ACKOMAS

Multi-Regulatory Compliance for Medical Device and IVD Manufacturers

UDI, regulatory databases, deadlines, and data governance

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Management Summary

Multi-regulatory compliance is no longer just a compliance issue. It is becoming a strategic capability for manufacturers of medical devices and IVDs.

Around the world, health authorities are implementing traceability systems, regulatory databases, and product data publication requirements. However, these systems are not advancing at the same pace or following the same rules. Some countries already have operational infrastructure in place, while others are still in transition, and requirements are constantly evolving.

The challenge, therefore, is no longer simply about achieving compliance. It lies in the ability to maintain consistent, up-to-date, and synchronized regulatory data across multiple markets simultaneously.

For senior management, the stakes go far beyond mere regulatory compliance. It directly impacts time-to-market, sales continuity, team workload, product data quality, and the ability to expand internationally. It is also a matter of safeguarding investments already made in technical dossiers, certifications, and marketing authorizations by ensuring the manufacturer's ability to publish and maintain compliant data in the regulatory databases that have become essential for market access. Since regulatory data is now largely public and accessible to authorities, healthcare institutions, distributors, or competitors, its quality, consistency, and reliability have become a strategic issue for compliance, reputation, and risk management. In this context, manual processes and data re-entry quickly become unsustainable when a manufacturer operates across multiple regions of the world.

For regulatory affairs teams, the role is also evolving. It is no longer just about managing submissions or manual data entry, but about maintaining a consistent, reliable, and aligned regulatory product repository across multiple authorities and markets. The goal is to reduce repetitive, low-value-added tasks so that teams can focus more on regulatory analysis, change management, international coordination, and supporting market launches.

For IT departments, multi-regulatory compliance is becoming a matter of product data architecture and governance. Manufacturers' legacy ERP and systems were generally not designed to support a global regulatory repository capable of serving multiple markets with differing and evolving requirements. The control, quality, and synchronization of regulatory data are now becoming as critical as the applications themselves

This booklet was designed to provide a clear overview of this transformation. It presents the key global UDI deadlines, the current status of major regulatory frameworks, and differences in maturity across countries. Its objective is to help manufacturers anticipate an inescapable reality: regulatory compliance is gradually becoming a matter of data governance and synchronization on a global scale.

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Background

Version	Date *(DD/MM/YYYY)*	Description of changes	affected
1.0	10 June 2026	Creation	All

There was a time when exporting a medical device meant mastering a set of regulations, registering with an authority, and affixing a label. Those days are gone. The 2020s have seen a proliferation of new traceability requirements around the world—each with its own logic, timeline, and technical specifications. In the United States, the European Union, Australia, Switzerland, Saudi Arabia, Brazil, China, and South Korea: so many markets, so many systems, so many deadlines not to be missed.

This booklet was designed to provide clarity—and to help you take action.

The complexity stems primarily from a three-tiered architecture, whose interdependencies are rarely made explicit.

- First level: UDI (Unique Device Identification) labeling, i.e., the requirement to affix a structured, machine-readable unique identifier to the device.
- Second level: the regulatory database, the national or supranational registry to which the manufacturer must submit the data associated with this identifier.
- Third level: regulatory synchronization (M2M—*Machine to Machine*), which automates this submission without the need for manual data re-entry.

These three levels are hierarchically interdependent: no publication without labeling, no reliable regulatory synchronization without published technical specifications. Furthermore, their deployment is not synchronized. This is where the real operational challenge lies.

The global landscape is currently divided into four groups of countries.

- The first group comprises markets where all three levels are in place: regulatory synchronization (M2M) is possible because specifications are published and the database is operational—this is the case in the United States (GUDID: Global Unique Device Identification Database), the European Union (EUDAMED: European Database on Medical Devices, mandatory as of May 28, 2026, for new devices), Switzerland (Swissdamed, mandatory as of July[1,] 2026), and Australia (AusUDID, mandatory as of July[1,] 2026, for Classes III and IIb).
- The second group comprises countries with an operational UDI database and a mandatory requirement in place, but without publicly accessible regulatory synchronization (M2M): Saudi Arabia (Saudi-DI / Ramz) is the most advanced example.
- The third group includes countries engaged in a UDI program—mandatory labeling currently being rolled out, a database under construction or with restricted access, and regulatory synchronization (M2M) not yet specified or made public: Brazil (SIUD), China (UDID NMPA: National Medical Products Administration), and South Korea, for example.
- Finally, the fourth group comprises markets that have an operational registration system but no UDI database to date: the United Kingdom, where the DORS has been fee-based since April 2026 and for which the future UK UDI database has not yet had a mandatory implementation date published, is a case in point.

The dates mentioned in this booklet are the main regulatory deadlines. Special cases exist in each market—direct marking, IVD (In Vitro Diagnostic) classes, devices in transition from MDD to IVDD, and devices under certificates during the transitional period. Canada, which launched a UDI consultation in 2021, has not yet published final regulations. South Korea (IMDIS: Integrated Medical Device Information System) has had a fully operational UDI database for all classes since 2023, but access to regulatory synchronization (M2M) is not publicly documented in English, making it effectively inaccessible without a local partner.

It is within this evolving landscape, where each market moves at its own pace and according to its own standards, that Ackomas steps in. Our mission is not to ask you to navigate this complexity, but to take full ownership of this complexity. This involves anticipating specifications even before they are finalized, maintaining active M2M connections with operational bases, ensuring continuous monitoring of developing markets—and ultimately allowing you to focus on what matters: your devices, your patients, your markets.

This booklet reflects that commitment.

Who is this booklet for?

This document is intended for regulatory, quality, and information systems managers at medical device manufacturers.

It is designed to answer a simple question that is being asked more and more frequently: “What are our obligations regarding UDI and regulatory databases, depending on the markets where we distribute our products?”

What you’ll find here

- A global timeline of UDI deadlines—country by country, class by class—including the status of databases, access fees, and M2M availability for regulatory synchronization.
- Detailed fact sheets by regulatory database—each covering: regulatory context, technical specifics, hot topics, and future outlook (EUDAMED, GUDID, AusUDID, SIUD Brazil, Swissdamed, UK, SFDA).
- A comparative table of 160+ data elements—field by field, database by database: what is common, what differs, and what is specific to each regulation. With a color-coded source: green (data verified from official source), yellow (to be confirmed), gray (missing).
- A strategic analysis of the implications—what the data element table means operationally for a manufacturer distributing across multiple markets simultaneously.

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Who must do what, and by when: the global UDI timeline

ABOUT THIS GUIDE

This Reference Guide reflects publicly available regulatory information as of June 2026. Databases, requirements and deadlines evolve continuously; given the breadth of the subject, some points are necessarily simplified and open to interpretation. ACKOMAS is not a regulatory authority and this document is not regulatory advice – always confirm against official sources before acting.

By 2026, multi-regulatory compliance will be an operational reality for any manufacturer of exported medical devices.

This table classifies countries into four groups based on their UDI maturity level:

(1) Regulatory synchronization (M2M) available – specifications published, operational database, and requirement in effect;

(2) Operational UDI database and requirement in effect, without publicly accessible regulatory synchronization (M2M);

(3) UDI program in progress – mandatory labeling deployed or imminent, database under construction or with restricted access;

(4) Outside the UDI database – operational registration system with no UDI requirement to date.

The dates listed are key deadlines; specific cases (direct marking, IVD classes, transition periods) are detailed in the database-specific fact sheets.

Country / Region	Database	Classes Affected	UDI labeling · Database registration (key deadlines — see fact sheet for special cases)	Access fees	"Regulatory synchronization (M2M)" availability
GROUP 1 — Regulatory synchronization AVAILABLE (operational base + published M2M specifications)					
United States	GUDID	• Class III • Class II • Class I	**UDI labeling + GUDID registration (same date):** • Class III: since 2014 • Class II: since 2016 • Class I: starting in 2018	Free	✓ **Operational**
European Union	EUDAMED	• New MDs (MDR/IVDR) • *Existing medical devices Notified Body (NB) certificates*	**UDI labeling:** mandatory under MDR/IVDR since 2021 (depending on class) **Registration** **EUDAMED:** • May 28, 2026 (new MDs) · • Nov. 27, 2026 (medical devices already on the market) • *May 28, 2027 (certificate)*	Free	✓ **Operational**
Switzerland	Swissdamed	• **All medical devices (transitional period)**	**UDI labeling + Swissdamed registration:** • July 1, 2026 (transitional period until Dec. 31, 2026)	Fees based on UDI-DI devices placed on the market: 200 CHF for the first device, then 20 CHF per additional device, with an annual cap of 10,000 CHF. (No fees for drafts, deletions, or updates.)	✓ **Operational**

Country / Region	Database	Classes Affected	UDI labeling · Database registration (key deadlines — see fact sheet for special cases)	Access fees	"Regulatory synchronization (M2M)" availability
Australia	AusUDID	• Class III + IIb • Class IIa + Is/Im: • Class IIa + Is/Im: • Class I + IVD:	**UDI labeling + AusUDID submission (same date):** • Class III + IIb: 07/01/2026 ✅ • Class IIa: 07/01/2027 • Class Is/Im: 07/01/2028 • Class IVD 4+3: 07/01/2028 • Class IVD 2+1 + Class I: 07/01/2029	Transition to a fee-based system (currently being defined)	✓ **Two M2M methods published by the TGA: HL7 SPL (XML, same standard as GUDID) and NPC/GDSN (GS1 Australia). Public specifications available.**
GROUP 2 — OPERATIONAL UDI DATABASE, WITHOUT PUBLICLY ACCESSIBLE M2M					
Saudi Arabia	Saudi DI (Ramz)	• Class B, C, D • Class A	**UDI labeling + submission to Saudi-DI (same date):** • Class B, C, D: 09/01/2023 • Class A: 09/01/2024	⚠ Not published	× No M2M — manual entry and Excel file only (specifications not published)
South Korea	IMDIS	• Class IV • Class III • Class II • Class I	**UDI labeling + IMDIS registration (same date, submission prior to distribution):** • Class IV: 07/2020 • Class III: 07/2021 • Class II: 07/2022 • Class I: 07/2023	⚠ Not published	⚠ M2M technically available via local specialized providers, but specifications not publicly released. Submission subject to a local Korea License Holder.
GROUP 3 — UDI PROGRAM IN PROGRESS (mandatory labeling deployed, database under construction or restricted access)					
Brazil	SIUD	• Class IV: UDI labeling • Class III: UDI labeling • Class II: UDI labeling • Class I: UDI labeling	**UDI labeling:** • Class IV: 07/10/2025 ✅ • Class III: 07/10/2026 ✅ • Class II: 07/10/2027	⚠ Not published	FHIR (Fast Healthcare Interoperability Resources) R4 / JSON deployment *(Technical specifications/API not published)*

Country / Region	Database	Classes Affected	UDI labeling · Database registration (key deadlines — see fact sheet for special cases)	Access fees	"Regulatory synchronization (M2M)" availability
		• Direct Marking: all classes SIUD submission	• Class I: 07/10/2028 **SIUD registration:** • Class IV: 09/01/2029 • Class III: 03/01/2030 • Class II: 03/01/2031 • Class I: 03/01/2032 *According to Anvisa's 2nd Board of Directors Meeting (February 26)*		
China	UDID NMPA	• Class III • Class II (extension) • Class I	**UDI labeling + UDID submission (same date):** • Class III: since June 2022 • Class II (including IVD): 06/01/2027 • Class I: 06/01/2029 (same date for labeling + database)	⚠ Not published	⚠ Restricted access — two separate databases: UDID (NMPA, regulatory) and NHSA database (National Healthcare Security Administration, reimbursement). Submission only via authorized local agent. No third-party M2M.
Japan	National database (under development)	UDI marking mandatory National UDI database	• **Labeling: in effect** • **Public database: date not published**	Not applicable	⚠ Database not available
GROUP 4 — OUTSIDE UDI DATABASE (operational registration, no published UDI requirement)					
United Kingdom	SOR (registration)	All medical devices marketed in the UK (UDI not yet mandatory)	• **Registration: mandatory** (GMDN database frozen as of 03/31/2026) • **UK UDI database: date not published**	Annual DORS fees effective 04/01/2026 based on GMDN Level 2	In progress (UK UDI database to be defined)

