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EUDAMED Implementation under the IVDR – Implications for Device Traceability, UDI, and Labelling

AUTHOR(S): KRZYSZTOF SZLACHETKA, SGS BELGIUM
CATARINA HELIODORO, SGS BELGIUM

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Executive Summary

EUDAMED (European Database on Medical Devices) is a centralized European IT database on medical devices established by the European Commission after consultation with the MDCG (Medical Device Coordination Group), supporting European Union regulations (EU) 2017/745 on medical devices (MDR) and (EU) 2017/746 on *in vitro* medical devices (IVDR). It was developed in accordance with the conditions and detailed provisions set out in Articles 33-34 of the MDR and Article 30 of the IVDR.

The implementation of the EUDAMED represents a fundamental transformation of regulatory data governance under the IVDR. Its purpose is to act as a central repository for information on device manufacturers, authorized representatives, and the devices themselves. However, it also serves as a regulatory backbone that links device identification, certification, vigilance, and post-market surveillance. It aims to unify and streamline data to improve transparency, traceability, and patient safety across the EU.
Unlike earlier national registers, EUDAMED will make much of the data publicly available. Future public data will include, e.g., device information, certificates, safety notices, and SSP.

EUDAMED operates through six key interconnected modules, including:

- Actor Registration;
- UDI/Device Registration;
- Notified Bodies and certificates issued by Notified Bodies;
- Clinical Investigations and Performance Studies;
- Vigilance and Post-Market Surveillance;
- Market Surveillance.

Following the publication of Commission Decision (EU) 2025/2371 in the Official Journal of the EU on 27 November 2025, and in line with the transitional provisions in Regulation (EU) 2024/1860, the first four EUDAMED modules will be mandatory to use after a six-month transition period:

- Actor registration;
- UDI/Device Registration;
- Notified Bodies and certificates issued by Notified Bodies;
- Market Surveillance.

This marks the first significant milestone in EUDAMED implementation, transitioning the system from voluntary use to mandatory compliance for key data flows.
Manufacturers, authorized representatives, and importers must prepare to register in EUDAMED before 28 May 2026. This transition introduces new expectations regarding:

- Data integrity and traceability across the lifecycle;

- Consistency between technical documentation; labelling, and EUDAMED records;
- Real-time regulatory visibility of device performance and safety.

List of abbreviations

Abbreviation	Meaning
AIDC	Automated Identification for Data Capture
CE	Conformitй Europйenne (European conformity marking)
EUDAMED	European Database on Medical Devices
EU	European Union
FSCA	Field Safety Corrective Action
HRI	Human-Readable Information
IFU	Instructions for Use
IVD	In Vitro Diagnostic Medical Device
IVDD	In Vitro Diagnostic Medical Devices Directive (Directive 98/79/EC)
IVDR	Regulation (EU) 2017/746 on in vitro diagnostic medical devices
MDCG	Medical Device Coordination Group
MDR	Regulation (EU) 2017/745 on medical devices
NB	Notified Body
PMS	Post-Market Surveillance
SRN	Single Registration Number
SSP	Summary of Safety and Performance
UDI	Unique Device Identification
UDI-DI	Unique Device Identifier – Device Identifier
UDI-PI	Unique Device Identifier – Production Identifier
Basic UDI-DI	Basic Unique Device Identifier – Device Identifier
XML	Extensible Markup Language

Background and Regulatory Context

The introduction of Regulation (EU) 2017/746 (IVDR) represents a significant shift in the EU's regulatory framework for *in vitro* diagnostics (IVDs). Unlike the previous *In Vitro* Diagnostic Directive (IVDD), the IVDR is a directly applicable regulation. It aims to harmonize data requirements, thereby enhancing transparency, traceability, and patient safety across Member States. Key factors driving these changes include:

- Limited traceability of devices placed on the market;
- Fragmented national databases and poor data exchange;
- Insufficient PMS and vigilance oversight;
- Inadequate transparency for competent authorities, healthcare professionals, and patients.

Within this context, EUDAMED was established as a key component of the new regulatory framework.

