EUDAMED PRACTICAL GUIDE

Understand the challenges and complexities of EUDAMED before deploying the ACKOMAS solution effectively and efficiently.

Dear readers,
Welcome to this practical guide to loading product data into EUDAMED, the European Commission's IT system for the management of medical devices and *in vitro* diagnostic medical devices.
This guide is designed to help you use this essential regulatory database.
You'll find explanations of data requirements, formats, steps and best practices to ensure compliance and accuracy of submitted information.
We hope this guide will help you navigate the EUDAMED data transfer process with confidence.

We would like to express our deep gratitude to all those who contributed to the writing of this document. Their expertise and collaboration were essential to the realization of this project.

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1 INTRODUCTION TO EUDAMED

1.1 Presentation

The EUDAMED (European Database on Medical Devices) database is a European Commission initiative designed to enhance transparency and coordination in the field of medical devices within the European Union (EU).

1.1.1 Objective of the EUDAMED database.

EUDAMED's main objective is to improve the transparency and safety of medical devices in Europe. It aims to :

- **Provide public access** to detailed information on medical devices marketed in the EU,
- **Facilitate monitoring** and traceability of medical devices,
- **Improve coordination** between the competent national authorities of EU member states,

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- **Enhance patient safety** by providing information on clinical incidents and investigations,

1.1.2 Products concerned

EUDAMED covers a wide range of medical devices, including :

- **General medical devices**: such as implants, surgical instruments and diagnostic equipment,
- ***In vitro* diagnostic (IVD) medical devices**: used to analyse biological samples (blood, urine, etc.) for medical diagnosis,
- **Active implantable medical devices**: such as pacemakers and insulin pumps,
- **The "System/Procedure Pack (SPP)**" according to EUDAMED terminology are defined by MDR 2017/745 regulation, article 22, which takes up the definitions of Directive 93/42/EEC, article 12. These definitions are as follows:
    - A "System" is a combination of products, packaged together or separately, intended to be interconnected or combined to achieve a specific medical purpose. For example, X-ray systems,
    - A "Procedure Pack" is a combination of products packaged together and marketed for use for a specific medical purpose. Examples include first aid kits, orthodontic procedure packs and skin traction kits,
- **Non-medical devices (Annex XVI of Regulation (EU) 2017/745).**

It is important to note that these definitions are specific to the European Union and may differ from other regulations around the world, such as those of the FDA in the United States.

"The term "Medical Devices" (MD) shall be understood for medical devices within the meaning of Regulation 2017/745 and for *in vitro* diagnostic medical devices within the meaning of European Union Regulation 2017/746.
This expression therefore includes :

- General medical devices,
- Implantable devices,
- *In vitro* diagnostic devices & accessories,
- Non-medical devices (Annex XVI of EU Regulation 2017/745),
- Systems & Procedure Packs (SPP).

1.1.3 EUDAMED database features

EUDAMED is made up of several interconnected modules that enable:

- **Registration of economic operators** (manufacturers, assemblers, importers, agents),
- **Registration of medical devices** and their characteristics,
- **Management of incidents and vigilance reports**,
- **Follow-up of clinical investigations**,
- **Access to CE conformity certificates** and summaries of safety and clinical performance characteristics.

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In short, EUDAMED is an essential database for guaranteeing the safety and transparency of medical devices in Europe, while facilitating access to information for healthcare professionals and the general public.

1.2 Regulations (EU) 2017/745 and 2017/746

The MDR (Medical Device Regulation) and IVDR (*In Vitro* Diagnostic Regulation) are European Union regulatory frameworks designed to guarantee the safety and efficacy of medical devices and *in vitro* diagnostic medical devices. Here's an overview of these regulations and of the CE marking:

1.2.1 MDR Regulation (EU) 2017/745

The MDR regulation concerns medical devices and was adopted to replace Directive 93/42/EEC (MDD or "Medical Device Directive"), and Directive 90/385/EEC (active implantables). It aims to:

- **Enhance patient safety** by imposing stricter requirements for post-market surveillance and clinical evaluation,
- **Improve traceability** of medical devices through the introduction of Unique Device Identification (UDI),
- **Harmonize standards** across the EU to facilitate access to the European market.

1.2.2 IVDR Regulation (EU) 2017/746

The IVDR regulation applies to *in vitro* diagnostic medical devices and replaces Directive 98/79/EC. Its objectives include :

- **Guarantee the reliability and safety of** *in vitro* diagnostic tests,
- **Reinforce clinical performance** and post-marketing surveillance **requirements**,
- **Facilitating innovation** while maintaining high safety standards.

1.2.3 CE marking

CE marking is a compulsory certification for medical devices and *in vitro* diagnostic devices marketed in the EU. It indicates that the product complies with the essential safety and performance requirements defined by the MDR and IVDR regulations. The steps involved in obtaining CE marking include :

- **Conformity assessment**: Manufacturers must demonstrate that their products meet regulatory requirements through testing and evaluation,
- **Technical documentation**: Manufacturers must prepare detailed documentation including proof of conformity,

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- **Post-marketing surveillance**: Once a product is on the market, manufacturers must continue to monitor its performance and report any incidents.

These regulations aim to ensure that medical and *in vitro* diagnostic devices are safe and effective for patients and users in Europe.

1.3 Overview of EUDAMED regulatory database modules

The EUDAMED database is made up of six interconnected modules, each with specific functions to ensure the transparency and safety of medical devices in the European Union. Here is a description of these modules, their descriptions and the actors involved for each module:

1.3.1 Actor registration module

Description: This module enables the registration of economic operators (manufacturers, assemblers, importers, authorised representatives) and competent authorities. Each actor receives a unique registration number (SRN), which facilitates the identification and traceability of medical devices.
Stakeholders involved :

- ✓ Manufacturers,
- ✓ Assemblers: system and procedure pack producers,
- ✓ Authorised representatives,
- ✓ Importers.

1.3.2 Device registration module and UDI database

Description: This module is dedicated to medical device registration and management of unique device identifiers (UDIs). It enables each device to be tracked throughout its lifecycle, ensuring complete traceability.
Players involved in medical device registrations:

- ✓ Manufacturers,
- ✓ Assemblers: system and procedure pack producers.

Nota Bene: Authorised representatives and importers have read-only access to the UDI database. They cannot register manufacturers' or assemblers' devices.

1.3.3 Certificates and notified bodies module

Description: This module contains information on CE conformity certificates issued by notified bodies. It can be used to check the validity of certificates and ensure that devices meet regulatory requirements.

Stakeholders involved :

- ✓ Notified bodies

Nota Bene: Notified bodies are registered as Actors in this module, not in the "Actors" module.

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1.3.4 Clinical investigations and performance studies module

Description: This module manages data relating to clinical investigations and performance studies for medical devices. It tracks clinical trials and ensures that devices are safe and effective before they are put on the market.
Stakeholders involved :

- ✓ Manufacturers,
- ✓ Sponsors.