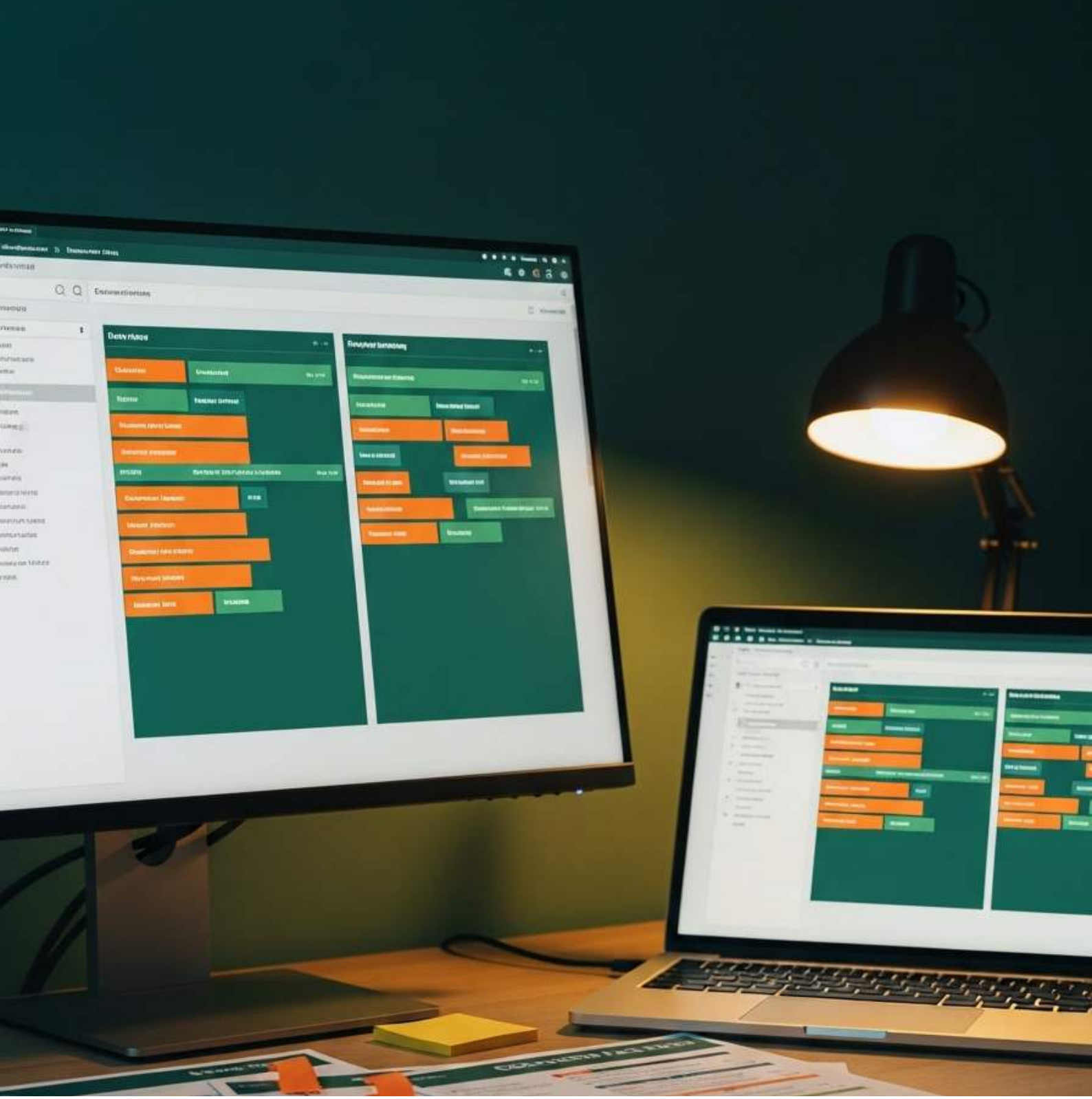
Country / Region	Database	Classes Affected	UDI labeling · Database registration (key deadlines — see fact sheet for special cases)	Access fees	"Regulatory synchronization (M2M)" availability

Sources: European Commission · TGA (Australia) · Swissmedic · MHRA · SFDA · FDA · MFDS · ANVISA · NMPA · MHLW — All information marked ⚠ indicates data not yet officially published by the competent authority.

⚠️ EUDAMED: The date of May 28, 2026, is final for new devices. No further extensions are currently planned by the European Commission.

⚠️ Australia: Official TGA timeline (v2.0, May 2026). Labeling + AusUDID: Class III + IIb: 07/01/2026 ✅ · Class IIa: 07/01/2027 · Class Is/Im: 07/01/2028 · IVD 4+3: 07/01/2028 · IVD 2+1 + Class I: 07/01/2029. Direct Marking: Class III: 01/01/2028 · Class IIb: 01/01/2029 · Class IIa + Is: 01/01/2029 · IVD 4+3: 07/01/2029 · IVD 2+1 + Class I: 07/01/2030. AusUDID submission fees have not yet been published by the TGA. Source: TGA.gov.au – Complying with the UDI timeframes (v2, Feb. 2026).

⚠️ Brazil: UDI labeling is already mandatory for Class IV (July 10, 2025) and Class III (January 10, 2026). Confirmed M2M standard: FHIR R4 / JSON – 68 documented fields. ⚠️ ANVISA requests waiting for the new version of the M2M batch/mass manual before any batch integration.



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Priority databases in detail: what has been done, what is in progress, what is coming

UDI labeling has become the global standard. In less than a decade, what was once an isolated U.S. requirement has become a de facto global standard: Europe, Australia, Switzerland, Saudi Arabia, South Korea, Brazil, China—all have adopted the principle of a unique identifier on the device. On this point, the IMDRF (International Medical Device Regulators Forum) has fulfilled its mission.

But the IMDRF is not a regulatory body. It is a voluntary convergence body—with the US, EU, Australia, Brazil, Canada, China, Japan, South Korea, Russia, and Singapore on the steering committee; Saudi Arabia and Switzerland as official observers—that produces guidance documents which each member freely adopts and adapts to its own national framework. And this is where the promise of harmonization collided with the reality of regulatory sovereignty.

Each database has built its own model. Divergent nomenclatures—EMDN (European Medical Device Nomenclature) in Europe, NMPA codes in China, GMDN (Global Medical Device Nomenclature) used differently depending on the market. Incompatible stakeholder models—the U.S. Labeler, the European SRN (Single Registration Number), the Australian Sponsor, the authorized local agent in China and Korea. Specific fields with no equivalents elsewhere —the European Basic UDI-DI, the equivalent Saudi DIs, the Australian ARTG ID (Australian Register of Therapeutic Goods). A common core exists—60 to 70% of basic data (container and non-container) is shared—but the remaining 30 to 40% are not mere details: these are often the fields that determine market access.

The real lesson that has gradually emerged is that labeling alone is not enough. What matters is data integrity and compliance—consistency between what is on the label, what is in the regulatory database, and what is included in the manufacturer's quality dossier. Europe was the first to formalize this: the 2017 MDR makes the Basic UDI-DI the cornerstone of EUDAMED's documentation and requires strict consistency between submitted data, certificates from notified bodies, and post-market surveillance. The United States has drawn the same lesson in its own way, more recently and more explicitly: as of February 2026, Compliance Program 7382.850 makes the GUDID an inspectable component of the quality system. Other markets will follow. It is in this context that the following fact sheets take on their meaning.

GUDID — United States (FDA / 21 CFR Part 830)

What has been done

GUDID was created as a result of the 2013 UDI Final Rule (21 CFR Part 830), issued under pressure from Congress following years of inadequate traceability for implantable devices. Its rollout was phased: Class III devices in 2014, Class II devices in 2016, and Class I devices starting in 2018. The database's complete free access and public availability via AccessGUDID—which can be queried via a REST API (Application Programming Interface)—made it a world first, widely used by foreign authorities, including the IMDRF, to model their own systems. The M2M submission standard (HL7 SPL via the Electronic Submission Gateway, then ESG NextGen starting in 2025—API capabilities) has been publicly documented since its inception.

What's Happening

Two major developments took effect simultaneously in February 2026.

- First, the QMSR (Quality Management System Regulation) replaced the QSR, aligning the U.S. quality framework with ISO 13485—UDI must now be included in design history files (DHF), device history records (DHR), correction and recall procedures, and adverse event reports.

- On the other hand, Compliance Program 7382.850 (effective February 2, 2026) formally incorporates the GUDID into manufacturer inspections: the GUDID is now an "Other Applicable FDA Requirement" (OAFR) that is systematically verified. Any discrepancy between the physical label, internal records, and data submitted to the GUDID constitutes a documentation non-compliance. This requirement also extends to the verification of data history.

Furthermore, the update to the GUDID Guidance Document (December 2024) replaced FDA Preferred Terms with GMDN Terms, thereby aligning the U.S. nomenclature with the international standard.

Outlook and Legislative Intent

The FDA has always positioned GUDID as a public health tool as much as a compliance tool—public access, free of charge, interoperability with hospital systems. Its integration into the QMSR marks a turning point: GUDID ceases to be an external registry and becomes a constituent element of the quality system. Pressure on data integrity will increase with each inspection cycle.

IMDRF Convergence

The United States is a founding member of the IMDRF and has significantly influenced UDI guidelines (notably the IMDRF/UDI WG/N7 document). The GUDID served as an explicit model for AusUDID and has inspired several emerging databases. However, the FDA has retained its own specific identifiers—Product Code, FDA Listing Number, Premarket Submission Number—which have no equivalents in other global databases.

EUDAMED — European Union (MDR 2017/745 / IVDR 2017/746)

What Has Been Done

EUDAMED emerged from the dual regulatory crises of the 2010s—the PIP scandal (fraudulent breast implants) and the failures of metal hip implants—which revealed the limitations of a fragmented European system lacking centralized traceability and effective post-market surveillance. The MDR 2017/745 and the IVDR 2017/746 laid the foundations for an integrated ecosystem extending far beyond a simple UDI database: six modules covering the registration of economic operators (SRN), device identification (Basic UDI-DI and UDI-DI), notified body certificates, vigilance, post-market surveillance, and clinical investigations. UDI labeling has been mandatory under the MDR/IVDR since 2021, depending on the class.

What is currently underway

Decision (EU) 2025/2371 of November 27, 2025 triggered the requirement for the first four modules as of May 28, 2026: registration of actors, UDI/devices, notified bodies & certificates, and market surveillance. For new devices placed on the market after this date, registration in EUDAMED is required prior to the first placing on the market. Devices already on the market have a transition period until November 27, 2026. The validity of existing Notified Body certificates has been extended to May 28, 2027. Furthermore, on December 16, 2025, the European Commission published a legislative proposal to simplify the MDR and the IVDR—removing the 5-year validity limit on certificates and introducing simplifications for low-risk devices—aiming for estimated savings of 3.3 billion euros per year. This proposal is currently under review by the European Parliament and the Council.

Outlook and the Legislator's Intent

Europe's ambition is unparalleled globally: to make EUDAMED the single hub for the entire regulatory chain—from CE marking to pharmacovigilance, including certificates from notified bodies. The Basic UDI-DI, a concept unique to Europe, embodies this approach: it groups all devices with the same intended use, class, and characteristics under a single administrative identifier. The December 2025 simplification proposal reflects a growing awareness: the MDR, designed with maximum rigor in mind, has generated disproportionate burdens for low-risk devices and forced the market to rely on insufficient capacity from notified bodies.

IMDRF Convergence

The EU is a founding member of the IMDRF and chaired the steering committee in 2023. However, EUDAMED differs structurally from all other global databases: the Basic UDI-DI has no equivalent, the EMDN nomenclature is a European adaptation of the GMDN that requires explicit mapping, and the SRN model differs from the U.S. Labeler model or the Australian Sponsor model. Interoperability remains a work in progress.

Swissdamed — Switzerland: the most extensive MDR alignment outside the EU

What has been done

Switzerland, a non-EU member, has made a deliberate choice to align its regulatory framework as closely as possible with the European MDR—the ODim (Ordinance on Medical Devices) is its national implementation. Swissdamed, developed by Swissmedic, accepts EUDAMED Basic UDI-DI and XML files in the European format, thereby reducing the re-entry burden for manufacturers already EUDAMED-compliant. Registration of economic operators with Swissmedic has been mandatory since November 2021.

What's Next

The requirement to register devices in Swissdamed takes effect on July 1, 2026, for all medical devices placed on the Swiss market, with a transition period until December 31, 2026—except for devices subject to a reporting obligation (serious incidents, safety corrective actions), for which the requirement is immediate. The UDI Devices module has been in production since August 2025, and the REST API is operational.

Outlook and the Legislator's Intent

Swissmedic positions Swissdamed as the natural extension of the European MDR for the Swiss market—a strategic alignment that facilitates access for manufacturers already compliant with EU regulations but creates a structural dependency on the evolution of EUDAMED. The issue of costs could affect the attractiveness of the Swiss market for small manufacturers. Alignment with the proposed MDR simplification in December 2025 warrants monitoring.

IMDRF Convergence

Switzerland is an official observer at the IMDRF. Swissdamed is the global database most closely aligned with EUDAMED—it is a case of voluntary and deliberate bilateral convergence, rather than IMDRF multilateral harmonization.

AusUDID — Australia: the most successful international convergence

What has been done

Australia developed its UDI framework with a view to aligning it with IMDRF principles, explicitly drawing on the experiences of the United States (GUDID) and Europe (EUDAMED) before finalizing its regulatory framework. The amendments introduced in March 2025 via the Therapeutic Goods (Medical Devices) Regulations 2002 established the UDI requirements and marked the operational launch of AusUDID.
The UDI framework took effect on March 27, 2025, with the option for voluntary compliance and early data submission.

At the same time, post-market vigilance obligations, including the precise identification of devices in incident reports, are part of an already established framework for the TGA's ongoing surveillance of medical devices.