EUDAMED was developed in accordance with the conditions and detailed provisions outlined in Articles 33-34 of the MDR and Article 30 of the IVDR as a centralized EU-wide database to support:

- Traceability of devices through Unique Device Identification (UDI);
- Transparency of device, certificate, and economic operator information;
- Coordination of market surveillance and vigilance activities;
- Regulatory oversight of clinical investigations (MDR) and performance studies (IVDR).

It replaces and greatly expands the scope of earlier national databases, turning them from authority-only repositories into a multi-stakeholder regulatory platform with both restricted and public-facing parts.

Traceability of devices is achieved through the UDI system, which mandates that manufacturers must:

- Assign a Basic UDI-DI, which is a regulatory identifier, to specific devices or groups of devices;
- Assign UDI-DI to all devices and their packaging levels;
- Place the UDI carrier containing UDI-DI and UDI-PI on the device labels or, where possible, on the devices themselves, and on their packaging;
- Upload UDI and device master data into EUDAMED.

EUDAMED's UDI/Device Registration module serves as a centralized source that links devices, economic operators, certificates, and vigilance and post-market surveillance data.

Compared with the *In Vitro* Diagnostic Directive (IVDD), the *In Vitro* Diagnostic Regulation (IVDR) places significantly greater emphasis on transparency and ongoing surveillance throughout the product lifecycle. It's included in:

- Much broader scope, with most *in vitro* diagnostics (IVDs) transitioning from self-certification to requiring oversight from Notified Bodies (NBs);
- Enhanced requirements for performance evaluation and follow-up (PMPF);
- Increased reliance on post-market data to confirm clinical evidence;
- Higher expectations for regulatory visibility of device variants, assay configurations, and intended use.

In this context, EUDAMED facilitates the detection of signals across numerous IVDs, enables trend analysis, coordinates responses by authorities, and enhances the traceability of IVD assays, reagents, and kits.

Originally, EUDAMED was expected to be fully operational by May 2020, with mandatory use starting only after the system was fully available. However, these expectations proved unrealistic, mainly due to system complexity, data model challenges, and governance and testing constraints. As a result, EUDAMED's deployment was delayed for several years, during which interim solutions, including voluntary use, were allowed. To address these issues, the EU introduced legislative amendments that enabled a phased, module-by-module rollout. This approach separated EUDAMED's availability from the completion of the entire system. Under this revised strategy, each EUDAMED module is audited and can be declared functional independently. Once published in the Official Journal, mandatory use applies after a six-month transition period. Currently, the first four modules are functional: Actor Registration, UDI/Device Registration, Notified Bodies and Certificates, and Market Surveillance. These modules will become mandatory in May 2026.

EUDAMED Architecture / Module overview

EUDAMED is a centralized, modular IT system. Its architecture is structured around interconnected functional modules, each addressing a specific regulatory process and sharing common identifiers and datasets, such as Single Registration Number (SRN), Basic UDI-DI, and UDI-DI. This modular design enables end-to-end device traceability, consistent identification of economic operators and devices, cross-linking of certificates, and the linking of surveillance, vigilance, and study data. This approach allows seamless navigation from a device record to its manufacturer, certification status, and post-market history. It also supports progressive implementation through a phased rollout.

EUDAMED comprises six primary modules, supported by a common authentication and user-management framework:

1. **Actor Registration module**

Its main purpose is to uniquely identify and register all economic operators active in the EU medical device and IVD markets. It allows the registration and assignment of a Single Registration Number to manufacturers, authorized representatives, and importers, and links economic operators to devices and certificates. This module serves as the gateway to EUDAMED for economic operators. They must start with this module to obtain a SRN, which is required to register devices or interact with other modules. This module establishes accountability and enables traceability at the organizational level.

2. **UDI / Device Registration module**

This module enables traceability of devices placed on the EU market through the Unique Device Identification (UDI) system. It is used to register devices, including their Basic UDI-DI, UDI-DI, and other device-associated master data, such as device characteristics, intended purpose, and risk class. It links to the economic operators and certificates and supports public and authority-level access. It provides the foundation for linking devices to vigilance reports, market surveillance activities, and corrective actions.