The competent authorities of EU member states and the European Commission can access these data.

1.3.5 Vigilance and post-marketing surveillance module

Description: This module is used to report and track incidents relating to medical devices after they have been placed on the market. It enables device performance to be monitored and corrective action to be taken if necessary.
Stakeholders involved :

- ✓ Manufacturers,
- ✓ Authorised representativves (on behalf of manufacturers).

Importers must inform manufacturers and the relevant authorities, but they are not directly involved in this module.

The competent authorities of EU member states and the European Commission can access these data.

1.3.6 Market surveillance module

Description: This module facilitates coordination between competent authorities for the market surveillance of medical devices. It enables information to be shared on inspections, controls and measures taken to ensure device conformity.
Stakeholders involved :

- ✓ Competent authorities of EU member states.

The competent authorities of EU member states and the European Commission can access these data.

Basic UDI-DI is the key between the various modules for medical device traceability in the EUDAMED database. Its main features are :

1. **Main identifier** : It groups together and represents a family of medical devices with the same purpose and the same essential characteristics.
2. **Label-independent**: Unlike UDI-DI, Basic UDI-DI does not appear on the product label.
3. **Regulatory use**: It is used in regulatory documentation, such as certificates, declarations of conformity, and technical documentation.
4. **Traceability**: Connects devices with the same purpose, risk class, and essential design and manufacturing features.
5. **Database**: This is the main key in the EUDAMED database for linking medical device information.

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These criteria ensure clear identification and effective traceability of medical devices on the European market.

1.4 EUDAMED Benefits and Perceptions of Manufacturers

EUDAMED offers several advantages for medical device manufacturers, and their perception is generally positive, although some challenges remain.

1.4.1 Benefits for manufacturers:

1. **Greater transparency**: EUDAMED improves the transparency of information on medical devices, which can boost the confidence of users and healthcare professionals.
2. **Traceability and safety**: The database enables better device traceability, making it easier to manage recalls and corrective actions.
3. **Market access**: By complying with EUDAMED requirements, manufacturers can access the European market more easily, by demonstrating the conformity of their products.
4. **Improved coordination**: EUDAMED facilitates coordination between different EU member states, which can simplify regulatory procedures for manufacturers.

1.5 EUDAMED what public access?

Public access to EUDAMED is designed to offer greater transparency while protecting certain sensitive information. Here are the main restrictions:

1. **Accessible information**: The public can access data on medical devices, including information on safety and clinical performance.
2. **Restricted information**: Certain sensitive data, such as confidential business details and personal information, are not accessible to the public.
3. **Specific modules**: Vigilance, market surveillance and clinical investigation modules contain information that may be partially restricted to protect patient confidentiality and safety.

These measures aim to strike a balance between transparency and the protection of sensitive information.

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2 UDI-DI MODULE

2.1 Main information required for a device in EUDAMED

To register a medical device in EUDAMED, manufacturers must provide a certain amount of essential information. Here are the main data requirements:

- ✓ **Basic UDI-DI**: Main identifier for a family of medical devices.
- ✓ **UDI-DI**: Unique identifier for each medical device.
- ✓ **The main elements making up the UDI-PI** (Production Identifier), including the batch or serial number.
- ✓ **Trade name(s)**: Trade names, models and part numbers/catalogues of the device.
- ✓ **Device classification**: Medical device risk class.
- ✓ **Device description**: Detailed description of the device, including its technical features and intended use.
- ✓ **Manufacturer information**: Name, address and contact details of the legal manufacturer.

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- ✓ **Authorized representative**: If applicable, details of authorized representative.
- ✓ **Importer information**: Name, address and contact details of importer.
- ✓ **Target market**: Countries where the device is or will be marketed.
- ✓ **CE certificate details**: Information on CE certificates, including issue and expiry dates.
- ✓ **EMDN code**: European Medical Device Nomenclature (EMDN) code.

This information guarantees the traceability, safety and conformity of medical devices on the European market.

And, in some cases, submission to the notified body for confirmation of device data.

Nota Bene: a medical device corresponds to a set of data. Some of these data attributes are mandatory in EUDAMED, while others are optional or conditional. The data set represents the EUDAMED data model and may vary when EUDAMED versions are upgraded.
Manufacturers will focus on mandatory data and seek to improve its quality on the basis of an EUDAMED data dictionary linked to data in their wider information system.

2.2 What are the characteristics of an UDI in EUDAMED?

UDI (Unique Device Identifier) is a standardized identification system for medical devices, designed to improve patient safety and healthcare efficiency. Its definition and main features are as follows:

2.2.1 Definition of UDI

The UDI is a unique code made up of two main parts:

- ✓ **Device Identifier (UDI-DI)**: Fixed part of the UDI that identifies the manufacturer and the specific version or model of a device.
- ✓ **Production Identifier (UDI-PI)**: Variable part of the UDI which can include information such as batch or serial number, expiry date, and date of manufacture.

2.2.2 Main features of the UDI

- ✓ **Unique identification**: Each medical device is assigned a unique UDI code, enabling it to be distinguished from other devices.
- ✓ **Labeling**: The UDI must be affixed to the device label, its packaging, and, if possible, directly on the device itself. It is presented in both human-readable format (plain text) and machine-readable format (barcode and RFID added where appropriate).
- ✓ **Traceability**: UDI enables the device to be tracked throughout its distribution chain, from manufacture to end use.
- ✓ **Reduced errors**: By providing a clear, unique identifier for each device, UDI helps reduce medical errors caused by misidentification or confusion between similar devices.
- ✓ **Facilitating recalls**: In the event of a device recall, the UDI enables affected devices to be quickly identified and located in the supply chain or in care facilities.

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- ✓ **Improved supply chain management**: UDI helps healthcare providers and manufacturers better manage device inventory, track device usage and streamline procurement processes.
- ✓ **Support for post-market monitoring**: UDI is used to collect and analyze data on device performance and safety, enabling more effective post-market monitoring and research.

These features ensure clear identification and effective traceability of medical devices, contributing to patient safety and market transparency.

2.3 What are the four issuing entities?

The issuing entities recognized by European regulations and in EUDAMED for assigning unique device identifiers (UDIs) are as follows:

- ✓ **GS1**: International organization that develops and maintains global standards for trade between trading partners, including the barcodes used for UDIs.
- ✓ **HIBCC (Health Industry Business Communications Council)**: Organization that provides standards for the identification of healthcare products, including UDIs.
- ✓ **ICCBBA (International Council for Commonality in Blood Banking Automation)**: Organization that manages the ISBT 128 system, used to identify biological products, including medical devices.
- ✓ **IFA (Informationsstelle für Arzneispezialitäten)**: Organization providing coding systems for the unique identification of pharmaceutical products and medical devices.

GS1 is used for barcodes and unique device identifiers (UDIs) in many countries.
The UDI-DI corresponds to GS1's GTIN (Global Trade Item Number).

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2.4 What are the characteristics of a BASIC UDI in EUDAMED?