What's Happening

The first mandatory registration deadline in AusUDID is set for July 1, 2026, for Class III and IIb devices, with a simultaneous requirement for UDI labeling and data submission. Class IIa devices will follow in 2027, Class Is/Im in 2028, IVD (Classes 4 and 3) in 2028, and then IVD (Classes 2 and 1) and Class I in 2029, according to a phased, risk-based approach.

Several submission methods are planned: portal, bulk upload, and two documented machine-to-machine channels –HL7 SPL (aligned with the U.S. GUDID) and GS1 Australia's National Product Catalogue (NPC).

However, the M2M interfaces (HL7 SPL and NPC) were introduced gradually after the initial launch and underwent testing phases before becoming fully available.

Outlook and Legislative Intent

The TGA (Therapeutic Goods Administration) explicitly designed the Australian UDI system to meet the needs of manufacturers operating in multiple markets. Alignment with the HL7 SPL standard and the IMDRF model reflects a commitment to international convergence and the reuse of existing data flows.

The defining feature of the Australian model lies in the Sponsor/Manufacturer duality: the local sponsor, responsible for inclusion in the ARTG and regulatory obligations, reflects the reality of a market largely supplied by foreign manufacturers.

This architecture clearly distinguishes between:

- marketing authorization (ARTG),
- and product data management (AusUDID).

The economic terms (fees for submitting and maintaining UDI data) remain partially disclosed at this stage and are still subject to consultation.

IMDRF Convergence

Australia, a founding member of the IMDRF, designed AusUDID as a system highly aligned with international principles of unique identification. The use of the GMDN, data structuring, and the adoption of HL7 SPL bring the Australian model very close to the U.S. GUDID.

AusUDID thus stands as one of the most successful examples of genuine multilateral convergence, with native interoperability geared toward global manufacturers.

Local specificities nevertheless remain fundamental:

- The mandatory link to the ARTG,
- The central role of the sponsor,

- Certain data extensions (particularly regarding clinical or logistical characteristics),
- And explicit adaptation to software devices (SaMD: Software as a Medical Device).

Saudi DI — Saudi Arabia: operational base, regulatory synchronization (M2M) still closed

What has been done

Saudi Arabia was among the first countries, outside of the IMDRF Steering Committee, to mandate the Unique Device Identification (UDI) for medical devices.

The Saudi Food and Drug Authority (SFDA) launched the Saudi-DI database in October 2020, with a phased rollout by risk class:

- Classes B, C, and D: mandatory since September 2023
- Class A: requirement effective since September 2024

After several delays, the regulatory timeline has now been finalized and is being effectively implemented.

Furthermore, the SFDA holds official observer status with the IMDRF, confirming its partial alignment with international initiatives.

Current Status

The Saudi-DI system is now operational, with submission procedures based on:

- Manual entry via a portal,
- Or the upload of standardized Excel files.

However, there is currently no machine-to-machine (M2M) mechanism comparable to those of other major international databases (GUDID, EUDAMED):

- The technical specifications are not publicly available,
- And access to the database is contingent upon the involvement of a local Authorized Representative.

The data model also features key national-specific elements, notably:

- The management of equivalent medicinal products,
- Traceability of medicinal products previously marketed in Saudi Arabia,
- And the assignment of an MD Listing Number specific to the Saudi market.

These elements have no direct equivalents in international standards and therefore require specific adaptations of industry data models.

Outlook and the Legislator's Intent

The Saudi-DI is designed primarily as a national regulatory tool, serving two main objectives:

- Strengthening post-market surveillance,
- And the control of border flows.

Device traceability is closely integrated into the Saudi vigilance system, following an approach similar to that of pharmacovigilance.

In the medium term, the SFDA has expressed a desire to align with IMDRF principles. Nevertheless, the system currently remains:

- Primarily focused on domestic control needs,
- rather than toward full international interoperability.

IMDRF Convergence

Official observer but not a member of the steering committee. The Saudi-DI draws on IMDRF principles for classification and core data, but diverges structurally on specific fields and the lack of regulatory synchronization (M2M). Convergence is partial and voluntary.

SIUD — Brazil (ANVISA / RDC 591/2021)

What has been done

ANVISA established the regulatory framework for the UDI system through RDC 591/2021, as amended in particular by RDC 884/2024. This framework requires the unique identification of medical devices and the creation of a corresponding national database.

The establishment of the SIUD database was formally approved at the 2nd meeting of the ANVISA Board of Directors (February 2026) and published in the Official Gazette.

UDI labeling requirements are already in effect for Class IV (July 2025) and Class III (July 2026) devices. The requirement to register data in the SIUD is scheduled to begin in 2029, starting with Class IV devices. Prior to these deadlines, data submission remains optional.

A Normative Instruction currently being finalized is expected to specify the implementation procedures, notably by introducing the requirement to submit UDI data prior to market authorization and by confirming that the submitted data pertains exclusively to the UDI-DI.

Current Status

The operational framework is taking shape around data transmission and governance rules. Transmission may be carried out either on a per-unit basis or in bulk, including via machine-to-machine integration, under the responsibility of the marketing authorization holder.

The SIUD also provides for the possibility of delegation to a third party (“Usuário Terceiro”) authorized to act on behalf of the holder.

Technically, the target architecture is based on the FHIR R4 / HL7 standard (XML and JSON) with a model comprising approximately 68 fields. Industrial M2M integration remains contingent upon the publication of the complete implementation guide (API URLs not yet published as of this writing).

Outlook and Legislative Intent

The SIUD is designed as an operational regulatory tool rather than a simple declaratory registry. It is part of a broader approach to market surveillance, device traceability, and control of import flows.

The framework for the data lifecycle (possible corrections, conditions for modification, replacement of UDI-DI, management of marketing withdrawals) reflects a commitment to ensuring the long-term reliability of the recorded information.

IMDRF Convergence

Brazil, a founding member of the IMDRF, has adopted a broadly aligned approach: structuring data around the UDI-DI and separating it from production data.

The choice of FHIR R4, however, positions the SIUD beyond traditional UDI standards, with a view to interoperability with digital health systems. There is therefore strong convergence on principles, but its effectiveness will depend on the stabilization of the technical model and its operational implementation.

DORS — United Kingdom (MHRA: Medicines and Healthcare products Regulatory Agency)

What has been done

Since leaving the EU on January 1, 2021, the United Kingdom has developed its own regulatory framework, administered by the MHRA. DORS (Device Online Registration System) is the operational registration system for economic operators and devices for the UK market—it is not a UDI database but a market access registry. This registry is part of a more fragmented architecture that includes, in particular, a public database (PARD) and a separate system for vigilance. Since April 1, 2026, DORS registration has been subject to a fee.

Furthermore, for vigilance, the MHRA relies on the MORE (Manufacturer's Online Reporting Environment) system, a centralized platform for reporting and tracking incidents, accessible via a portal and API. All incidents must be reported through this system, which now forms the core of the post-market surveillance system.

What's Happening

On May 11, 2026, the MHRA published an impact questionnaire on the Medical Devices (Amendment) Regulations 2026, open for comments until June 19, 2026. These pre-market amendment regulations notably introduce the requirement to assign a UDI to devices prior to their placing on the UK market, with a three-year transition period for general medical devices and a five-year period for IVDs.

At the same time, the MHRA is preparing separate legislation aimed at phasing out the UKCA (UK Conformity Assessed) marking. This phase-out will only take place once the UDI system is operational—a system whose format and timeline have yet to be specified. At this stage, the existing DORS database serves as the reference, even though it does not require the mandatory use of the UDI-DI.

The text also provides for the possibility of relying on authorizations already issued in certain countries (Australia, Canada, United States) to facilitate access to the UK market, as well as new IVD classification rules aligned with the IMDRF and strengthened cybersecurity requirements for software.

Outlook and the Legislator's Intent

The United Kingdom finds itself in a structurally uncomfortable position: leaving the EU has severed automatic access to EUDAMED, but building a comprehensive UDI database takes time and resources. The MHRA's stated intention is to maintain a level of requirements close to the European MDR while asserting post-Brexit regulatory autonomy, and to reduce barriers to entry by relying more heavily on decisions made by other authorities.

In line with this approach, the UK is moving toward a model based on several complementary components (DORS registration, MORE vigilance, and the public PARD database), pending the establishment of a unified UDI foundation. The replacement of the UKCA marking with the UDI simply reflects a shift in approach: replacing a compliance logo with a unique identifier that can actually be used to track devices and manage incidents.

IMDRF Convergence

The MHRA is a founding member of the IMDRF. The ability to rely on authorizations issued by other countries such as the United States, Canada, or Australia demonstrates a clear commitment to international convergence.

However, the lack of an operational UDI database currently keeps the UK out of step with international traceability systems, despite the existence of an already established vigilance system like MORE. The 2026 Regulations are therefore a key milestone to monitor closely between now and June 2026 and beyond.

3

160+ data elements scrutinized: common ground, structural differences, and pitfalls to avoid

Approximately 60 to 70% of UDI (container) attributes exist in a comparable form across the major regulatory databases. This common foundation allows for some degree of data sharing. However, this convergence remains partial: the same field does not necessarily mean the same data (content). Definitions, management rules, the reference frameworks used, or format constraints may vary from one database to another. In practice, therefore, data sharing focuses more on the structure of the data than on its exact content.

The concept of risk class is a good example. On the one hand, classifications do not always rely on the same categories across jurisdictions. On the other hand, the same device may fall into a different class depending on the market in question. Sterile examination gloves, for example, are generally classified as Class I under the European MDR, whereas comparable products fall under Class II in the U.S. FDA system. Behind an apparently similar field—"risk class"—therefore lie different regulatory logics and compliance requirements.

The remaining 30 to 40% of categories correspond to requirements specific to each jurisdiction. It is often these specific attributes—the European Basic UDI-DI, the Australian ARTG ID, the FDA Product Code—that determine market access and prevent full harmonization.

These fields are not merely descriptive information: they reflect the regulatory logic specific to each authority. The European Basic UDI-DI structures the link between technical documentation, certificates, and vigilance in EUDAMED; the FDA Product Code determines the regulatory framework applicable in the United States; the ARTG ID links the device to its Australian registration.

Stakeholder models also illustrate these differences: the European Union relies on the SRN and the roles of economic operators, the United States on the concept of the Labeler associated with the DUNS (Data Universal Numbering System), while Australia explicitly distinguishes the local Sponsor from the Manufacturer. Behind seemingly similar concepts, therefore, lie different regulatory responsibilities and data structures.

verified (official source) to be confirmed × not in this database

Attribute / Data Element	EUDAMED (EU)	SWISSDAMED (CH)	GUDID (USA)	AusUDID (AU)	SFDA Saudi DI (SA)
GENERAL					
Basic UDI-DI Code	Basic UDI-DI Code	Basic UDI-DI Code	×	×	×
Label DUNS Number	×	×	Label DUNS Number	×	×
Sponsor ID	×	×	×	Sponsor ID	×
Manufacturer ID	×	×	×	Manufacturer ID	×
Issuing Entity UDI-DI	Issuing Entity UDI-DI	Issuing Entity UDI-DI	Primary Issuing Agency	Primary DI Issuing Agency	Issuing Agency
UDI-DI Code	UDI-DI code	UDI-DI code	Primary DI Number	Primary DI	Primary UDI-DI
Device Class (Manufacturer)	×	×	×	Device Class (Manu-facturer)	×
Secondary UDI	Secondary UDI	Secondary UDI	×	×	×
Issuing Entity Secondary DI	Issuing Entity Sec-ondary DI	Issuing Entity Sec-ondary DI	Secondary Issuing Agency	Secondary DI Issuing Agency	×
Secondary UDI-DI Code	Secondary UDI–DI Code	Secondary UDI – DI code	Secondary DI Num-ber	Secondary DI	×
Previous DIs in the Saudi market?	×	×	×	×	Does this device have previous DIs in the Saudi market?
Previous Issuing Agency	×	×	Previous Issuing Agency	Previous Issuing Agency	Previous DI Issuing Agency
Previous DI Number	×	×	Previous DI Number	Previous DI	Previous DI
Equivalent DIs in the Saudi Mar-ket?	×	×	×	×	Does this device have equivalent DIs in the Saudi market?
Equivalent DI Issuing Agency	×	×	×	×	Equivalent DI Issuing Agency
Equivalent DI	×	×	×	×	DI Equivalent
Trade Name	Name / Trade Name	Name / Trade Name	Brand Name	Brand Name	×
Version / Model	×	×	Version or Model	Model or Version	×
Nomenclature code (EMDN/ GMDN)	Nomenclature code	Nomenclature code	×	×	×