3. **Notified Bodies and Certificates module**

The purpose of this module is to centralize information on conformity assessment activities and certification status. It is intended to register NBs, upload and maintain certificates issued under the IVDR, link certificates to Basic UDI-DIs and devices, and provide information on the scope, validity, and conditions of the certificates. This module enables competent authorities to verify whether a device is properly certified and supports coordinated enforcement and oversight across Member States.

4. **Market Surveillance module**

This module was designed to support competent authorities in planning, recording, and coordinating market surveillance activities. Surveillance actions and findings are documented here, along with cross-references to devices, manufacturers, and certificates. It supports the exchange of surveillance information between authorities, strengthens regulatory cooperation, and enables a more risk-based, data-driven oversight model. This module is authority-facing only, and manufacturers do not interact with it directly.

5. **Vigilance module (not yet mandatory)**

This module is intended to manage reporting and analysis of serious incidents and field safety corrective actions (FSCAs). The key planned features are: submission of vigilance reports by manufacturers, assessment and coordination by the authority, linkage to affected devices and batches via UDI, and public safety communications, where applicable. Once mandatory, this module will significantly facilitate linking incidents, devices, and corrective actions, thereby enhancing the effectiveness of EU-wide vigilance.

6. **Clinical Investigations and Performance Studies module (not yet mandatory)**

This module is intended to support oversight of clinical investigations (MDR) and performance studies (IVDR). The key planned features are: submission and management of study applications, monitoring study status and outcomes, and linking to the devices and their manufacturers under investigation. This module is especially important under the IVDR, where performance studies and post-market performance follow-up play a central role in demonstrating ongoing compliance.

Traceability requirements

Under the IVDR, traceability is no longer limited to internal quality records or recall readiness. It is a foundational element of Regulation (EU) 2017/746 (IVDR) and a prerequisite for effective post-market surveillance, vigilance, and regulatory

enforcement. Under the IVDR, traceability extends beyond basic product identification to encompass the ability to track devices, components, batches, and performance data throughout the entire lifecycle.
The IVDR establishes traceability through three interrelated layers:

1. Internal (manufacturer-level) traceability, including batch/lot numbers, production, suppliers, etc.
2. Supply-chain traceability, including economic operators, distributors, and importers.
3. UDI-enabled regulatory traceability, making connections between UDI, batch/lot numbers, and EUDAMED.

Together, these three layers support fast, easy device identification, risk containment, and coordinated EU-wide surveillance.

- Internal traceability

The IVDR requires manufacturers to maintain documented procedures and records that enable devices to be traced throughout their design, manufacture, and post-market lifecycle. Traceability must be ensured for:

- Device configuration and version history, including assay composition and formulation changes, and software versions, where applicable;
- Raw materials, critical components, and reagents, including calibration materials and controls, where applicable;
- Manufacturing lots/batch records;
- Release and distribution status;
- Linkages between batches and performance or vigilance data, including stability and shelf-life data.

Manufacturers must ensure that their internal systems can correlate performance signals or incidents back to specific batches, configurations, or device variants.

- Supply chain traceability

The IVDR requires not only manufacturers but also other economic operators, including authorized representatives, importers, and distributors, to identify both the supplier and the recipient of each device. It supports fast containment of non-compliant or unsafe devices. According to IVDR requirements, manufacturers must maintain distribution records sufficient to support recalls and FSCAs, while importers and distributors must keep records of suppliers and clients for a defined period after the last device is placed on the market. All economic operators must verify the presence of required identifiers, including UDI where applicable, before placing devices on the market.

In practice, an effective supply-chain traceability system should provide: lot/batch tracking within logistics systems, alignment of shipping documentation with device identifiers, and the ability to rapidly identify potentially affected clients during corrective actions.

- UDI-enabled traceability

The UDI system plays a critical role in standardizing and improving traceability across the EU. UDI comprises:

- Basic UDI-DI, the main regulatory grouping identifier used in conformity assessments and certificates. It is used for regulatory documentation and database records, but it isn't placed on the device labels or packaging;
- UDI-DI, which is the specific device model/version identifier, and is placed on the device labels and packaging along with UDI-PI;
- UDI-PI, a production identifier, includes data such as batch number, serial number, expiry date, and date of manufacture. It is placed on the device labels and packaging along with UDI-DI.