UDIs (Unique Device Identifiers) with the same Basic UDI-DI share several common features. A Basic UDI-DI can be linked to several UDI-DIs, but a UDI-DI is linked to one and only one Basic UDI-DI.
Here are the main features

Characteristics of IDUs with the same Basic UDI-DI:

- ✓ **Identical purpose**: Devices grouped under the same Basic UDI-DI have the same purpose of use,
- ✓ **Similar essential features**: They share the same essential design and manufacturing features,
- ✓ **Risk class**: Devices belong to the same risk class,
- ✓ **Regulatory documentation**: Basic UDI-DI is used in regulatory documentation, such as certificates, declarations of conformity and technical documentation,
- ✓ **The same legal manufacturer**,
- ✓ **The same notified body** (if applicable).

Basic UDI-DI can be found as a primary key in EUDAMED, in MDR/IVDR technical documentation, on CE certificates and EU declarations of conformity, as well as in Vigilance (MIR, FSCA, FSN, Trend Reports).

Basic UDI-DI corresponds to GS1's GMN (Global Model Number). The GMN is a maximum 25-character code.

While the UDI-DI must be printed on the product in the form of a barcode and a clear marking, the Basic UDI-DI must never appear on device labelling.

2.5 What are the conditions for a change of UDI-DI?

A new UDI-DI is required in the event of product modification with a risk of misidentification of the device or ambiguity in its traceability.

Among the attributes resulting in a change of UDI-DI are:

- Name or trade name,
- Device version or model,
- Labelled as single-use,
- Sterile packaging,
- Must be sterilized before use,
- Number of devices supplied in one package,
- Critical warnings or contraindications: for example, containing latex or DEHP,
- Software (MDCG 2018-5).

Nota Bene: A change in these attributes is most often linked to a major change in the physical device, from the device itself to its packaging (commercial) and associated documents (IFU).

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2.6 Modification of UDI-DI data in EUDAMED

It is important not to confuse the modification of a product resulting in a new "UDI-DI" with the modification of data corresponding to a UDI-DI attribute in EUDAMED.
However, few attributes can be modified in EUDAMED once the data has been published with a registered status. Each modification, when possible, leads to the creation of a new version in EUDAMED.

***Nota Bene**:*

- *It is possible to delete an unregistered UDI-DI ("Draft") in EUDAMED.*
- *It is also possible to mark a UDI-DI as "Discarded" in EUDAMED. In this case, the UDI-DI still appears in the history. However, this operation must be carried out manually (no automated processing in M2M).*

2.7 EUDAMED deployment and database access

2.7.1 Modules operational in Q1/2025

Four EUDAMED modules are operational and can be used without obligation, although their use is strongly recommended:

- Player Registration" module, open since December 2020,
    - Player registration is possible on the basis of the SRN (Single Registration Number).
- Medical Device Registration" module, available since September 2021,
- Notified bodies and certificates" module.

The commissioning of all modules as a prerequisite for its compulsory use was lifted in the summer of 2024 by Regulation (EU) 2024/1860 amending Regulations (EU) 2017/745 and (EU) 2017/746 with regard to a gradual deployment of EUDAMED.
An EUDAMED module can be put into service once it has been deemed operational, i.e. developed, functional, audited and validated.
Thus, in the event of publication in the OJEU of the Commission's opinion on the functionality of the UDI/DEV module on July 1, 2025, medical devices would have to be registered by July 1, 2026. The exact date, however, depends on publication in the EU Official Journal.

2.7.2 Initial overview of registration procedures

Manufacturers and Systems & Procedure Pack producers must register the company in the Actor module before registering medical devices.
Once approved by the authorities, the SRN number is issued. It must be mentioned in the technical documentation and declaration of conformity.
Only manufacturers and producers of Systems & Procedure Packs can access the Devices module to register products in EUDAMED.
Devices must be registered in EUDAMED before Vigilance declarations can be registered.

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2.7.3 Legacy devices

Legacy devices are medical devices covered by a certificate under the old European directives (MDD), which continue to be placed on the market after the date of application of the new European regulations (MDR/IVDR) and which benefit from the conditions linked to the transitional periods.

In cases where they are registered in EUDAMED,

- The Basic UDI-DI must be different from that used under MDR/IVDR regulations, with one Basic UDI-DI per certificate or,
- EUDAMED-DI can be used as a Basic UDI-DI; it is formed by adding the prefix "B" to the existing device identifier,
- Basic UDI-DI and legacy devices have a 1:1 relationship, i.e. 1 Basic UDI-DI for 1 legacy device only.

2.7.4 Initial mandatory requirements on January 1, 2026 (if Official Journal publication on 01/07/25)

Regulation (EU) 2024/1860 has enabled a gradual roll-out of EUDAMED modules, contrary to what was envisaged in the initial regulations.

A module will thus become mandatory 6 months after the audit has confirmed its functionality, and after publication in the Official Journal of the European Union (OJEU) of the Commission's opinion on the functionality of the UDI/DEV module. To date,

- Four modules are developed,
- One module (Vigilance) has a development deadline of late 2024,
- The last one (Clinical Investigations & Performance Studies) is under study.

It is reasonable to assume that the Devices module (UDI/Dev) will be mandatory from January 1, 2026 for some cases, and from July 1, 2026 for all others.

2.7.4.1 EUDAMED registration schedule (Medical device data)

The new regulation (EU) 2024/1860 has clarified the EUDAMED registration timetable, as modules are validated independently of each other.

The EUDAMED registration schedule stipulates that:

- If a device is an "old device" or a "custom-made device", then it does not need to be registered, except in the case of a vigilance action,
- If a device has been registered under MDR/IVDR, then the same device under MDD, the legacy device, does not need to be registered, except in the case of a vigilance action
- If the device under MDR/IVDR is placed on the market for the first time 6 months after the date of publication in the OJEU of the Commission's opinion on the functionality of the UDI/DEV module (i.e. January 1, 2026 if publication in the OJEU on July 1st, 2025), it must be registered immediately,
- If the device under MDD/IVDD or MDR/IVDR was placed no later than 6 months after the date of publication in the OJEU of the Commission's opinion on the functionality of the UDI/DEV module (i.e. January 1, 2026 if publication in the OJEU is on July 1st July 2025), then it must be registered no later than 12 months after the date of publication in the OJEU (i.e. July 1, 2026 if publication in the OJEU is on July 1st, 2025), unless the device under private label is no longer marketed.

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<u>Nota Bene:</u> There is some confusion between the EUDAMED registration timetable and the transition period timetable. As the deadlines for transition periods are further apart, it is often assumed that those for EUDAMED registration are also further apart. This is an incorrect assumption.

2.7.4.2 Timetable for transition periods (physical medical devices)

Transitional periods enable manufacturers of medical devices that comply with European directives (MDD/IVDD) to continue marketing their products while complying with European regulations (MDR/IVDR). These periods vary according to the type of medical device and its main class.