Attribute / Data Element	EUDAMED (EU)	SWISSDAMED (CH)	GUDID (USA)	AusUDID (AU)	SFDA Saudi DI (SA)
URL for additional information	URL for additional information	URL for additional information	×	×	×
Reference / Catalog Number	Reference / Catalog Number	Reference / Catalog Number	Catalog Number	Catalog Number	Catalog Number
Additional Product Description	Additional Product Description	Additional Product Description	Device Description	Device Description	×
Device Type (SFDA)	×	×	×	×	Device Type
MD Listing Number / Product Number	×	×	×	×	MD Listing Number / Product Number
Is this the listing number for the accessory?	×	×	×	×	Is the listing number for an accessory
Model / Variant (SFDA)	×	×	×	×	Model / variant
Accessory Brand Name (SFDA)	×	×	×	×	Accessory Brand Name
Accessory Model Number (SFDA)	×	×	×	×	Accessory Model Number
Is it software (SFDA)?	×	×	×	×	Is it a software
DI Record Publication Date	×	×	DI Record Publication Date	DI Record Published Date	×
DI Record Status	×	×	×	DI Record Status	×
Commercial Distribution End Date	×	×	Commercial Distribution End Date	×	×
Commercial Distribution Status	×	×	Commercial Distribution Status	×	×
Commercial Distribution End Date	×	×	×	Commercial Sponsor Distribution End Date	×
Commercial Distribution Sponsor Status	×	×	×	Commercial Sponsor Distribution Status	×
MARKING					
Device Quantity	Device Quantity	Device Count	Device Count	Device Count	Quantity
Unit of Use – DI code	Unit of Use – DI code	Unit of Use – DI code	Unit of Use DI Number	Unit of Use DI	Unit of Use UDI-DI

Attribute / Data Element	EUDAMED (EU)	SWISSDAMED (CH)	GUDID (USA)	AusUDID (AU)	SFDA Saudi DI (SA)
Issuing Entity Unit of Use DI	Issuing Entity Unit of Use DI	Issuing Entity Unit of Use DI	×	×	×
Directly Marked	Directly Marked	Directly Marked	Device Subject to Direct Marking (DM), but Exempt	Device Subject to Direct Marking (DM), but Exempt?	×
Same as UDI-DI / DM DI	Same as UDI-DI	Same as UDI-DI	Is the DM DI different from the primary DI?	Direct Marking DI Different from Primary DI?	×
Marked UDI-DI code / DM DI Number	Marked UDI-DI code	Marked UDI – DI code	DM DI Number	Directly Marked DI	×
Issuing Entity Marked DI	Issuing Entity Marked DI	Issuing Entity Marked DI	×	Direct Marked DI Issuing Agency	×
Lot / Batch Number (label present)	Batch Number	Batch Number	Lot or Batch Number	Lot or Batch Number on the label?	LOT Number
Manufacturing Date (label present)	Manufacturing Date	Manufacturing Date	Manufacturing Date	Manufacturing Date on the label?	Manufacturing date
Serial Number (label present)	Serial Number	Serial Number	Serial Number	Is the serial number on the label?	SerialNumber
Expiration Date (label present)	Expiration Date	Expiration Date	Expiration Date	Expiration Date on the label?	Expiration (use by) date
Software Identification	SOFTWARE IDENTIFICATION	SOFTWARE IDENTIFICATION	×	×	Software Version
Donation Identification Number	×	×	Donation Identification Number	Donation Identification Number on the label?	×
Natural latex (21 CFR 801.437 / equivalent)	×	×	Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437)	Is the device required to be labeled as containing natural rubber latex or dry natural rubber?	Is the device labeled as "containing natural rubber latex or dry natural rubber"?
Non-latex / Not made with natural rubber latex	×	×	Device labeled as "Not made with natural rubber latex"	Device labeled as 'Not made with natural rubber latex'	Device labeled as "Not made with natural rubber latex"?

Attribute / Data Element	EUDAMED (EU)	SWISSDAMED (CH)	GUDID (USA)	AusUDID (AU)	SFDA Saudi DI (SA)
MRI Safety	×	×	What MRI safety information does the labeling contain?	MRI Safety Status	MRI Safety Status
USE					
Contains latex	Contains latex	Contains latex	×	×	×
Human Cell, Tissue, or Cellular/ Tissue-Based Product (HCT/P)	×	×	Human Cell, Tissue, or Cellular or Tissue-Based Product (HCT/P)	×	×
Kit (combination device)	×	×	Kit	Is the medical device a kit?	×
Combination Product	×	×	Combination Product	×	×
GMDN Code	×	×	Code (GMDN Code)	GMDN Code (Manufacturer)	×
GMDN Name	×	×	Name (GMDN)	×	×
GMDN Definition	×	×	Definition (GMDN)	×	×
Single Use	Single use	Single use	For Single Use	Intended for single use?	×
Define a maximum number of reuses	Define a maximum number of reuses	Define a maximum number of reuses	×	×	×
Maximum number of reuses	Maximum number of reuses	Maximum number of reuses	×	Restricted number of reuses	Limited number of reuses
Device Packaged as Sterile	×	×	Device Packaged as Sterile	Is the device packaged as sterile?	×
Requires Sterilization Before Use	Must be sterilized before use	Must be sterilized before use	Requires sterilization prior to use	Requires Sterilization Prior to Use?	×
Sterilization Method	×	×	Sterilization Method	Sterilization Method(s)	×
Reprocessed single-use device	Reprocessed single-use device	×	×	×	×
Device labeled sterile	Device labeled sterile	Device labeled sterile	×	×	×

Attribute / Data Element	EUDAMED (EU)	SWISSDAMED (CH)	GUDID (USA)	AusUDID (AU)	SFDA Saudi DI (SA)
Is the medical device software or does it incorporate software?	×	×	×	Is the medical device software, or does it incorporate software?	×
New device	New device	New device	×	×	×
Intended purpose other than medical (Annex XVI)	Intended for non-medical use (Annex XVI)	Intended purpose other than medical (Annex XVI)	×	×	×
MARKET					
Device Status	Device Status	Device Status	×	×	×
Country	Country	×	×	×	×
From (date)	From	×	×	×	×
To (date)	To	×	×	×	×
First placed on the EU market	First placed on the EU market	×	×	×	×
Device Exempt from Premarket Submission	×	×	Device Exempt from Premarket Submission	×	×
FDA Premarket Submission Number (510k / PMA...)	×	×	FDA Premarket Submission Number	×	×
Supplement Number	×	×	Supplement Number	×	×
Product Code	×	×	Product Code	×	×
Product Code Name	×	×	Product Code Name	×	×
FDA Listing Number	×	×	FDA Listing Number	×	×
Prescription Use (Rx)	×	×	Prescription Use (Rx)	×	×
Over-the-Counter (OTC)	×	×	Over the Counter (OTC)	×	×
ARTG ID	×	×	×	ARTG ID	×
CONTACT					
Customer Contact Phone	×	×	Customer Contact Phone	×	×

Attribute / Data Element	EUDAMED (EU)	SWISSDAMED (CH)	GUDID (USA)	AusUDID (AU)	SFDA Saudi DI (SA)
Customer Contact Email	×	×	Customer Contact Email	×	×
CLINICAL SIZE					
Clinical Size Type	Clinical Size Type	Clinical Size Type	Size Type	Clinical Size Type	×
Precision	Precision	Precision	×	×	×
Minimum	Minimum	Minimum	×	×	×
Maximum	Maximum	Maximum	×	×	×
Clinical Size Value	Value	Value	Size Value	Clinical Size Value	Clinically relevant size
Clinical Size Unit of Measure	Measurement Unit	Measurement Unit	Size Unit of Measure	Clinical Size Unit of Measure	×
Clinical Size Type Text	Text	Text	Size Type Text	Clinical Size Type Text	×
SUBSTANCES (EUDAMED / Swissdamed-specific)					
CMR Substances – Category	CMR Substances - Category	CMR Substances - Category	×	×	×
CMR Substances – CAS#	CMR Substances - CAS#	CMR Substances - CAS#	×	×	×
CMR Substances – EC#	CMR Substances - EC#	CMR Substances - EC#	×	×	×
CMR Substances – Language	CMR Substances - Language	CMR Substances - Language	×	×	×
CMR Substances – Substance Name	CMR Substances - Substance Name	CMR Substances - Substance Name	×	×	×
Endocrine Substances – CAS#	Endocrine Substances - CAS#	Endocrine Disruptors - CAS#	×	×	×
Endocrine Disruptors – EC#	Endocrine Disruptors - EC#	Endocrine Substances - EC#	×	×	×
Endocrine Substances – Language	Endocrine Substances - Language	Endocrine Substances - Language	×	×	×
Endocrine Substances – Substance Name	Endocrine Substances - Substance Name	Endocrine Substances - Substance Name	×	×	×
Medicinal Product Substance – INN	Medicinal Product Substance - INN	Medicinal Product Substance - INN	×	×	×

Attribute / Data Element	EUDAMED (EU)	SWISSDAMED (CH)	GUDID (USA)	AusUDID (AU)	SFDA Saudi DI (SA)
Medicinal Product Substance – Language	Medicinal Product Substance - Language	Medicinal Product Substance - Language	×	×	×
Medicinal Product Substance – Substance Name	Medicinal Product Substance - Substance Name	Medicinal Product Substance - Substance Name	×	×	×
Medicinal Product Substance derived from human blood/plasma – INN	Medicinal Product Substance derived from human blood or plasma - INN	Medicinal Product Substance derived from human blood or plasma - INN	×	×	×
Medicinal Product Substance derived from human blood/plasma – Language	Medicinal Product Substance derived from human blood or plasma - Language	Medicinal Product Substance derived from human blood or plasma - Language	×	×	×
Medicinal Product Substance derived from human blood/plasma – Substance Name	Medicinal Product Substance derived from human blood or plasma - Substance Name	Medicinal Product Substance derived from human blood or plasma - Substance Name	×	×	×
STORAGE / HANDLING					
Storage / Handling Condition Type	Storage / Handling condition type	Storage / Handling condition type	Storage and Handling Type	Storage and Handling Type	×
Storage Low Value	×	×	Low Value	Storage and Handling Low Value	×
Storage High Value	×	×	High Value	High-Value Storage and Handling	×
Storage Unit of Measure	×	×	Unit of Measure	Storage and Handling Unit of Measure	×
Special Storage Conditions	×	×	Special Storage Conditions	Special Storage and Handling Conditions	×
Storage Description (free text)	Description	Description	×	×	Special storage conditions as labeled
WARNINGS / CONTRAINDICATIONS					
Critical warnings or contraindications	Critical warnings or contraindications	Critical warnings or contraindications	×	×	×
Warning Description (free text)	Description	Description	×	×	Critical warning as labeled

Attribute / Data Element	EUDAMED (EU)	SWISSDAMED (CH)	GUDID (USA)	AusUDID (AU)	SFDA Saudi DI (SA)
PACKAGING					
Package Issuing Entity	Package Issuing Entity	Package Issuing Entity	×	×	×
Package UDI-DI Code / Package DI	UDI-DI Code Package	UDI-DI Code Package	DI Number Package	DI Package	Identifier
Quantity per Package	Quantity per package	Quantity per package	Quantity per Package	Quantity per Package	Quantity of items
Contains DI Package	×	×	Contains DI Package	Package contains DI	×
Package Type	×	×	Package Type	Package Type	Packaging Type
Package Discontinuation Date	×	×	Package Discontinu-ation Date	Sponsor Package Commercial Distribu-tion End Date	×
Package Status / Commercial Dis-tribution Status	Package Status	Package Status	Package Status	Sponsor Package Commercial Distribu-tion Status	×
DOCUMENTS (Specific AusUDID)					
Document Type	×	×	×	Document Type	×
Document Effective Date	×	×	×	Document Effective Date	×
Document End Date	×	×	×	Document End Date	×
Related ARTG	×	×	×	Related ARTG	×
Document URL	×	×	×	Document URL	×
Document attachment	×	×	×	Document attachment	×
Document Status	×	×	×	Document Status	×
Document Status Reason	×	×	×	Document Status Rea-son	×
BASIC UDI – GENERAL (EUDAMED / Swissdamed specific)					
Eudamed Actor SRN/ID (CHRN for Swissdamed)	Eudamed Actor SRN/ID	Eudamed Actor SRN/ID	×	×	×
Authorized Representative SRN	Authorized Representa-tive SRN	×	×	×	×
Medical Device Type	Medical Device Type	Medical Device Type	×	×	×

Attribute / Data Element	EUDAMED (EU)	SWISSDAMED (CH)	GUDID (USA)	AusUDID (AU)	SFDA Saudi DI (SA)
Issuing Entity Basic UDI-DI	Issuing Entity Basic UDI-DI	Issuing Entity Basic UDI-DI	×	×	×
Basic UDI-DI code	Basic UDI-DI code	Basic UDI-DI code	×	×	×
Applicable Legislation	Applicable Legislation	Applicable Legislation	×	×	×
Device Model	Device Model	Device model	×	×	×
Device Name	Device Name	Device Name	×	×	×
Tissues & cells – Presence of animal tissues or cells	Tissues and cells – Presence of animal tissues or cells, or their derivatives	Tissues and cells – Presence of animal tissues or cells, or their derivatives	×	×	×
Tissues & cells – presence of human tissues or cells	Tissues and cells - Presence of human tissues or cells, or their derivatives	Tissues and cells – presence of human tissues or cells, or their derivatives	×	×	×
Device Type	Device Type	Device Type	×	×	×
Special Device	Special Device	Special Device	×	×	×
Special Device Type	Special Device Type	Special Device Type	×	×	×
Risk Class	Risk Class	Risk Class	×	×	×
Active Device	Active Device	Active Device	×	×	×
Device Intended to Administer and/or Remove Medicinal Product	Device Intended to Administer and/or Remove a Medicinal Product	Device intended to administer and/or remove a medicinal product	×	×	×
Implantable	Implantable	Implantable	×	×	×
Measuring Function	Measuring Function	Measuring Function	×	×	×
Reusable Surgical Instruments	Reusable Surgical Instruments	Reusable Surgical Instruments	×	×	×
Presence of a substance—a medicinal product derived from human blood or plasma	Presence of a substance which, if used separately, may be considered to be a medicinal product de-	Presence of a substance which, if used separately, may be considered to be a medicinal product de-	×	×	×