Under the IVDR, manufacturers must affix the UDI carrier to the device label and at relevant packaging levels, ensure that UDI-DI and UDI-PI information supports production-level traceability, and align label content with EUDAMED device data. Therefore, labelling becomes a key interface between physical devices and digital traceability systems.
Effective traceability compliance under the IVDR depends on alignment across all three traceability levels: internal systems, supply chain records, and EUDAMED data.

Labelling requirements

Under the IVDD, labelling was primarily a static compliance requirement. Under the IVDR, it becomes an active regulatory interface, directly connected to EUDAMED and UDI data. The IVDR significantly expands labelling expectations. Label information must be accurate, consistent with the intended purpose and EUDAMED device records, and support downstream traceability, including batch/serial level identification.

The complete list of IVDR labelling requirements is set out in Annex I, section 20.2, and all of these requirements must be met. However, some of the most important ones include the following (this is not a comprehensive list):

- *Device name or trade name;*
- *Details strictly necessary for a user to identify the device and, where it is not obvious for the user, the intended purpose of the device;*
- *Name, registered trade name, or registered trademark of the manufacturer and the address of its registered place of business;*
- *Name of its authorized representative and the address of the registered place of business of the authorized representative (where applicable);*
- *Lot number or serial number;*
- *Storage and/or handling conditions;*
- *Expiry date or date of manufacture;*
- *Any warnings, precautions, and limitations;*
- *Intended use (professional / near-patient testing / self-testing);*

- *UDI carrier (please see more details below);*
- *Applicable conformity markings (CE, Notified Body number).*

Label content must align with Technical Documentation, certificates, the Basic UDI-DI scope, and EUDAMED UDI and device master data. Additionally, the IVDR requires that the label language must comply with national requirements.
One of the mandatory elements on the label under the IVDR is the UDI carrier. It must be placed on the device label and on all higher packaging levels. The UDI must be presented in plain text (Human-Readable Information - HRI) and in a form that uses AIDC (Automated Identification for Data Capture) technology, e.g., DataMatrix or barcode. The UDI carrier must remain legible throughout the device's intended lifetime.

Special UDI carrier criteria apply to software devices. If the software is delivered on a physical medium, e.g., a dongle or a CD, each packaging level must bear the HRI and AIDC forms of the complete UDI. The UDI applied to the physical medium containing the software and its packaging must match the UDI assigned to the system-level software. For the software itself, the UDI should be displayed on a readily accessible screen in plain text or included on the start-up screen. Software without a user interface must be able to transmit the UDI through an application programming interface (API). Only the human-readable part of the UDI is required on the software's electronic displays.

The UDI carrier placed on the device must contain UDI-DI and UDI-PI components. The UDI-PI enables production-level traceability, including batch number / lot number / serial number and expiry date / manufacturing date. It must support the manufacturer's internal traceability and PMS processes.

UDI carriers should be applied to the device itself and to each higher packaging level intended for supply to the user or distributor. Each packaging level is assigned a unique UDI-DI. The manufacturer should clearly define packaging hierarchies in the UDI strategy and ensure they remain consistent with applicable labels and EUDAMED submissions.

Labelling plays a key role in the traceability system under the IVDR. Even minor label changes may require updates to the internal traceability system or EUDAMED. Therefore, the manufacturer must establish and follow an effective label change control process. It should include defined procedures within the QMS, including cross-functional review (with RA, QA, labelling, supply chain, IT, etc. involved) and evaluation of whether, e.g., proposed label changes affect device safety and performance, intended purpose or claims, UDI data, and EUDAMED records, certificates, and the Notified Body scope. All labelling changes should be fully traceable.

Language requirements

Under Article 10(10) and Annex II 2(a) of the IVDR, labels and IFUs must be provided in the languages accepted in the Member States where the device is intended to be sold. Each Member State may require one or more official national languages, allow exemptions for specific device types, and/or allow English-only IFUs under limited circumstances. The current language requirements for manufacturers of medical and IVD devices are available on the European Commission website: "Overview of language requirements for manufacturers of medical devices".

Consequently, manufacturers must ensure that labels and IFUs are translated into all required national languages and that country-specific language rules are reflected in distribution and supply-chain controls. In some cases, manufacturers must manage multiple language variants for the same device while maintaining consistency across all regulatory representations. Failure to meet national language requirements is considered non-compliance.