The date of the transition period applies to the manufacturer, who must therefore have sold out of private label medical devices by this date. This date does not apply to distributors, since the legal entity bearing the notion of legal manufacturer is not a distributor.

EUDAMED represents a significant step forward in the regulation of medical devices in Europe, improving the safety, transparency and traceability of medical devices. It plays a crucial role in the current regulatory framework, ensuring continuous monitoring and facilitating manufacturers' compliance with new European regulations.

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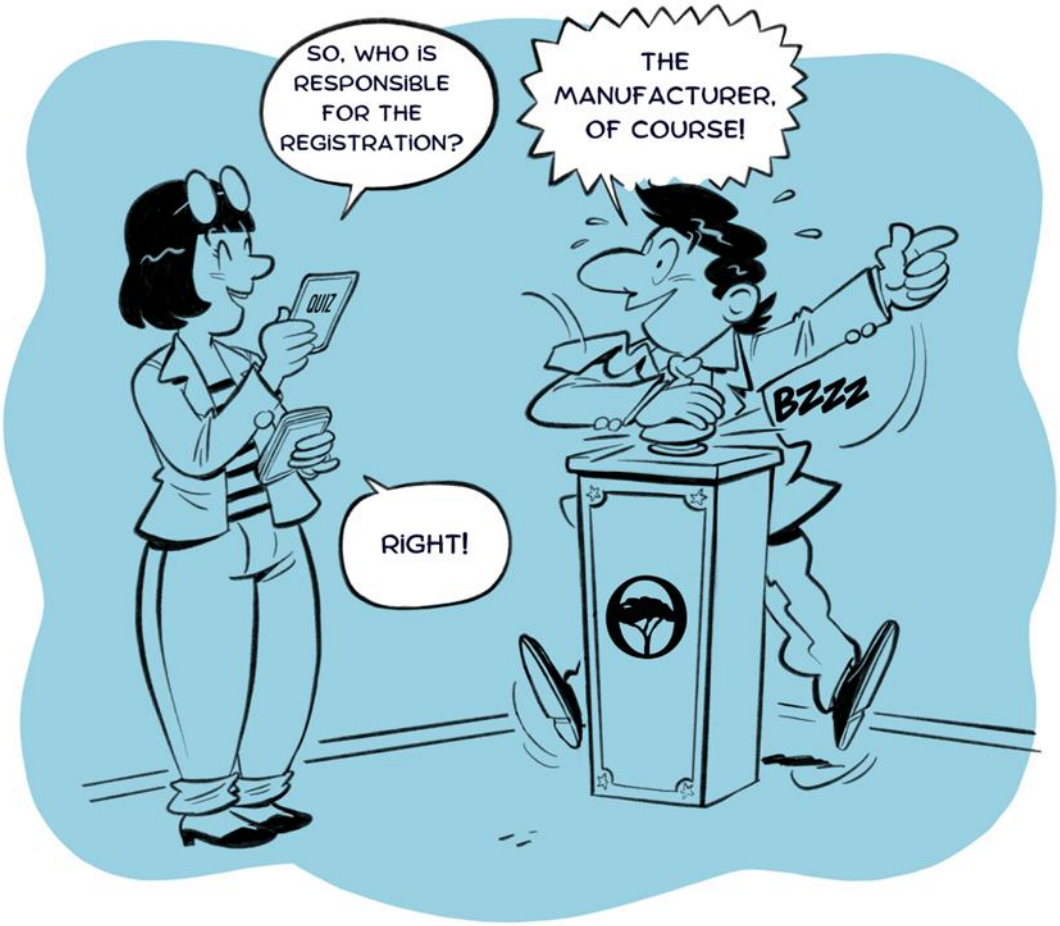

3 ROLES AND OBLIGATIONS OF EUDAMED ACTORS

EUDAMED concerns all stakeholders involved in the life cycle of medical devices in the European Union.

3.1 Which actors are required to register with EUDAMED (Actor module)?

1. **Legal manufacturers** (in the legal sense of the term, not the production site):
   - ✓ **Description**: A legal manufacturer, according to the Medical Device Regulations (MDR/IVDR), is the natural or legal person responsible for the design, manufacture, packaging and labelling of a medical device, before it is placed on the market under its own name.
   - ✓ **Obligations** :
     - Register in EUDAMED as an Actor,
     - Register their medical devices in EUDAMED,
     - Submit information on their MDR/IVDR compliance to the competent authorities (notified bodies where applicable),

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- Report serious incidents, trend reports, FSN (Field Safety Notice) and FSCA (Field Safety Corrective Action), periodic reports if implemented, and PSURs (Periodic Safety Update Report).

2. System/Procedure Pack Producers:
   - ✓ **Description**: A "system/procedure pack producer", as defined in Article 22 of the Medical Device Regulation (MDR), is a natural or legal person who combines CE-marked medical devices with other devices or products to place them on the market as a "system/procedure pack".
   - ✓ **Obligations** :
     - Register in EUDAMED as an Actor,
     - Register system/procedure pack in EUDAMED.
3. **Authorised representatives**:
   - ✓ **Description**: An authorised representative is a natural or legal person appointed by a medical device manufacturer located outside the European Union to act on its behalf in regulatory matters relating to its devices in the European Union. The registered office of the representative must be in the European Union.
   - ✓ **Obligations** :
     - Register in EUDAMED as an Actor,
     - Ensure in practice that the manufacturer has fulfilled its regulatory obligations.
4. **Importers** :
   - ✓ **Description**: An importer is a person or entity who brings medical devices into the European Union from a third country.
   - ✓ **Obligations** :
     - Register in EUDAMED as an Actor,
     - Check regulatory compliance of medical devices,
     - Check the accompanying documentation, at least the leaflet and label,
     - Take responsibility in the event of non-compliance,
     - Market surveillance,
     - Ensure traceability throughout the supply chain.

3.2 Which actors cannot register in EUDAMED (Actor module)

5. **Distributors** :
   - ✓ **Description**: Any natural or legal person in the supply chain, other than the manufacturer or importer, who makes a medical device available on the market, up to the point of commissioning.
   - ✓ **Obligations** :
     - Check regulatory compliance of medical devices,
     - Ensure traceability throughout the supply chain,
     - Monitoring and communicating with economic players and authorities,
     - Manage the storage and distribution of medical devices,
     - Check accompanying documents.

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As a distributor cannot register as an Actor in EUDAMED, its responsibilities must be based solely on access to public information.

Nota Bene: The health authorities, relying on the MDCG, have been able to ask distributors to question the classification of a "border" product (DM vs. drug), taking into account its use and the information provided on the package leaflet.

6. **Competent authorities:**
   - ✓ **Description**: Competent Authorities are the national regulatory bodies for medical devices in each member state of the European Union. They are responsible for monitoring and enforcing medical device regulations, including Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR).
   - ✓ **Roles of the competent authorities:**
     - Market surveillance: They monitor the conformity of medical devices placed on the market,
     - Incident assessment: They evaluate serious incidents and corrective safety actions,
     - Inspection and audits: They carry out inspections and audits of manufacturers, importers and distributors,
     - Registration and certification: They oversee the registration of medical devices and certification by notified bodies,
     - Communication: They communicate with other competent authorities, the European Commission and economic players.