Attribute / Data Element	EUDAMED (EU)	SWISSDAMED (CH)	GUDID (USA)	AusUDID (AU)	SFDA Saudi DI (SA)
	rived from human blood or plasma	rived from human blood or plasma			
Presence of a substance – medicinal product	Presence of a substance which, if used separately, may be considered a medicinal product	Presence of a substance which, if used separately, may be considered a medicinal product	×	×	×
Is the device a suture, staple, dental filling, brace…?	Is it a device such as a suture, staple, dental filling, or dental brace (…)?	Is it a suture, staple, dental filling, dental brace (…)?	×	×	×
Medical Purpose of the System or Procedure Pack	Medical Purpose of the System or Procedure Pack	Medical Purpose of the System or Procedure Pack	×	×	×
Is it a Kit?	Is it a Kit?	Is it a Kit?	×	×	×
Tissues & cells – Presence of cells or substances of microbial origin	Tissues and cells – Presence of cells or substances of microbial origin	Tissues and cells - Presence of cells or substances of microbial origin	×	×	×
Companion Diagnostic (IVDR)	Companion Diagnostic	Companion Diagnostic	×	×	×
Near-Patient Testing (IVDR)	Near-Patient Testing	Near-Patient Testing	×	×	×
Patient Self-Testing (IVDR)	Patient Self-Testing	Patient Self-Testing	×	×	×
Reagent (IVDR)	Reagent	Reagent	×	×	×
Professional Testing (IVDR)	Professional Testing	Professional Testing	×	×	×
Device (IVDR)	Instrument	Instrument	×	×	×
BASIC UDI – CERTIFICATE (EUDAMED-specific)					
Standard Certificate	Certificate Template	×	×	×	×
Certificate Number	Certificate Number	×	×	×	×
Certificate version	Certificate version	×	×	×	×
Notified Body	Notified Body	×	×	×	×
Expiration Date (certificate)	Expiration Date	×	×	×	×

4

What the table reveals: three layers of structure and their operational implications

The table of data elements (160+ fields, 6 databases) may give the impression of harmonization among the major global regulatory frameworks. In reality, this convergence is largely structural: fields often have comparable names or purposes, but their content, management rules, reference standards, and regulatory implications differ by jurisdiction.

In practice, manufacturers do not structure their product data according to a multi-country regulatory framework. The information primarily comes from ERP, PLM, quality management systems, or historical Excel files, organized around the industrial product rather than the specific requirements of each regulatory authority.

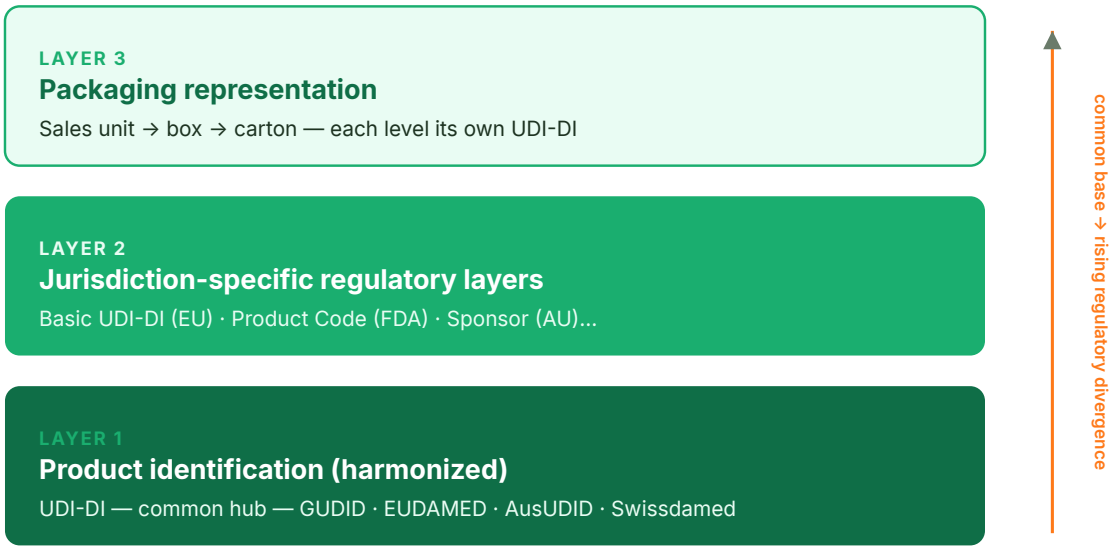
The product regulatory repository provides precisely this layer of regulatory structuring. Its value lies not in creating a harmonized global database—which does not exist de facto—but in transforming internal product data into distinct regulatory representations according to the relevant jurisdictions.

Analysis of the table reveals three successive layers of structure in major UDI systems:

(1) A relatively harmonized product identification layer;

(2) Complementary regulatory layers specific to each jurisdiction;

(3) And, a layer of packaging representation focused on regulatory traceability.



The UDI-DI: the only truly common identifier across all databases

The UDI-DI is now becoming the common hub for product identification across the major regulatory databases. A single UDI-DI can thus be used in GUDID, EUDAMED, AusUDID, or Swissdamed. Even the United Kingdom, which does not yet have a fully operational UDI database, is now moving toward a UDI-based regulatory model in its upcoming MHRA reforms.

This identifier relies on an accredited issuing *entity*. Not all jurisdictions recognize exactly the same issuing entities. The European Union, for example, recognizes GS1, HIBCC, ICCBBA, and IFA, while other markets recognize only some of these organizations.

Among these models, GS1—via the GTIN—has gradually established itself as the dominant standard for UDI-DI coding in major international UDI systems.

Beyond the UDI-DI: Regulatory Layers Specific to Each Jurisdiction

The UDI-DI is now the common thread linking most international regulatory systems. It enables the identification of a specific marketable device or configuration. However, in practice, authorities do not structure their regulatory frameworks around the UDI-DI alone.

Each jurisdiction thus adds its own regulatory layers to organize the relationships between devices, economic actors, certificates, technical documentation, marketing authorizations, and post-market surveillance activities.

The European Union—followed by Switzerland in Swissdamed—has thus introduced the Basic UDI-DI as a cross-cutting identifier. Unlike the UDI-DI, which corresponds to a specific marketable device, the Basic UDI-DI represents a regulatory family of devices sharing the same intended use, the same risk class, and common essential characteristics. In particular, it serves as a link between several processes: certificates, declarations of conformity, vigilance, clinical investigations, or market surveillance.

This additional layer is not without implications for manufacturers. In practice, the Basic UDI-DI imposes rules for grouping, segmentation, and consistency that do not automatically follow from the product model or existing ERP data. The relationship between the Basic UDI-DI and the UDI-DI thus becomes a key element of European compliance, with direct impacts on certificates, technical dossiers, and product change processes.

The European model also relies on identifiers specific to economic operators, such as the SRN (Single Registration Number), used in EUDAMED to identify manufacturers, authorized representatives, importers, and other economic operators.

In certain specific cases, Europe is also introducing the concept of a Master UDI-DI to represent devices that are highly configurable, customizable, or have a very large number of variants, without artificially multiplying individual UDI-DI records.

The United States follows a different approach, focused more on device registration in the GUDID. Each *device record* links a UDI-DI to a set of information specific to the FDA ecosystem: Product Code, *premarket submission* information, commercial status, or identifier of *the Labeler*. The FDA Product Code does not designate an individual

device but rather a regulatory category used by the FDA to classify devices based on their technology and intended use.

Other jurisdictions are also introducing their own complementary layers. Australia, for example, structures part of its model around the relationships between the local sponsor, Manufacturer ID, and ARTG ID within the AusUDID.

These regulatory layers reflect different oversight architectures depending on the authorities involved. They require manufacturers to manage, within a single product portfolio, segmentations specific to each jurisdiction, along with their identifiers, relationships, and specific management rules.

Behind a common international principle, regulatory models therefore remain deeply local. This reality makes it extremely difficult to build a fully unified global regulatory framework based on a single product data logic.

Packaging: a convergent approach, but primarily regulatory

Packaging concepts are generally more harmonized across major UDI regulations than stakeholder models or complementary regulatory identifiers. This convergence is largely due to the influence of the IMDRF's work and GS1 Healthcare standards, which have established common principles for packaging identification and hierarchy.

The main regulatory frameworks are thus based on a similar logic: each marketable packaging level must have its own UDI-DI, with hierarchical relationships between the different packaging levels. A unit of sale, a master carton, or a marketable intermediate package therefore has distinct identifiers, even when they contain the same device in different quantities.

This convergence, however, remains primarily regulatory. UDI frameworks primarily describe the packaging levels necessary for the identification, marketing, and regulatory traceability of the device: marketable levels, quantities contained, relationships between packages, and identifiers associated with the different *packaging levels*.

Conversely, manufacturers' complete supply chain logic is generally not covered by regulatory frameworks. Detailed logistics data—dimensions, weight, pallets, handling units, transport constraints, or warehouse organization—remain largely outside the scope of regulatory UDI.

Moreover, not all packaging layers are necessarily subject to registration. The main UDI frameworks primarily require the identification of those packaging levels that are actually marketed or used in the regulated distribution of the device. Purely logistical levels—pallets, internal transport groupings, or handling units—generally remain outside the scope of mandatory regulations.

Some jurisdictions, however, allow for the optional registration of additional packaging levels. In practice, this option should be used with caution. Publishing non-required logistics data can, over time, lead to additional regulatory maintenance burdens during packaging changes, data model updates, or revisions to the specifications of the regulatory databases themselves. For this reason, many manufacturers prefer an approach limited to the levels actually required by regulations or necessary for regulated distribution processes.

The key principles for structuring packaging levels thus remain relatively consistent across EUDAMED, GUDID, AusUDID, and Swissdamed. However, this harmonization primarily concerns the regulatory representation of packaging, not the manufacturer's entire logistics model.

Why Fragmented Architectures Pose a Risk of Non-Compliance

An analysis of the various UDI databases shows that the main issue is no longer simply the identification of the device. The real challenge now lies in manufacturers' ability to maintain consistent regulatory data across multiple jurisdictions simultaneously over time.

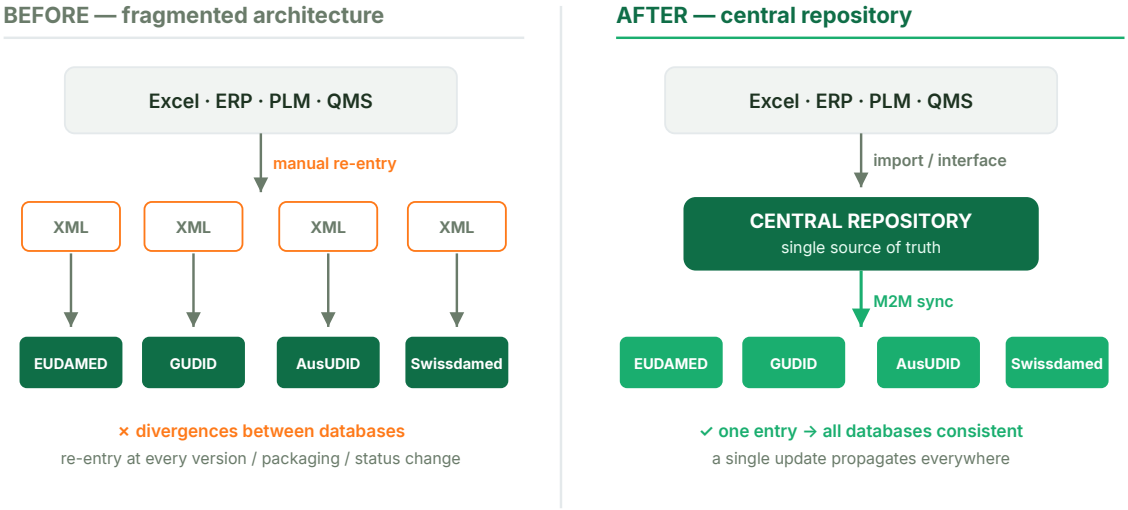
All major regulatory authorities are gradually converging on a single requirement: to have access to reliable, traceable, consistent, and continuously updated regulatory data. The United States is thus strengthening its control mechanisms regarding UDI data quality under FDA regulation 7382.850, while the European Union is gradually preparing for the operational launch of EUDAMED and the associated controls. Australia is following the same path with AusUDID and its increasing regulatory structuring requirements.