Translated content is still regulatory content and shouldn't be treated as secondary or less important. It has direct implications for the interpretation of the intended purpose, safe and correct device use, the interpretation of vigilance signals, and liability and enforcement actions.

Manufacturers are expected to implement clear and effective translation workflows within their QMS. The translation process should include the use of qualified translators with medical/regulatory expertise, verification or validation of translations, especially for safety-critical content, and change control mechanisms that link the source and translated versions. A single approved source text with traceable links to all translated versions is the recommended approach.

EUDAMED data submissions, including device master data, intended purpose descriptions, and certificate-related information, must be in English, even when market-facing materials are provided in national languages other than English. In practice, English serves as a regulatory reference language. Certain EUDAMED information is publicly accessible, supporting transparency for healthcare professionals, lay users, patients, and competent authorities across the EU. It must be ensured that EUDAMED entries in English accurately reflect the authoritative meaning of possible multilingual labels and IFUs, and that no contradictions exist between EUDAMED information and national-language materials.

Language affects traceability when, for example, device names or variants are translated inconsistently, product identifiers are combined with language-specific descriptors, or labels differ substantially across markets. As a result, this can cause problems with the correct identification of affected devices, cross-border coordination of FSCAs, or communication with users and authorities. During possible recalls or FSCAs, appropriate communications must be issued in the

appropriate national languages. Errors in translations can slow recall or FSCA execution, increasing residual risks and attracting regulatory scrutiny.

Key language-related risk areas include (this is not a comprehensive list):

- Divergent translations of the intended purpose or performance claims;
- Inconsistent safety warnings across languages;
- Inconsistency between EUDAMED English data and national-language labels or IFUs;
- Poor control of labels/IFUs updates/changes across multiple languages;
- Inadequate translation of recall or FSCA communication.

Manufacturers should assess these and other potential language-related risks and implement appropriate control measures. Possible risk mitigation strategies include, e.g., defining a clear, detailed language strategy aligned with market distribution plans, maintaining a single, controlled source document for regulatory content, implementing translation validation and review processes, integrating language management into labelling change control and UDI governance, and preparing multilingual recall and FSCA templates in advance.

Current status

On 27 November 2025, the European Commission published Commission Decision (EU) 2025/2371 in the Official Journal of the EU, confirming that the following four EUDAMED modules meet the legal functional specifications required under the IVDR regulatory framework and declaring them fully functional:

- Actor Registration
- UDI/Device Registration
- Notified Bodies and Certificates
- Market Surveillance

This decision triggers the transition period for mandatory use under Regulation (EU) 2024/1860, which amended the IVDR provision to allow a phased, module-by-module rollout rather than waiting for all modules to be fully functional before any become mandatory.

Based on the above decisions and regulations, the current mandatory rollout timeline is as follows:

27 November 2025| Decision published confirming full functionality of the four modules

28 May 2026 | Mandatory use of the four modules begins after the 6-month transition:

- Actor Registration
- UDI/Device Registration

- Notified Bodies and Certificates
- Market Surveillance

28 November 2026| Deadline to register legacy devices that remain on the market before the mandatory date in the UDI/Device module

28 May 2027 | Deadline by which Notified Bodies must upload certificates issued prior to 28 May 2026, and associated data into the Certificates module.

After 28 May 2026, national device registries and notification systems will no longer be used and will be replaced by modules implemented in the EUDAMED database.
While the four EUDAMED modules above are now fully functional, the remaining two are still under development and are not yet mandatory. These are:

1. Vigilance and Post-Market Surveillance module, intended to manage safety reports, FSCAs, trend reporting, and post-market surveillance coordination. No official functional declaration date has been provided yet.
2. Clinical Investigations and Performance Studies module, intended to manage submissions, tracking, and reporting of clinical investigations (MDR) and performance studies (IVDR). No official functional declaration date has been provided yet.

Manufacturers, authorized representatives, and importers must complete Actor registration and obtain a Single Registration Number by 28 May 2026. This is required to register new devices before they are placed on the market from 28 May 2026, and to register legacy devices still on the market by 28 November 2026. To avoid potential complications, manufacturers should coordinate with their Notified Bodies to ensure that certificates and relevant updates are uploaded to EUDAMED. Notified Bodies have an extended period to upload legacy certificate data (by 28 May 2027).