   In France, for example, the Agence nationale de sécurité du médicament et des produits de santé (ANSM) is the competent authority for medical devices.

7. **Notified bodies.**
8. **Healthcare professionals.**
9. **Patients and the general public via the EUDAMED WEB platform.**
10. **Sponsors of clinical investigations or performance studies.**

Only manufacturers ("Manufacturer") and assemblers ("System/Procedure Pack Producer" or "SPPP") are authorized to create or modify a record in the Medical Devices module of the EUDAMED regulatory database; distributors are excluded.

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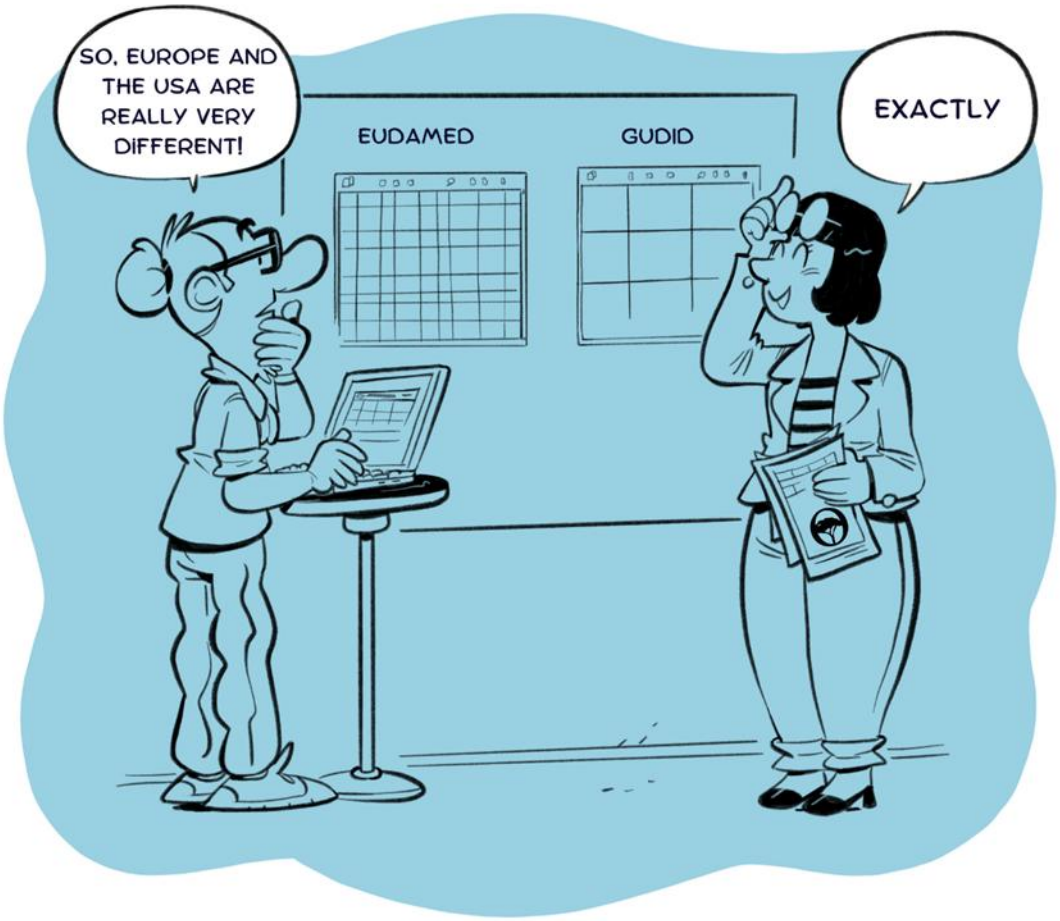

4 EUDAMED & GUDID TWO REGULATORY BASES WRONGLY COMPARED!

4.1 Fundamental differences

Although both concern the monitoring of medical devices, they differ in their regulatory requirements and implementation constraints. The notions of Medical Device (MD) and MD Class are not identical between the USA and the EU. “Consumer” medical devices, for example, do not have to be registered in GUDID, whereas they must be registered in EUDAMED. We can therefore legitimately expect a greater number of medical devices to be registered in EUDAMED than in GUDID when devices are marketed in both territories.

In addition, vocabulary and rules often vary. Here are two examples to illustrate these differences: device assemblies and packaging levels.

Example 1: Terminology of kits/sets (device assemblies)

- ✓ According to Regulation (EU) 2017/745, we speak of systems and kits ("System/Procedure Pack") or configurable medical devices ("Configurable Medical Devices"). Regulation (EU) 2017/746 refers to kits,

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- ✓ In GUDID, assemblies of medical devices are called "kits" or "systems", without any specific definition. FDA UDI guidelines refer to them as "convenience kits".

Example 2: Handling packaging levels

GUDID follows a GS1-compliant approach to logistics, while EUDAMED does not.

4.2 General differences between the two bases

The EUDAMED and GUDID databases have many differences in terms of structure, scope and purpose.

4.2.1 EUDAMED, the European Union database

- ✓ **Structure**: EUDAMED is made up of several interconnected modules, each dedicated to a specific aspect of medical device regulation, such as the registration of economic operators, device surveillance, clinical trials and certificates of conformity.
- ✓ **Scope**: EUDAMED covers all medical devices and *in vitro* diagnostic (IVD) medical devices marketed in the European Union.
- ✓ **Objectives**: To facilitate the implementation of European regulations on medical devices (MDR) and *in vitro* diagnostic medical devices (IVDR), with the main aim of market surveillance and patient safety.

4.2.2 GUDID, the database of the USA

- ✓ **Structure**: GUDID is centered on the Unique Device Identification (UDI) system, with a simpler data model that focuses primarily on UDI information.
- ✓ **Scope**: GUDID covers medical devices marketed in the United States.
- ✓ **Objective**: Improve traceability of medical devices, reinforce patient safety and facilitate product recalls.

4.2.3 Comparison between the two Data Models

EUDAMED and GUDID data models are difficult to reconcile in practice.

- ✓ **Complexity**: EUDAMED's data model is more complex and modular, covering various aspects of medical device regulation and surveillance. In contrast, GUDID has a simpler data model, focusing on the unique identification of devices.
- ✓ **Interconnectivity**: EUDAMED integrates several modules that interact with each other, while GUDID focuses primarily on the collection and management of UDI data.
- ✓ **Regulations**: EUDAMED is designed to meet the requirements of European regulations, while GUDID is aligned with FDA regulations in the USA.

EUDAMED takes a more global, modular approach to medical device management in Europe, while GUDID focuses on device identification and traceability in the USA. EUDAMED's "Medical Device Registration" module, which is more comparable to GUDID in terms of scope, presents increased complexity, notably with the addition of an additional key categorization data: the Basic UDI-DI.

