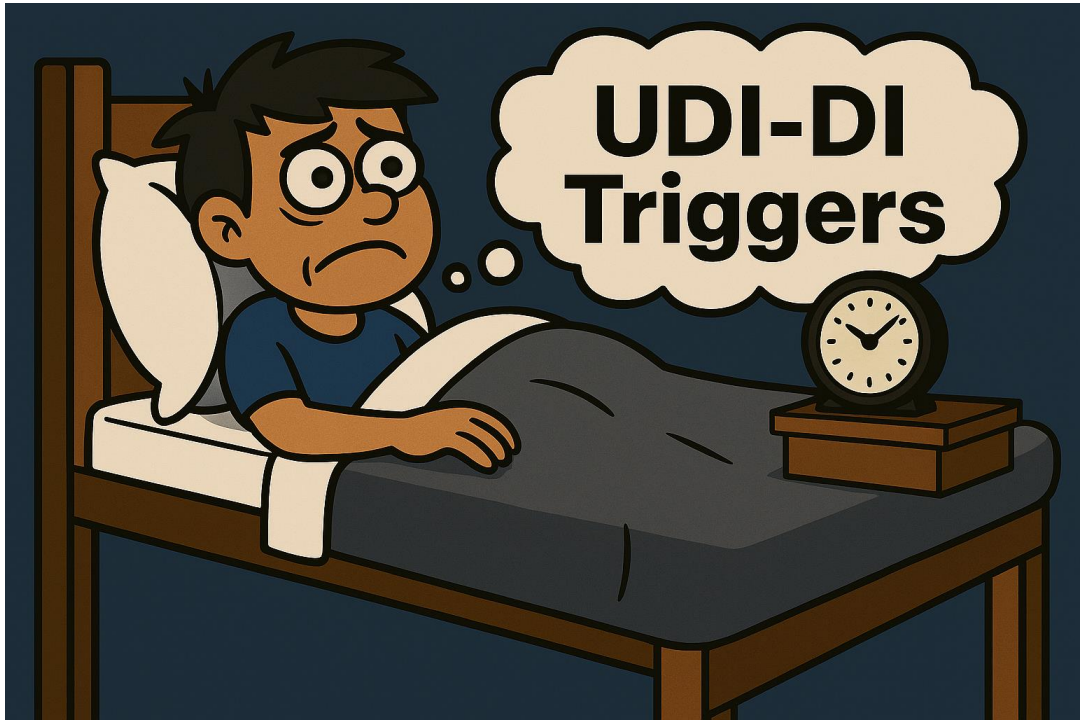
Long-Term UDI Sustainability (What keeps us awake at night)

- **UDI-DI Triggers:** Many disparate rules, locked data fields, and conditions that differ from IMDRF suggestions will cause frequent UDI-DI changes and decreased utility of UDI
  - Obstacle for healthcare providers
  - Safety/Surveillance challenge
  - Supply Chain confusion

- **Other Topics:** UDI for Software and Configurable Devices and UDI Data are worth exploring in future conversations



UDI-DI Triggers we can agree on include:

- A change from a medicated to a non-medicated stent
- Adding Latex and DEHP to a device
- Changing from a 22 Gauge to a 28 Gauge catheter size
- Sterile device converting to a non-sterile device

Examples of UDI-DI Triggers Challenges:

- A change in an alcohol swab (device/drug) in a procedure pack causes a classification change to a Combination Product and therefore a new UDI-DI.
- A change to a risk class of a device causes a new Basic UDI-DI and therefore a new UDI-DI.
- A locked field in a UDI Database in one jurisdiction requires us to change our UDI-DI for that device globally.
- If trace levels of DEHP are removed from a device, this is a UDI-DI Trigger in some jurisdictions. Not all jurisdictions have this requirement.

We should harmonize/rationalize UDI-DI Triggers requirements to align with IMDRF.