On the other hand, Notified Bodies must transition from national systems to EUDAMED for certificates and other associated data management (by 28 May 2026 for ongoing certificate data entry, including certificates issued, amended, suspended, withdrawn, or refused; by 28 May 2027 for legacy certificate data).

Challenges

EUDAMED is intended to enhance traceability, transparency, and regulatory oversight. However, its implementation introduces significant operational, technical, and organizational challenges, especially for manufacturers with complex portfolios and multi-market distribution models.

EUDAMED demands structured, interconnected data across various modules. The volume and depth of data to be uploaded are significantly greater than those

needed for national registries. This elevates the risk of submitting incomplete or inconsistent data or of misalignment between regulatory, quality, and commercial datasets. Errors or omissions in EUDAMED can cause delays in market access and result in more intensive review by authorities.

Particular challenges arise when registering legacy devices. Historical data may be incomplete, inconsistent, or available in non-structured formats. Certificates issued under previous directives (MDD/IVDD) may not align with EUDAMED data structures. These shortcomings increase the risk of inaccuracies. Getting legacy device data right and ready to upload to EUDAMED can be a difficult and time-consuming task.

Another challenge may arise from shortcomings in internal data governance and unclear ownership of regulatory master data. Sometimes, different organizational units within the same manufacturer possess and use their "own" datasets that are not properly controlled and are inconsistent with the current "true" datasets. This can result, e.g., in inconsistencies between device names uploaded to EUDAMED and those in IFUs, labels, SSPs, and/or other technical documents. Such cases must be identified and resolved to avoid regulatory problems.

Label and language complexity may be another challenge. Under the IVDR, labels and IFUs must be provided in the languages required by Member States, while EUDAMED submissions are in English. A multilingual environment creates new challenges, especially when managing updates across multiple translations and maintaining semantic consistency across language versions. Language discrepancies can raise regulatory concerns, especially when authorities use EUDAMED data as a reference.

UDI implementation introduces additional complexity. Grouping devices under Basic UDI-DIs remains very problematic for many manufacturers. Ensuring correct placement and formatting of UDI-DI and UDI-PI, maintaining consistency with UDI/device data in EUDAMED, and managing UDI carriers across multiple packaging levels make labelling management even more challenging.

Traceability gaps and their resolution are another challenging area for manufacturers. If batch/lot/serial number tracking isn't fully digitized, the product lifecycle is fragmented across departments, and/or legacy systems don't support UDI linkage, achieving full, easy internal traceability may be very difficult. Also, supply-chain traceability may be problematic due to multiple economic operators, varying digital maturity across them, and inconsistent data exchange mechanisms. The use of consistent identifiers by all economic operators in the supply chain is critical, especially if corrective actions or recalls are necessary.
Many manufacturers use separate IT systems for regulatory information management, product lifecycle management, and/or manufacturing and labelling. Integrating or at least coordinating these platforms can be operationally

challenging, which can lead to manual data entry, delays in data updates and corrections, and increased error rates.
In addition to the simplest user interface and manual data entry, EUDAMED also supports structured submissions in XML format. It can facilitate the manufacturer's work, particularly with large volumes of data, but implementing and validating these data-input methods requires strong technical expertise, ongoing maintenance, and alignment with evolving guidance and technical specifications. This may be problematic, especially for smaller organizations.

Achieving compliance with EUDAMED obligations is not a one-time project. It is an ongoing operational requirement that involves multiple departments, including regulatory affairs, quality assurance, IT and data management, labelling, and supply chain management. Effective implementation and maintenance of EUDAMED requirements also require new competencies. Special training may be necessary to understand and become familiar with EUDAMED data models and workflows, UDI governance and traceability principles, and cross-functional coordination among regulatory, IT, and operations teams.

The main challenges related to implementing EUDAMED include not only meeting formal requirements but also (and mostly), ensuring data quality, language consistency, traceability integrity, and organizational readiness on a continuous basis.