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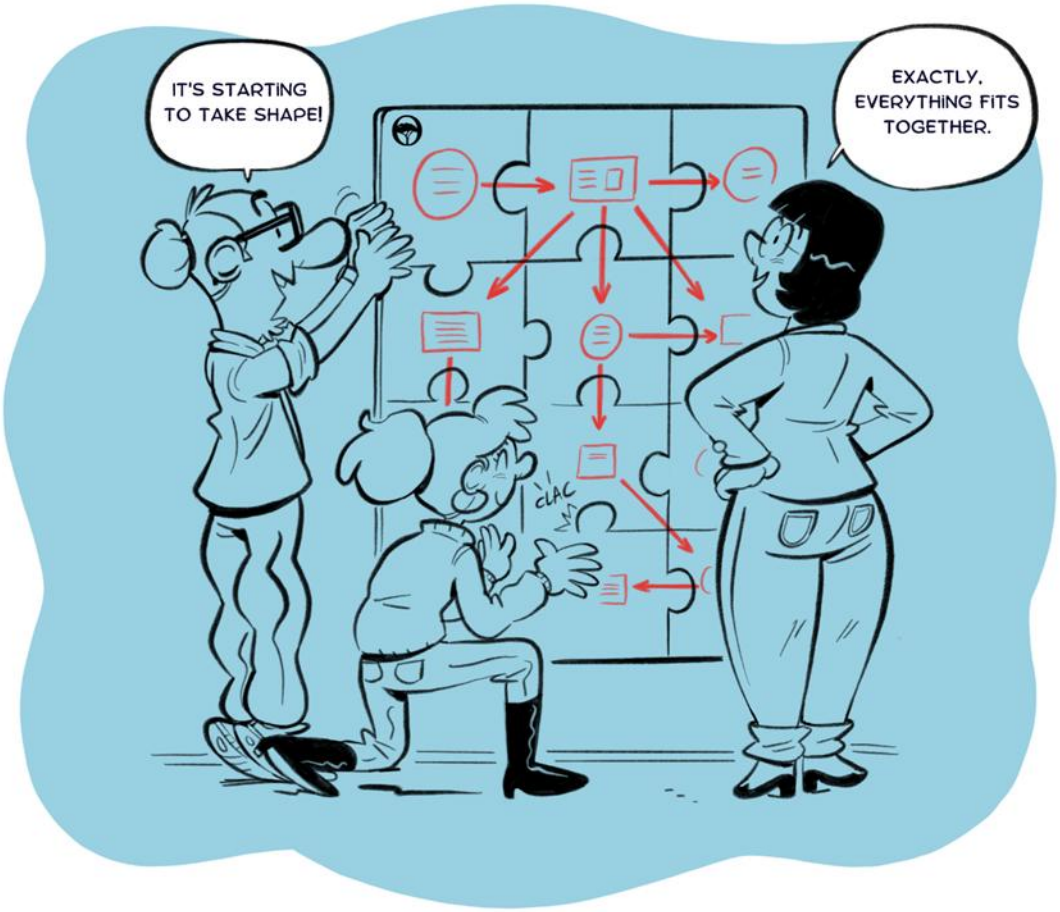

5 FEATURES OF THE EUDAMED DATA MODEL

5.1 An introduction to the European Union's MDR and IVDR regulations

Regulation (EU) 2017/745, also known as the Medical Device Regulation (MDR), was adopted to replace Directives 90/385/EEC and 93/42/EEC. It aims to guarantee a high level of safety and performance for medical devices marketed in the European Union. The regulation introduces stricter requirements for post-market surveillance, device traceability and transparency of information for patients and healthcare professionals.

Regulation (EU) 2017/746, known as the *In Vitro* Diagnostic Medical Devices Regulation (IVDR), replaces Directive 98/79/EC. It establishes a rigorous regulatory framework for *in vitro* diagnostic medical devices, aimed at ensuring their safety and efficacy. The regulation also emphasizes post-market surveillance, traceability and transparency of information.

5.1.1 General data.

- Commercial name: The name under which the device is marketed,

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- UDI-DI code: Unique Device Identification (Device Identifier), as required by Article 27 of the MDR and Article 24 of the IVDR,
- Risk class: According to the classification established in Annex VIII of the MDR and IVDR,
- Device type: Indication of the specific category of medical device (implantable, *in vitro* diagnostic, etc.),
- General description: A brief description of the device's intended use and indications.

5.1.2 Data on economic players

- Manufacturer's name and address: Information required by Article 29(2) of the MDR and Article 26(2) of the IVDR,
- Name and address of representative: Where applicable, for manufacturers not established in the EU, in accordance with Article 11 of both regulations,
- Importer's name and address: As stipulated in Article 13 of the MDR and IVDR,
- Name and address of assembler (system and kit manufacturer): According to the requirements of article 22 of the MDR.

5.1.3 Medical Device Data

- Product features: Including size, composition, and materials used,
- Clinical data: Information on clinical data or clinical investigations carried out, in compliance with Article 61 of the MDR and Article 56 of the IVDR,
- Instructions for use: In accordance with Annex I, Chapter III of the MDR and IVDR,
- Labelling: Labelling content as required by Annex I, section 23 of the MDR and IVDR,
- Expected life: If applicable, the expected life or useful life of the device,
- Storage conditions: Any specific conditions for storage and handling.

5.1.4 Information on certificates and regulatory compliance

- CE certificates: Details of certificates issued by notified bodies, including certificate numbers and date of issue, as stipulated in Article 56 of the MDR and Article 51 of the IVDR,
- Declaration of conformity: In accordance with Article 19 of the MDR and Article 17 of the IVDR,
- Information on conformity assessments: According to the procedures detailed in Annexes IX, X, and XI of both regulations.

5.1.5 Information on vigilance and post-marketing surveillance

- Serious incident reports: In accordance with Article 87 of the MDR and Article 82 of the IVDR,
- Periodic Safety Update Reports (PSUR): Mandatory for Class IIa devices and above, under Article 86 of the MDR, and Class D for IVDs under Article 81 of the IVDR,
- Safety corrective action: Details of any Field Safety Corrective Action (FSCA), in accordance with Article 89 of the MDR and Article 84 of the IVDR,
- Trend reports.

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5.1.6 Recording data in EUDAMED

- Initial registration: Manufacturers must register information on devices before they are placed on the market, in accordance with Article 29 of the MDR and Article 26 of the IVDR,
- Periodic updates and revisions required by regulations (actor module only): Information must be updated without delay, particularly in the event of significant changes or incidents, as required by Article 31 of the MDR and Article 28 of the IVDR.

5.1.7 Registration requirements

5.1.7.1 Concerning data on economic operators

The following economic operators: Manufacturer, assembler, importer, authorized representative, have one week to publish or update the operator registration data published on EUDAMED (article 31 paragraphs 4 & 5).

