IMDRF International Medical Device Regulators Forum

Session 5: Implementation and Challenges of UDI

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

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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.**

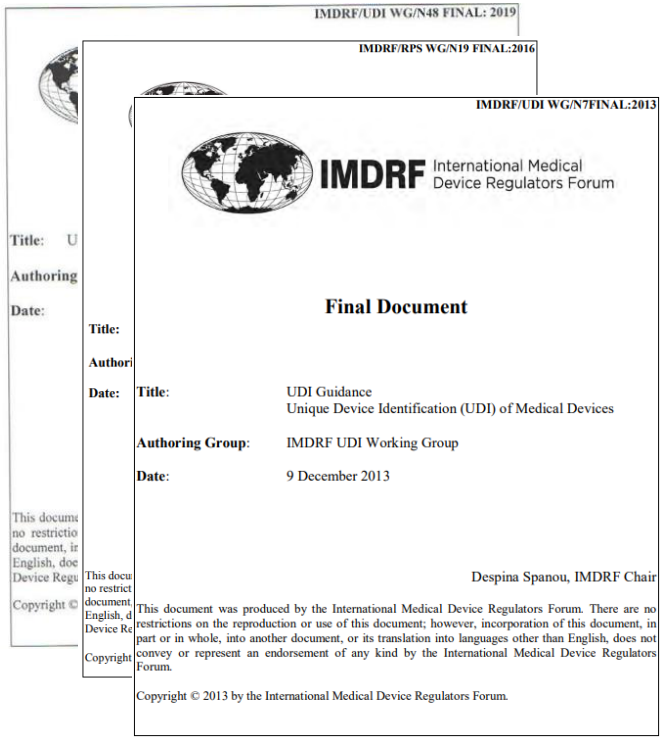
How the Brazilian UDI Regulation was built

- 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

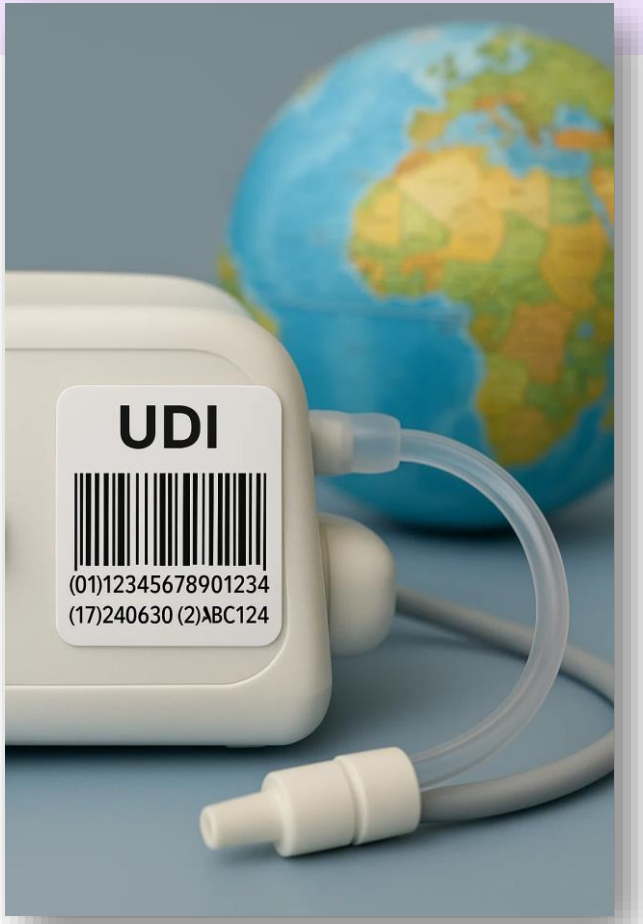
- SIUD official release expected — Oct/25
- Classe IV — Apr/29
- Classe III — Oct/29
- Classe II — Oct/30
- Classe I — Oct/31

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
REDE NACIONAL DE DADOS EM SAÚDE

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.

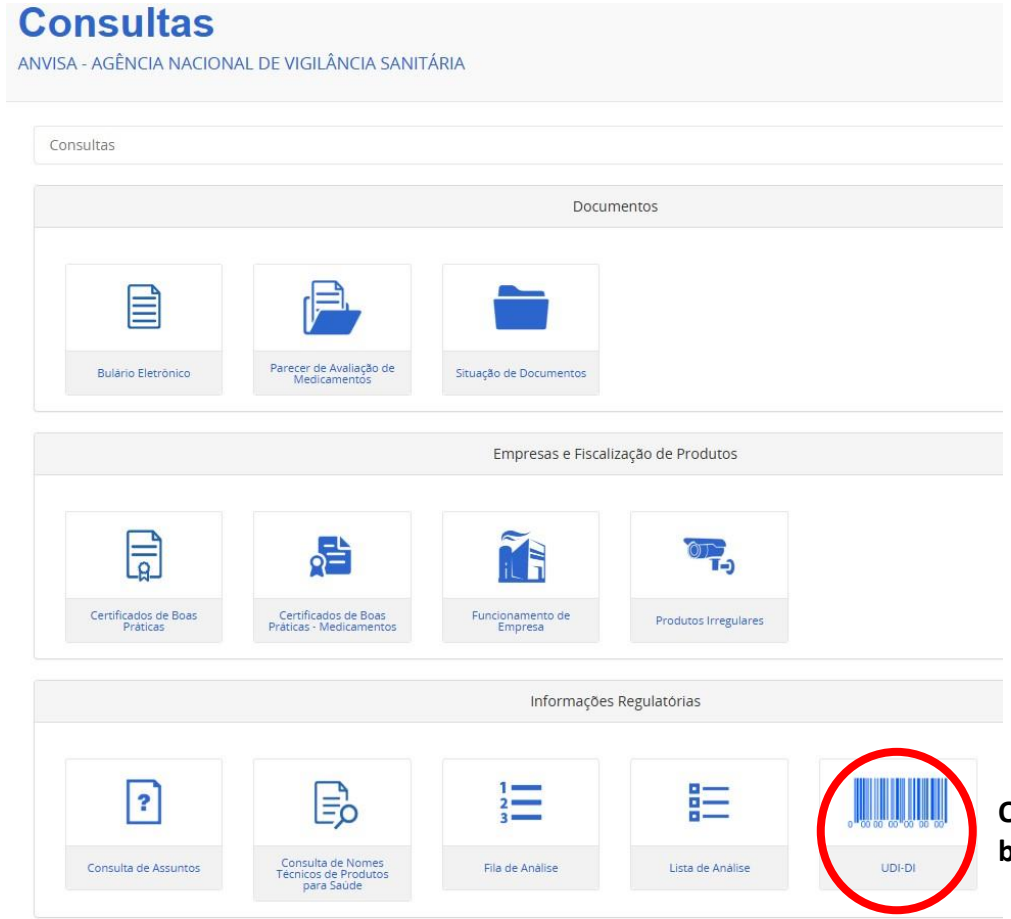
SIUD documentation

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!