In this context, compliance is no longer limited to publishing data in a regulatory database. It requires ensuring long-term consistency across multiple regulatory systems, multiple data versions, and multiple quality processes.

This evolution inherently undermines fragmented architectures relying on multiple isolated tools, manual data re-entry, intermediate files, or ad-hoc generation of XML files. These approaches multiply points of failure and significantly increase the risk of divergence across jurisdictions.

These discrepancies primarily arise during:

- Version changes;
- Changes in packaging;
- Changes in commercial status;
- Regulatory updates;
- Or changes affecting the relationships between regulatory identifiers.



A manufacturer publishing simultaneously in EUDAMED, GUDID, AusUDID, and Swissdamed thus handles over a hundred distinct regulatory fields, a significant portion of which exist in only a single jurisdiction. Behind the apparent harmonization driven by the UDI, the operational reality therefore remains deeply multi-regulatory.

In such an environment, compliance can no longer be sustainably maintained through simple manual duplication of data or by juxtaposing local publication processes.

The question is therefore no longer: “Which identifier should we choose?” but rather: “How can we ensure the integrity, consistency, traceability, and timeliness of regulatory data across multiple jurisdictions without increasing data re-entry and the risk of discrepancies?”

In a multi-regulatory context, re-entry mechanisms and isolated XML generation chains become high-risk approaches. They complicate the tracking of changes, make it difficult to maintain consistency across databases, and increase the risk of regulatory non-compliance during updates.

Regulatory synchronization (M2M) therefore becomes a central challenge in regulatory data governance. In particular, it enables:

- Limiting discrepancies between jurisdictions;
- Reducing manual data re-entry;
- Maintaining a traceable history of changes;

- Improving the integrity of published data;
- And secure multi-database regulatory updates.

The resulting regulatory repository is no longer merely a tool for regulatory submission. It becomes a layer of governance, control, and consistency for regulatory data on an international scale.

5

UDI in the quality system: traceability, consistency, and integrity as auditable requirements

Beyond simple registration in regulatory databases, all major global regulations now converge on a single fundamental requirement: ensuring complete traceability and data integrity throughout the medical device's lifecycle. UDI is no longer just a product identifier: it has become the anchor linking physical labeling, quality systems, regulatory databases, and post-market activities.

This requirement revolves around three complementary dimensions.

A discrepancy between the label, quality records, and regulatory database: a non-compliance

The FDA (GUDID + Program 7382.850), MDR/IVDR (EUDAMED), TGA (AusUDID), ODim (Swissdamed), or ANVISA (SIUD) regulations are all based on the same principle: data submitted to regulatory databases must be consistent with the information on the device's physical label and with the data maintained in the manufacturer's quality system.

Any discrepancy—even a minor one—between a label, a technical file, a quality system, or a regulatory database constitutes a non-conformity that could be identified during an inspection.

In the United States, FDA Program 7382.850 has explicitly formalized this approach since February 2026: the UDI must be consistently traceable in the GUDID, the Device History Record (DHR), the Device Master Record (DMR), and other associated quality records. In Europe, this consistency is structured around the Basic UDI-DI, which links devices to certificates, declarations of conformity, actor records, vigilance activities, and technical documentation in EUDAMED.

Regulatory convergence is clear: the authority no longer monitors just a product or a label, but the overall consistency of the data ecosystem that describes that product.

Change histories: what authorities can verify, and within what timeframe

UDI regulations also require traceable management of product changes over time.

Every significant modification—including changes to version, packaging, commercial status, indication, sterility, or regulatory configuration—must be reflected in the relevant databases with a retained and verifiable history.

The UDI Regulation imposes update deadlines when certain regulatory data changes. According to 21 CFR 830.330(b), the information on the label must be updated before or at the time of the first distribution of the modified device; for certain other data not directly appearing on the labeling, the update must occur within 10 business days. EUDAMED, Swissdamed, and other UDI databases are also based on a system of continuous updates and historical tracking of regulatory data. This allows authorities to compare the status reported in the databases with the manufacturer's internal records during an audit or inspection.

Regulatory databases thus become regulatory history systems that can be consulted during inspections. Authorities can compare:

- The status of a device reported on a given date;
- Recorded changes;

- Successive versions;
- And their consistency with the manufacturer's internal data.

In this context, fragmented architectures—multiple re-entries, separate tools, Excel files, or manual XML imports—become particularly risky. An update applied in one database but overlooked in another is now one of the main sources of regulatory discrepancies in multi-jurisdictional environments.

Advisories, recalls, incidents: an inconsistent UDI compromises the entire chain

The UDI is also becoming the central point for post-market traceability.

Systems for vigilance, post-market surveillance, incidents, FSCA (Field Safety Corrective Action), and product recalls are now based on standardized regulatory device identification.

In Australia, the use of the UDI in adverse event reports has been mandatory since March 1, 2025, even independent of the full AusUDID deployment schedule. In Europe, the vigilance and PMS (Post-Market Surveillance) modules of EUDAMED are designed around the UDI as the central product identifier. In the United States, Program 7382.850 also stipulates that traceability systems under 21 CFR 821 must be capable of documenting the UDI present on the device label.

The stakes are not theoretical. A product recall where the UDI is incomplete, inconsistent, or missing from regulatory databases becomes extremely difficult to execute properly:

- For the manufacturer;
- For distributors;
- For healthcare facilities;
- And for the competent authorities.

Data quality itself becomes a compliance issue

An often-overlooked point: regulatory data compliance is not proportional to the device's risk class.

Class III devices do indeed require more regulatory and documentary elements, but this does not mean that Class I devices can tolerate lower data quality. The absence of a notified body's involvement for some devices in no way reduces the obligation to ensure the consistency, accuracy, and traceability of the information recorded in regulatory databases.

The traditional criterion of "low UDI-DI volume" or "low risk class" is therefore no longer sufficient to justify manual or semi-manual processes.

In a multi-regulatory context, manual data re-entry and isolated XML upload mechanisms constitute high-risk approaches:

- Increased number of potential failure points;
- Discrepancies between databases;
- Difficulty in maintaining historical records;

- Lack of synchronization;
- And an overall decline in confidence in published data.

Conversely, the automation of regulatory exchanges via M2M (Machine-to-Machine) mechanisms directly contributes to:

- To data integrity;
- To consistency across jurisdictions;
- To the traceability of changes;
- And to reducing the risk of regulatory non-compliance.

Finally, we must not lose sight of the underlying reason for this growing demand: regulatory data is gradually becoming public, interconnected, and usable by the entire healthcare ecosystem—authorities, distributors, healthcare facilities, and sometimes patients themselves. Regulatory data thus ceases to be a mere administrative deliverable and becomes a permanent, exposed compliance asset.

6

What this overview means for your organization

This global overview of regulatory frameworks highlights a reality that is now here to stay: regulatory fragmentation is not a temporary anomaly awaiting harmonization. It constitutes the normal operational framework within which manufacturers of medical devices and IVDs must operate.

The IMDRF has helped establish a common principle—unique device identification—but not a single regulatory data model. Behind sometimes similar attributes, each regulation retains its own expectations, its own rules of interpretation, and its own required data. In other words, sharing the same data field does not necessarily mean publishing the same content. It is precisely this discrepancy between data structure and regulatory reality that explains the persistent high level of international complexity today.

Another major shift has emerged in recent years: regulatory compliance no longer ends with data submission. In both the United States and Europe, authorities now expect demonstrable consistency between regulatory databases, labeling, technical documentation, the quality system, and vigilance data. UDI is no longer a mere reporting exercise; it is now an integral part of the manufacturer's quality system.

At the same time, the regulatory specifications themselves are constantly evolving. Some databases publish several technical updates every month—EUDAMED being a particularly visible example. Manufacturers must therefore not only publish their data but also maintain continuous compliance over time in the face of shifting requirements.

For a manufacturer operating in multiple markets, the question is no longer simply: "What are our regulatory obligations?"—this booklet provides that clarity. The real question becomes: how can we ensure the long-term quality, consistency, traceability, and up-to-date status of regulatory data across all markets, without increasing data re-entry, intermediate files, and the risk of errors?

This is a strategic issue. Regulatory publication is now a prerequisite for compliance and maintaining market access. Furthermore, a significant portion of the published data becomes publicly accessible, directly exposing the quality and control of the information provided by the manufacturer.

In this context, the sometimes substantial investments made in technical dossiers, quality, and regulatory compliance cannot be undermined by poorly managed publication processes.

This explains the growing interest in specialized approaches, entirely dedicated to DM/IVD regulatory issues: solutions capable of integrating effectively into the manufacturer's existing information system without replacing it, while providing a high level of regulatory expertise, security, traceability, and quality control for published data.

Mastering regulatory data thus becomes much more than an operational issue. It now serves as a lever for sustainable compliance, securing regulatory investments, and ensuring continued access to international markets.

7

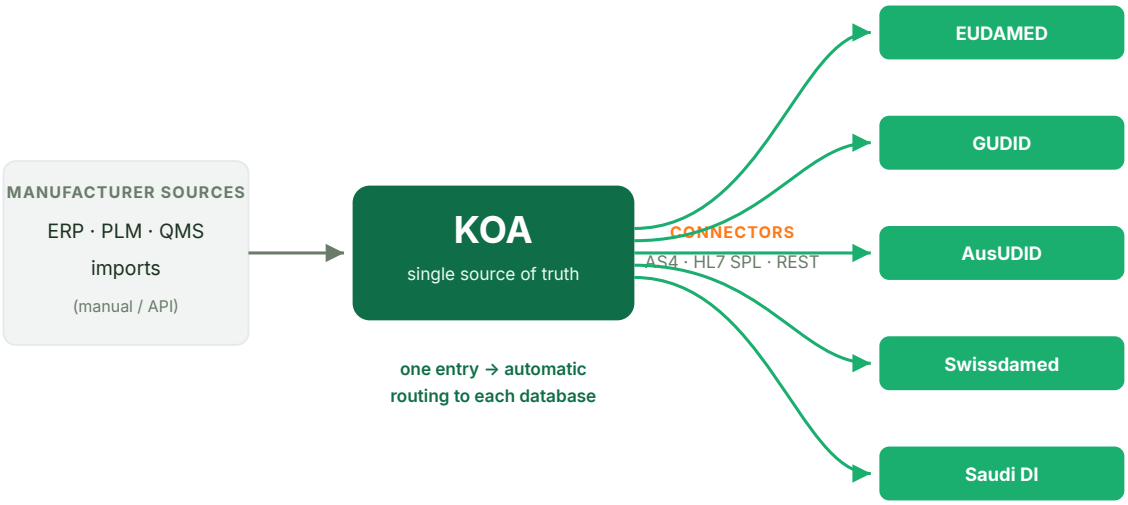
Ackomas: the multi-regulatory data governance platform for MD and IVD manufacturers

Managing a portfolio of medical devices and in vitro diagnostics across multiple markets simultaneously today means managing several regulatory frameworks in parallel—with different data models, separate update schedules, incompatible submission protocols, and authorities that now verify not only that you are registered, but that your data is consistent, up-to-date, and traceable. For a manufacturer distributing across four markets, this means potentially more than 100 distinct fields to keep in constant sync, a significant portion of which exist in only a single jurisdiction. It is within this specific operational context that Ackomas was designed—not as yet another data entry tool, but as a regulatory data governance platform.

A repository-based approach, not ad hoc files

In the day-to-day operations of most regulatory teams, UDI database management currently relies on Excel files created for each submission—one file per database, one file per change, recreated or adapted for each product-related event. It is precisely this process that Ackomas eliminates.

KOA, the Ackomas platform, functions as a central repository: product data is maintained and updated there—manually, via file import, or through interfaces with the manufacturer's IT system. KOA then determines what needs to be created, modified, or left unchanged in each of the connected regulatory databases, and automatically triggers the corresponding submissions. There is no need to create ad hoc files for each database, nor is there a manual publication process to coordinate.



This repository logic assumes that KOA is the source for all data creation in the databases. Records created prior to the platform's implementation—or entered directly into a regulatory database outside of KOA—create a desynchronization that cannot be corrected automatically: the deletion or modification of erroneous records in the databases must be handled manually, an operation that draws the attention of auditors and is something we seek to avoid as much as possible. This is why Ackomas advises against any direct updates to regulatory databases once the platform is in place, and supports its clients in migrating existing data to establish KOA as the single source of truth from the outset.

Risk class, volume of references: the wrong decision criteria

A common reflex is to calibrate regulatory data governance efforts based on the risk class of devices or the volume of managed references: few references, low risk classes, and tolerable manual processes. Ackomas demonstrates, through its clients' experience, that this reasoning is precisely what exposes organizations to non-compliance.