Best practices

To manage the operational and regulatory complexity introduced by EUDAMED, manufacturers must move beyond "reactive" compliance. Ongoing proactive planning, structured data governance, strong cross-functional coordination, and well-defined language management are key to success.

The first step is usually to identify devices subject to the IVDR requirements. Some manufacturers have a broad portfolio, and certain products may not appear to be medical or IVD devices. It is then worth distinguishing legacy devices from new or transitioned products and mapping certificate status, UDI readiness, and labelling maturity.

The best practice is not to wait until the deadline, but to conduct pre-submission validation checks against EUDAMED rules, prepare a "pilot" data set as soon as possible, and submit it to EUDAMED to ensure everything goes smoothly. If any problems arise with the data or their preparation, there is still time to fix them. If everything is OK, it is still better to submit the remaining data well before the mandatory dates to avoid any unexpected issues. Periodic reconciliation of EUDAMED records with internal systems, along with a formal review of public EUDAMED data for accuracy and consistency, is strongly recommended. Data governance must be ongoing, not limited to initial submissions.

Additionally, label changes should be managed through an integrated process that includes assessing the impact on UDI and EUDAMED data, triggering timely EUDAMED updates as needed, and coordinating translations and market release timing.

As mentioned earlier, manufacturers should define and maintain a single authoritative source for device identifiers and names, label and IFU content, UDI and packaging hierarchies, and intended purpose and risk classification.

Effective EUDAMED compliance depends on defining data owners for each EUDAMED data domain, establishing accountability for data accuracy, completeness, and timelines, and establishing mechanisms to resolve potential data conflicts. This governance structure should be embedded within the QMS and supported by management oversight.

Also, good coordination among all departments involved, including Regulatory Affairs, Quality, IT, Labelling, and Supply Chain Management, is critical to reducing rework and ensuring that regulatory decisions are operationally feasible.

Structured, early coordination with Notified Bodies is always useful for aligning on device naming and/or identification, confirming certificate data structures and scope representation in EUDAMED, and clarifying responsibilities for data submission and maintenance. Additionally, regular reconciliation of internal certificate records with EUDAMED entries, coordinated planning for certificate amendments, renewals, or withdrawals, and clear communication pathways for resolving discrepancies are strongly recommended, especially during the transition period for legacy certificates.
A market-specific language matrix is typically very useful for keeping easily accessible and up-to-date information on the required label and IFU languages for each Member State, permitted exemptions or English-only allowances, and any differences between professional use and self-testing devices.

An appropriate translation process and control measures ensure consistent translations, which are critical for meeting EUDAMED, traceability, and labelling requirements. As mentioned earlier, a single controlled source language for regulatory content should be defined, and formal review and validation of safety-critical translations are strongly recommended. Approved terminology and translation glossaries may also be very useful for maintaining consistent translations.

Conclusion and future outlook

The rollout of EUDAMED under the IVDR marks a major shift in the regulation, oversight, and transparency of IVD devices across the EU. While traceability and

labelling were mainly handled at the national level and document-based responsibilities under IVDD, they are now integral parts of a unified, data-driven regulatory system. Maintaining data accuracy and consistency has become key to achieving compliance.

These changes led to increased regulatory scrutiny and clearer expectations for data governance, language management, and cross-functional coordination.
The challenges discussed throughout this white paper (including data quality, multilingual labelling complexity, traceability gaps, system integration, and resource constraints) require sustained investment and ongoing operational discipline rather than a one-time fix.

The full regulatory impact of EUDAMED will continue to unfold with the future implementation of the two remaining modules and will especially influence performance studies, vigilance, and post-market surveillance activities. When these modules become mandatory, the linkage between traceability, labelling, safety reporting, and regulatory oversight will tighten further, reinforcing EUDAMED's role as the primary reference system for EU authorities. At the same time, public transparency is expected to increase, placing greater emphasis on the accuracy and consistency of the information provided by manufacturers.

In this changing environment, organizations that adopt a proactive, systematic strategy for EUDAMED readiness will be better equipped to stay compliant and uphold their regulatory credibility. EUDAMED serves not only as a necessary requirement under the IVDR but also as a driver for better regulatory data quality, enhanced market surveillance, and greater trust in the safety and performance of IVDs throughout the EU.

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