- Article 31: Paragraph 4: "Within one week of any change occurring in relation to the information referred to in paragraph 1 of this Article, the economic operator shall update the data in the electronic system referred to in Article 30."

- Article 31: Paragraph 5: "Not later than one year after submission of the information in accordance with paragraph 1, and every second year thereafter, the economic operator shall confirm the accuracy of the data. In the event of a failure to do so within six months of those deadlines, any Member State may take appropriate corrective measures within its territory until that economic operator complies with that obligation."

5.1.7.2 Concerning device data

- Article 29 device registration - paragraph 4: "Before placing a device on the market, other than a custom-made device, the manufacturer shall enter or if, already provided, verify in Eudamed the information referred to in Section 2 of Part A of Annex VI, with the exception of Section 2.2 thereof, and shall thereafter keep the information updated.".

The EUDAMED registration process is essential to ensure compliance with the stringent requirements of the MDR and IVDR regulations. Manufacturers and other stakeholders must ensure that all information is accurate, complete and up-to-date, to guarantee the safety and performance of medical devices on the European market.

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5.2 The new regulation (EU) 2024/1860

As a reminder, it is important not to confuse the transition period, which is the date up to which a (physical) medical device can be sold by a manufacturer, with the registration period, which is the date from which device data must be registered in EUDAMED.

Note: the registration dates given assume publication in the Official Journal of the EU on July 1, 2025; this is the most likely scenario.

5.2.1 Recording periods for medical device data

Medical devices newly placed on the market after January 1, 2026 will have to be registered in the Devices module (UDI/DEV) from the outset, before they are placed on the market.
Medical devices placed on the market before January 1, 2026 must be registered in the Devices module (UDI/DEV) by July 1, 2026 at the latest, if they are still on the market at that date.

Legacy devices (MDD/IVDD) must therefore be registered in the EUDAMED Devices module by July 1, 2026 in the case of publication in the European Official Journal (OJEU), except:

- If the same device under MDR/IVDR has been registered or,
- If the legacy device is no longer on the market by January 1, 2026,
- For old and custom-made devices.

Nota Bene: These exceptions do not apply to vigilance actions.

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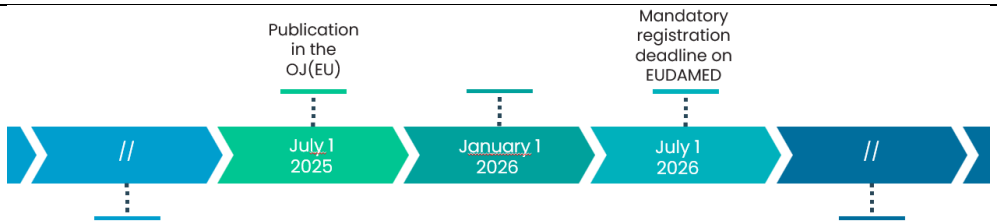
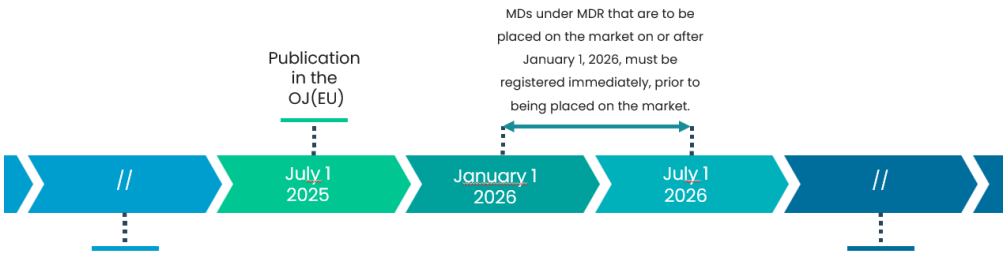
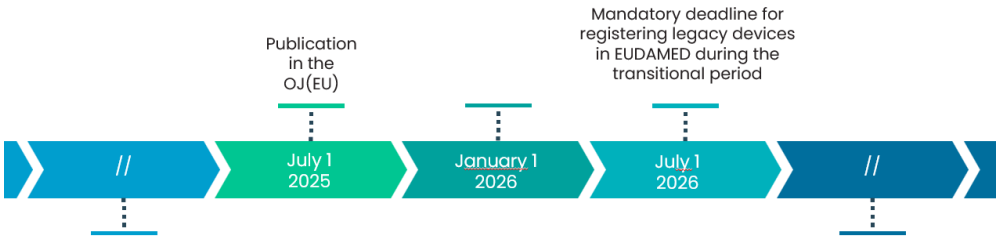
MDR/IVDR devices before January 1, 2026	
MDR/IVDR devices after January 1, 2026	
Legacy MDD/IVDD devices under transition period	

5.2.2 Transitional periods for medical devices on the EU market

Regulation (EU) 2023/607, published on March 15, 2023, and Regulation (EU) 2024/1860, published on June 13, 2024, amend the regulations on medical devices (MDR) and *in vitro* diagnostic medical devices (IVDR). This regulation aims to reinforce the safety and availability of medical devices, in particular in response to supply chain disruptions and delays in the development of certain modules of the EUDAMED database.

5.2.2.1 Transitional periods for medical devices and assemblies

The transitional periods for medical devices (excluding *in vitro* diagnostic devices) covered by certificates are:

- **Until May 26, 2026** for Class III custom-made implantable devices,
- **Until December 31, 2027** for implantable classes III and IIb (with the exception of certain devices such as sutures and staples),
- **Until December 31, 2028** for other classes IIb, Ia, Is/m (including class I requiring intervention by a notified body).

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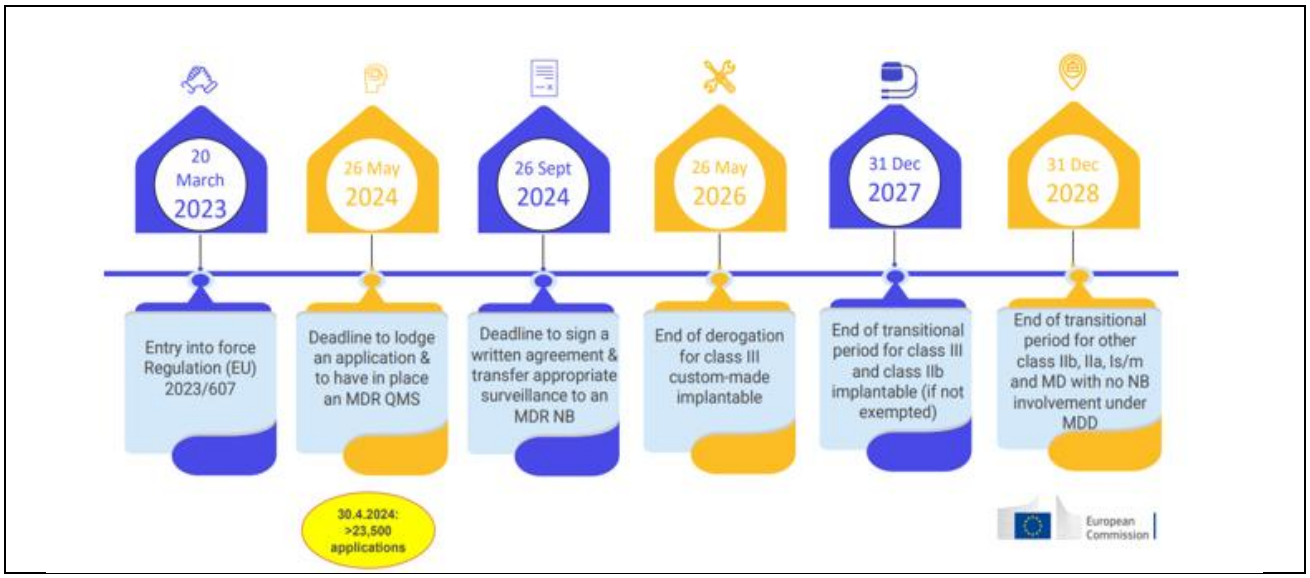