Regulatory data compliance is not proportional to the risk class. The absence of a notified body for part of the portfolio in no way reduces the obligation for consistency, accuracy, and traceability of the data submitted to the databases. A Class I device published in EUDAMED, GUDID, and AusUDID with data that is inconsistent across

these databases constitutes non-compliance—regardless of its clinical risk level. And a small number of references offers no additional protection: it is often in smaller portfolios—which are less well-equipped and less closely monitored internally—that discrepancies quietly accumulate across databases.

KOA is designed to address this reality regardless of portfolio size. Its design does not rely on a static data model: the platform evolves with every regulatory model change—new fields, new management rules, new databases—without requiring the manufacturer's regulatory team to detect and integrate these changes. It is this capacity for continuous adaptation—not merely the comprehensiveness of M2M connections—that ensures long-term compliance.

Questions to Ask About Your Solution

Not all solutions are created equal when it comes to this complexity. Before choosing one, five questions can help distinguish marketing claims from actual capabilities:

1. Is the solution connected via M2M to priority databases using an officially documented protocol—or does it rely on manual XML exports or ad-hoc uploads that guarantee neither traceability nor synchronization?
2. Does it natively handle structural discrepancies between databases—such as the European Basic UDI-DI, EMDN/GMDN mapping, and incompatible stakeholder models—or does it shift this processing burden to the regulatory team?
3. How are regulatory updates integrated, and within what timeframe after official publication? A database that lags behind regulatory changes exposes its users to silent non-compliance.
4. Does the solution cover the entire regulatory scope—medical devices and IVDs—with the same depth, or are IVDs treated as a secondary scope with poorly addressed specificities?
5. What level of submission traceability is provided—complete history, statuses by database, technical acknowledgments—so that during an inspection, you can answer the question: what data did you submit, when, and in what status?
6. Does the solution allow for the simple retrieval and re-entry of data already published in regulatory databases, in order to facilitate bulk corrections, avoid uncontrolled parallel files, and ensure reversibility in the event of a change in service provider?

KOA addresses this point by point:

Criterion	Ackomas — multi-regulatory DM & IVD platform
Regulatory database connections	EUDAMED (AS4) · GUDID (HL7 SPL / ESG) · AusUDID (HL7 SPL / NPC) · Swissdamed (REST API) · Saudi DI
Validation before submission	Check against official business rules for each database before submission — errors are detected before rejection
Multi-database consistency	Modified data is automatically propagated to all relevant databases
Database availability	Real-time information (EUDAMED, GUDID, etc.) — automatic submission queue
Architecture	Natively designed for MDs and IVDs — independent of any third-party data model or synchronization network not recognized by regulations
Specialization	100% medical device and IVD platform — not just one component in a general-purpose portfolio
Support	Dedicated support · Regular webinars · Monthly regulatory updates · Active user community

Criterion	Ackomas — multi-regulatory DM & IVD platform
Key Clients	Manufacturers of all sizes: SMEs, mid-sized companies, and large international groups — active in the European, American, and Australian markets, covering both medical devices and IVD

A validated technical dossier represents a significant investment. The data submitted to global regulatory bodies must accurately and up-to-date reflect this—it is the guarantee of it.

Learn more: www.ackomas.com

NOTE

Information current as of June 2026. Regulations evolve and interpretations may differ; always verify against the official sources of each database before making decisions.

8

Glossary

This glossary compiles the regulatory and technical terms used in this booklet. A practical note in the margin highlights operational considerations or differences between markets.

Regulatory scope: What is a medical device?

Medical device (MD) – comparison of official definitions by market

EU: MDR 2017/745, Art. 2§1 | United States: FD&C Act, Section 201(h)(1) | Australia: Therapeutic Goods Act 1989, Part 4-1, §41BD (as amended) | Saudi Arabia: Medical Devices Law (CM Resolution No. 337), Art. 1 | Brazil: ANVISA RDC 751/2022, Art. 4.

All major regulations agree on a common foundation: a medical device is an instrument, apparatus, equipment, software, implant, reagent, or other article intended by the manufacturer to be used in humans (alone or in combination) for a medical purpose—diagnosis, prevention, treatment, monitoring, or alleviation of a disease or disability—and whose primary action is not achieved by pharmacological, immunological, or metabolic means (which distinguishes it from a drug).

Differences between regulations concern the exact scope, the intended purposes covered, and the exclusions: – European Union (MDR 2017/745, Art. 2(1)): broadest definition; explicitly includes prognosis and prediction, software, and implants. Also covers non-medical devices listed in Annex XVI (non-corrective colored contact lenses, cosmetic liposuction equipment, skin lasers, etc.). Does not include in vitro diagnostic medical devices (IVD), which are covered by a separate regulation (IVDR 2017/746). – United States (FD&C Act, Section 201(h)(1)): similar definition; also covers animals. Explicitly excludes certain software functions (Section 520(o)). IVDs are "devices" within the meaning of the FD&C Act and governed by the same regulations (21 CFR Parts 820, 830); there is no separate IVD regulation as in Europe. – Australia (Therapeutic Goods Act 1989, §41BD): comparable structure; expressly includes devices intended to support or maintain a vital function (life-supporting) and those intended for contraception. Distinctive feature: distinguishes the manufacturer from the Sponsor (local entity responsible for placing the product on the market). – Saudi Arabia (Medical Devices Law, Art. 1): modeled on the MDR; also covers medical supplies and in vitro calibrators. Uses the same 22 classification rules as the MDR. – Brazil (ANVISA RDC 751/2022): definition aligned with IMDRF standards. Introduces an explicit definition of medical software (SaMD – Software as a Medical Device) in reference to IMDRF guidance. Risk classes: I (low) to IV (high), corresponding to South Korea's classes 1 to 4.

> ▸ *The same item may be classified as a medical device under one regulation and not under another—or be classified differently. Example: Sterile examination gloves are Class I under the European MDR but Class II according to the U.S. FDA. Diagnostic software is a medical device in Europe, the United States, and Australia, but its exact scope varies. The "intended use" declared by the manufacturer is decisive: it is the manufacturer who chooses the intended use and thus determines (or not) the application of medical device regulations.*

In vitro diagnostic medical device (IVD MD)

EU: IVDR 2017/746, Art. 2§2 | United States: 21 CFR §809.3(a) (FDA) | EU and other markets: concept covered by the general medical device regulation.

An IVD is a device used in vitro (outside the human body) to examine samples from the human body (blood, urine, tissue, etc.) in order to provide information for medical purposes: diagnosis of a disease, monitoring of treatment, assessment of compatibility for a transfusion, etc. Examples: PCR tests, pregnancy tests, blood glucose meters and

their test strips, automated blood analyzers, laboratory reagents. Differences between markets: in Europe, IVDs are governed by a separate regulation (IVDR 2017/746), with their own classification (Classes A through D). In the United States, IVDs are "devices" under the FD&C Act and follow the same general regulations, without a separate IVDR-level text. In Brazil and Saudi Arabia, they fall under the same general regulatory framework but with specific subclassifications.

▸ *A pregnancy test sold in pharmacies is an IVD medical device. In Europe, its manufacturer must register with EUDAMED under the IVDR. In the United States, the manufacturer submits its data to the GUDID like any other device.*

SaMD — Software as a Medical Device

IMDRF/SaMD WG/N10FINAL:2013 (international reference definition) | MDR 2017/745, Recital 19 | FDA, Software as a Medical Device guidance | ANVISA RDC 751/2022.

A SaMD is software intended for use for one or more medical purposes—diagnosis, prevention, monitoring, treatment, or mitigation of a disease—without being integrated into a hardware device. It runs on general-purpose computing platforms (smartphones, tablets, cloud servers). Examples: radiological image analysis algorithm, diabetes monitoring app, dose calculation software. Software embedded in a medical device (firmware) is not a SaMD: it is part of the device.

▸ *SaMD is a subject of active convergence among regulators: the FDA, the European Commission, the Australian TGA, and the IMDRF have published joint guidance. The AusUDID contains specific fields for SaMD characteristics.*

Risk class

MDR 2017/745, Annex VIII | IVDR 2017/746, Annex VIII | FD&C Act, Sections 513–515 (21 CFR Part 860) | TGA Therapeutic Goods (Medical Devices) Regulations 2002 | SFDA Medical Devices Law.

Each regulation classifies medical devices into groups of increasing risk. The class determines the level of regulatory control (self-declaration, audit by a notified body, prior market authorization) and the obligations for submission to databases. Indicative (non-exhaustive) correspondences: —

- EU MD (MDR): Class I | Class IIa | Class IIb | Class III — EU IVD (IVDR): Class A | Class B | Class C | Class D
- United States (FDA): Class I | Class II | Class III
- Australia (TGA): Class I | Class IIa | Class IIb | Class III (+ Is, Im)
- Saudi Arabia (SFDA): Class A | Class B | Class C | Class D
- Brazil (ANVISA): Class I | Class II | Class III | Class IV
- South Korea (MFDS): Class I | Class II | Class III | Class IV

▸ *A single device may belong to different classes depending on the country, due to distinct classification rules. Example: a sterile injection syringe is Class IIa in Europe and Class II in the United States. The risk class is a field present in all UDI databases, but its content cannot be copied from one market to another without verification.*

CE Marking

MDR 2017/745, Art. 20 and Annex V | Regulation (EC) 765/2008 (general framework for CE marking).

The CE marking (Conformité Européenne) is the symbol that certifies that a product complies with the essential safety and performance requirements defined by applicable European regulations. For medical devices, it is mandatory for any placing on the market within the European Economic Area. Depending on the risk class, it is obtained either through the manufacturer's self-declaration (Class I) or following an assessment by a notified body (Classes IIa, IIb, III).

▸ *The CE marking is not automatically recognized outside the EU/EEA: a CE-marked device must obtain specific approvals to be sold in the United States (FDA 510(k) or PMA), Australia (ARTG listing), the United Kingdom (DORS), etc. However, the Saudi SFDA and Swissmedic often accept the CE dossier as the basis for their evaluation.*

Device Identification and Traceability

UDI – Unique Device Identification

IMDRF/UDI WG/N7FINAL:2013 (international reference definition) | MDR 2017/745, Art. 2(15) and Art. 27 | 21 CFR Parts 801 and 830 (FDA) | TGA Therapeutic Goods (Medical Devices) Regulations 2002, Sch. 2A.

A unique, standardized identification system applied to each medical device and each level of its packaging. It allows for the unambiguous identification of a device throughout its distribution and use. The UDI consists of two elements: the UDI-DI (fixed device identifier) and the UDI-PI (production identifier). It is presented in human-readable format (HRI) and machine-readable format (AIDC barcode: Code 128, Data Matrix, QR code depending on the packaging level).

▸ *In plain terms: the UDI is the equivalent of an ISBN for books, but for medical devices. It allows a hospital, health authority, or distributor to know exactly which product they have on hand—which version, which lot, which expiration date—and to locate all affected units in the event of a recall.*

UDI-DI – Device Identifier

MDR 2017/745, Art. 2§16 | 21 CFR 830.3 (FDA) | IMDRF/UDI WG/N7FINAL:2013, §3.

A fixed and mandatory part of the UDI. Identifies the manufacturer and the specific version or model of the device. Does not change between two units of the same model. This identifier is the one recorded in regulatory databases (GUDID, EUDAMED, AusUDID, etc.). Issued under a system managed by an accredited issuing agency (GS1, HIBCC, ICCBBA, IFA depending on the market).

▸ *All Model X pacemakers manufactured by Company Y have the same UDI-DI. This is the permanent identifier for this model in official registries.*

UDI-PI – Production Identifier

MDR 2017/745, Art. 2§17 | 21 CFR 830.3 (FDA) | IMDRF/UDI WG/N7FINAL:2013, §3.

Variable part of the UDI, specific to each production unit or batch. Contains, as applicable: serial number, lot/batch number, date of manufacture, expiration date, software version. Present on the device label but not submitted to regulatory databases.

▸ *The UDI-PI makes it possible to precisely identify which units are affected by a recall. Without it, we know which model is being recalled (thanks to the UDI-DI), but not which lots.*

Basic UDI-DI

MDR 2017/745, Art. 2(18) and Annex VI, Part C | IVDR 2017/746, Art. 2(17). Concept specific to the EU and Switzerland (Swissdamed).

A European regulatory identifier that groups all devices within the same regulatory family (same intended use, same risk class, same essential characteristics) under a single administrative key. Not listed on the label. Serves as a link in EUDAMED to connect the device to its technical documentation, notified body certificates, vigilance activity reports, and post-market surveillance. Does not exist in the United States, Australia, or Saudi Arabia.

- *A 5-ml enteral syringe and a 10-ml enteral syringe each have their own UDI-DI, but share the same Basic UDI-DI because their intended use and class are identical.*

Direct Marking

MDR 2017/745, Art. 27§4 | 21 CFR 801.45 (FDA) | TGA Therapeutic Goods (Medical Devices) Regulations 2002.

Requirement to affix the UDI directly to the device itself (laser engraving, electrolytic marking, durable printing, etc.)—and not just on its packaging. Applicable to reusable devices that must be sterilized between uses, so that the identifier remains legible after removal from the packaging. Regulatory deadlines for direct marking are generally 1 to 3 years behind standard labeling deadlines in each market.

Regulatory databases and stakeholders

EUDAMED / GUDID / AusUDID / Swissdamed / DORS / SIUD

Respectively: MDR 2017/745 Art. 33 | 21 CFR Part 830 (FDA) | TGA Regs 2002 amended 2025 | ODim SR 812.213 (Switzerland) | UK MDR 2002 amended | RDC ANVISA 591/2021.

National or supranational databases in which manufacturers must register their UDI data (and other regulatory data). See Section 2 of this document for details. Each has its own data model, its own recognized entities (SRN, Labeler DUNS, Sponsor ID, etc.), and its own submission protocols.

SRN – Single Registration Number (EU)

MDR 2017/745, Art. 31 | Implementing Regulation (EU) 2021/2078, Annex II.

Number assigned to each economic operator (manufacturer, authorized representative, importer) registered in EUDAMED. Structure: ISO country code + role (MF/AR/IM) + 9 digits. Equivalents in other databases: DUNS Labeler (United States), Sponsor ID (Australia), CHRN (Switzerland).

ARTG – Australian Register of Therapeutic Goods

Therapeutic Goods Act 1989, Part 4-5 (Australia).

Australian national registry of all therapeutic goods (drugs and medical devices) authorized for marketing. A device must be 'listed' in the ARTG before it can be sold in Australia. The ARTG ID is the unique identifier for this registration and must be entered in the AusUDID.

Notified Body

MDR 2017/745, Art. 2(42) and Annex VII.

An independent third-party body, designated by an EU Member State and notified to the European Commission, authorized to assess the conformity of Class IIa, IIb, and III devices prior to market authorization. It issues CE

certificates. Its certificates are registered in EUDAMED with limited validity. Functional (but not institutional) equivalent: Conformity Assessment Bodies in Australia.

GMDN / EMDN — Medical Device Nomenclatures

GMDN: gmdn.org (independent international organization) | EMDN: Implementing Regulation (EU) 2021/2078, Annex II.

The GMDN (Global Medical Device Nomenclature) is an international nomenclature that assigns a 5-digit code and a definition to each generic device type. Used in GUDID, AusUDID, and DORS. The EMDN (European Medical Device Nomenclature) is the European version, used in EUDAMED and Swissdamed. Structured hierarchically (letters + numbers). Derived from the GMDN but not identical: a manufacturer publishing in EUDAMED and GUDID must maintain the mapping (correspondence table) between its EMDN codes and its GMDN codes.

Quality and Compliance System

QMSR / ISO 13485 — Quality Management System

United States: Revised 21 CFR Part 820 (QMSR, effective since February 2026) | International: ISO 13485:2016 (standard published by ISO).

ISO 13485 is the international reference standard for quality management systems of medical device manufacturers. The U.S. QMSR (Quality Management System Regulation) has replaced the former QSR since February 2026 and explicitly aligns with ISO 13485. In Europe, ISO 13485 is the harmonized reference standard under the MDR. Since the QMSR took effect, the UDI must be present and consistent in mandatory quality records: DHF (Design History File), DHR (Device History Record), corrective and recall procedures, and adverse event reports.

> *Starting in February 2026, an FDA inspector may request to verify consistency between the GUDID and the manufacturer's internal quality records. A discrepancy constitutes a documentation non-conformity.*

PMS / PMCF — Post-Market Surveillance

MDR 2017/745, Art. 83–86 | IVDR 2017/746, Art. 78–81.

PMS (Post-Market Surveillance) encompasses the activities a manufacturer must implement to collect and analyze data on its devices once they are on the market (feedback, incidents, scientific literature, registries, etc.). PMCF (Post-Market Clinical Follow-up) is the clinical component of this. In Europe, the data is fed into EUDAMED (vigilance module). The UDI is the cornerstone of device identification.

FSCA — Field Safety Corrective Action

MDR 2017/745, Art. 2§68 | IMDRF/MDSAP WG/N1FINAL:2015.

Corrective action implemented by a manufacturer to reduce a risk of death or serious harm associated with the use of a device already on the market: product recall, modification of the device or its labeling, restriction, or withdrawal from the market. A consistent UDI across regulatory databases is essential for identifying and locating affected devices and executing the FSCA effectively.

IT technical terms and protocols

UDI regulatory databases and regulatory synchronization (or machine-to-machine exchanges – M2M) rely on IT standards and protocols that IT and information systems teams must master. This section explains the key terms in plain language.

API – Application Programming Interface

Generic technical term. Used in this context by: FDA (AccessGUDID REST API) | European Commission (EUDAMED REST API) | Swissmedic (Swissmedic REST API) | ANVISA (SIUD FHIR R4 API).

An API is a set of rules and access points that allow two software systems to communicate with each other in a structured manner. In the context of UDI databases, the API refers to the technical interface exposed by a regulatory database (EUDAMED, GUDID, AusUDID, Swissdamed, etc.) that allows an external IT system to submit, modify, or query data automatically, without human intervention.

▸ *Without an API, a manufacturer must manually log in to the web interface of each database and enter or paste their data. With an API, their IT system does this automatically for all databases at the same time. Not all databases offer an API: Saudi-DI does not publish API specifications at this stage.*

REST – Representational State Transfer

Web architectural standard (Fielding, 2000). Used by GUDID (AccessGUDID REST), EUDAMED, and Swissdamed REST API.

REST is an architectural style for web APIs, based on standard internet protocols (HTTPS). A REST API communicates using URLs (web addresses) to identify resources and standard HTTP methods to act on them: GET (read), POST (create), PUT (update), DELETE (delete). Data is typically exchanged in JSON or XML format. It is currently the most widespread architecture for APIs in modern regulatory databases.

▸ *When GUDID or Swissdamed publishes a 'REST API', this means that any developer can query or submit data via standard HTTP calls, using common tools.*

AS4 – Applicability Statement 4

OASIS AS4 Profile of ebMS 3.0 (OASIS standard) | EUDAMED: Implementing Decision (EU) 2019/939 and EUDAMED AS4 technical specifications (European Commission).

AS4 is a protocol for exchanging secure electronic messages, derived from EDI (Electronic Data Interchange) standards. It guarantees the confidentiality, integrity, and non-repudiation of exchanged messages (it can be proven that a message was indeed sent and received as is). EUDAMED uses AS4 as its official machine-to-machine submission protocol, which distinguishes it from other databases (GUDID and AusUDID use HL7 SPL, Swissdamed uses REST).

▸ *AS4 is more complex to implement than REST or HL7 SPL: it requires the prior exchange of digital certificates with the European Commission and a compliant messaging infrastructure. This is one of the reasons why M2M integration with EUDAMED is more technically demanding than integration with GUDID or AusUDID.*

HL7 SPL – Health Level 7 Structured Product Labeling

HL7 International (hl7.org) | FDA GUDID Guidance Document, December 2024 | TGA AusUDID Guide v2.0, 2026.

HL7 SPL is an XML standard for structuring health product identification and labeling data in a machine-readable format. Developed by HL7 International, it is the standard M2M submission format for the U.S. GUDID (via the Electronic Submission Gateway / ESG NextGen) and one of two M2M formats recognized by the Australian AusUDID. HL7 SPL facilitates data reuse between the two databases.

FHIR – Fast Healthcare Interoperability Resources

HL7 International, FHIR R4 standard (hl7.org/fhir) | ANVISA Brazil: SIUD, RDC 591/2021 as amended.

FHIR is an international interoperability standard for the exchange of health data, developed by HL7 International. It structures data into JSON or XML "resources" and exposes a REST API. Originally designed for interoperability between hospital systems and electronic patient records ( ), FHIR R4 is the standard Brazil has chosen for its SIUD system—a choice that positions the Brazilian database within a framework of interoperability with the digital health ecosystem, going beyond traditional UDI standards.

XML / JSON – structured data formats

W3C (XML) and IETF RFC 8259 (JSON) standards. Used in all UDI submission protocols: HL7 SPL (XML), AS4 (XML), FHIR R4 (JSON and XML), REST EUDAMED (JSON/XML), Swissdamed REST (XML).

XML (eXtensible Markup Language) and JSON (JavaScript Object Notation) are two formats for representing structured data, readable by both humans and machines. XML uses nested tags (< >); JSON uses curly braces and square brackets ({ [}]). Both formats allow the data of a medical device (name, UDI-DI, class, packaging, etc.) in a file that IT systems can automatically generate, transmit, and interpret. – HL7 SPL and AS4 (EUDAMED) use XML. – FHIR R4 (SIUD Brazil) primarily uses JSON. – Modern REST APIs (Swissdamed, AccessGUDID) accept both, depending on the context.

▸ *XML should not be confused with Excel.*

GS1 / GTIN – Global Trade Item Number

GS1 General Specifications (current version, gs1.org) | Recognized by the FDA (21 CFR 830), MDR 2017/745, and TGA Australia as a UDI issuing agency.

GS1 is the global standardization organization for commercial product identification codes. The GTIN (Global Trade Item Number) is the GS1 standard for item identification, which has established itself as the dominant format for encoding UDI-DI. A GTIN is typically encoded in an EAN-13 barcode (13 digits) for unit packaging, or in a GS1 Data Matrix for small devices or hierarchical packaging levels. GS1 is an accredited issuing agency for UDIs in Europe, the United States, Australia, and other markets.

▸ *If you've ever scanned a barcode at a supermarket, you've used the GS1 system. The same standard identifies medical devices—making it easier to integrate them into hospital inventory management systems and traceability software.*

M2M – Machine-to-Machine (automated submission)

Generic technical term. Used in the UDI regulatory context by IMDRF, FDA (ESG/GUDID), European Commission (EUDAMED AS4), TGA (AusUDID HL7 SPL / NPC), Swissmedic (Swissdamed REST).

In the context of UDI databases, M2M refers to the ability of an IT system, such as a data governance platform, to communicate directly with a regulatory database to create, modify, or update data—without manual entry. M2M requires that the database have published technical interface specifications (APIs, protocols). Status at the time

of publication of this booklet: – GUDID: M2M operational (HL7 SPL / ESG NextGen) – EUDAMED: M2M operational (AS4) – AusUDID: M2M operational (HL7 SPL + NPC/GDSN) – Swissdamed: M2M operational (REST API) – Saudi-DI: no M2M (specifications not published) – SIUD Brazil: M2M being deployed (FHIR R4, specifications not finalized) – IMDIS South Korea: M2M via local providers (not publicly documented)

ERP – Enterprise Resource Planning (Integrated Management Software)

Generic technical term (no official regulatory source).

An ERP is enterprise software that centralizes and integrates operational data and processes: purchasing, sales, inventory, production, accounting, and human resources. In the context of medical devices, ERP typically contains a portion of product data (product codes, bill of materials, production data, batches, serial numbers). This data often serves as the source feed for a regulatory product repository or a UDI submission platform, but it is structured according to industrial logic rather than regulatory data models. Examples: SAP, Oracle, Microsoft Dynamics, Sage.

PLM – Product Lifecycle Management

Generic technical term.

A PLM is software that manages all information related to a product's lifecycle, from design to market withdrawal: technical specifications, design files, bills of materials, changes, versions, and regulatory documentation. In the medical device industry, PLM is often the reference system for the technical file (DHF/DMR). Like ERP, it structures data according to a product-based rather than regulatory logic: transforming this data into formats compliant with EUDAMED, GUDID, or AusUDID models requires a dedicated mapping and governance layer. However, it is rarely found among medical device manufacturers. Its implementation is also often lengthy and difficult.

Product Regulatory Repository

Operational term (no official regulatory definition). A central concept in the architecture of multi-regulatory data governance.

An information system that serves as the single source of truth for all regulatory data of a medical device manufacturer. It bridges the gap between internal product data (ERP, PLM, QMS) and the distinct regulatory representations required by each jurisdiction (EUDAMED, GUDID, AusUDID...). Its role is to transform industrial product data into data compliant with each database's models, trigger M2M submissions, and maintain a traceable history of all changes. Without a central repository, each database is populated separately—which increases the risk of discrepancies between submitted data and the manufacturer's internal data.

ESG / ESG NextGen2 – Electronic Submission Gateway (FDA)

FDA, Electronic Submissions Gateway (eSG) – fda.gov/electronic-regulatory-submission-and-review | API features available since 2025.

The ESG (Electronic Submission Gateway) is the FDA's technical portal through which manufacturers submit their regulatory data electronically, including GUDID data via HL7 SPL. ESG NextGen2 is the modernized version, operational since 2025, which provides API capabilities for automated submission. It is the official technical entry point for M2M submissions to the GUDID.

Interoperability

Generic technical term. In this context: IMDRF, European Commission (EUDAMED), HL7 International (FHIR).

Interoperability refers to the ability of separate computer systems to exchange, interpret, and correctly use data with one another without manual processing. In the context of UDI registries, technical interoperability is ensured by common standards (HL7 SPL, GS1, FHIR) and common accredited issuing agencies (GS1, HIBCC). Regulatory

interoperability, however, remains limited: even with a common UDI-DI, each database has its own mandatory fields, its own management rules, and its own stakeholder models.

Regulatory Data Governance

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