5.2.2.2 Extension of initial transition periods for in vitro diagnostic (IVD) medical devices

The transitional periods for *in vitro* diagnostic devices are related to several requirements. The manufacturer needs to lodge a formal application with a notified body in accordance with Section 4.3, first subparagraph, of Annex VII for conformity assessment:

- **Before May 26, 2025**, for devices covered by the IVDD certificate and Class D devices,
- **Before May 26, 2026**, for Class C devices,
- **Before May 26, 2027**, for Class B devices and Class A sterile devices.

And, if a written agreement is signed between the manufacturer and the notified body:

- **Before September 26, 2025**, for devices covered by the IVDD certificate and Class D devices,
- **Before September 26, 2026**, for Class C devices,
- **Before September 26, 2027**, for Class B devices and Class A sterile devices.

These transition periods **are extended** under the following extension conditions:

- Continued compliance with the requirements of Directive 98/79/EC,
- No significant changes in design or intended use,
- No unacceptable health/safety risks,
- IVDR quality management system in place from May 26, 2025,
- Application for conformity assessment of (replacement) device submitted.

The transition periods for devices covered by certificates under Directive 98/79/EC are extended as follows:

- **Until December 31, 2027** for for devices covered by the IVDD certificate and Class D devices,
- **Until December 31, 2028**, for Class C Devices,
- **Until December 31, 2029** for Class B and Class A in sterile condition.

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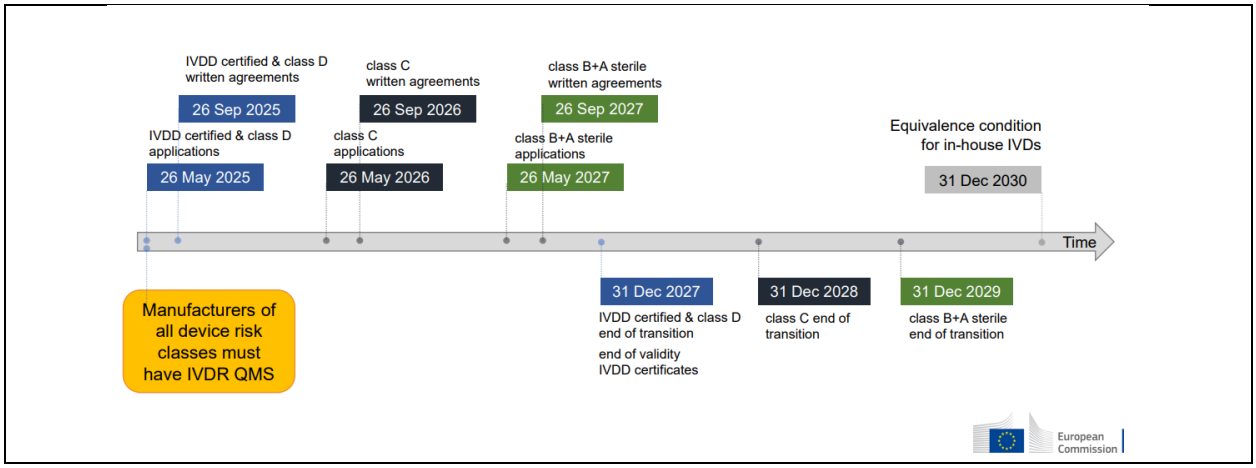
In a nutshell:



5.2.3 Supply chain interruption reports

Manufacturers must report any interruption or cessation of supply of critical devices at least six months in advance, except in exceptional circumstances (Article 10 of amended regulations 2017/745 and 2017/746). This measure aims to avoid public health crises due to shortages.

No registration is expected in EUDAMED but the transmission of a dedicated form: MDCG 2024 - 16 Manufacturer Information Form :
https://health.ec.europa.eu/document/download/919061d9-5dfa-4d0b-ab9b-3543eed98f76_en?filename=md_mdc-2024-16_en.pdf

5.2.4 Progressive implementation of EUDAMED modules

As mentioned above, the EUDAMED European database for medical devices will be implemented progressively, module by module, once each module has been verified and audited (Articles 33 and 34 of the amended regulation). This will enable the functional parts of the system to come into force more quickly, without waiting for the whole system to be operational.

These changes are designed to ensure continuity of supply for medical devices, while guaranteeing patient safety and compliance with the new requirements.

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5.3 Basic UDI-DI and UDI-DI: two key identifiers in EUDAMED

The EUDAMED "Medical Device Registration" module features the new use of two identifiers:

- **UDI-DI** uniquely identifies the medical device; the UDI-DI reference is found on the barcode printed on the product,
- **Basic UDI-DI** which covers a group of products. It is never printed on the product.

The manufacturer is responsible for assigning the Basic UDI-DI.
This implies a real governance of because it is common to the technical files, reviewed to obtain CE marking, and to EUDAMED.
The Basic UDI-DI is common to all EUDAMED modules. As a reminder, this identifier did not exist in earlier regulatory databases such as GUDID in the United States.

Attributes and management rules associated with UDI-DI and Basic UDI-DI are specific to EUDAMED. The most singular of these rules is that a Basic UDI-DI cannot technically be created in the database without at least one UDI-DI attached.

5.3.1 Mandatory key attributes attached to Basic UDI-DI.

The attributes attached to Basic UDI-DI are almost all unchangeable once published.
In addition to attributes that are often Boolean and mandatory, these include :

Attribute	Subject to change after publication	Comments
Basic UDI-DI type	No	
Basic UDI-DI code	No	The Basic UDI-DI code is defined by the manufacturer. The latter is based on the GS1 GMN (Global Model Number) standard.
Applicable regulations	No	Examples: MDR vs IVDR
Risk class	No	European risk class
Name or Model identifying medical devices associated with Basic UDI-DI	Yes	
Certificat	No	For risk classes IIb and III. This attribute opens other attributes such as certificate type, notified body, certificate number and revision number.

5.3.2 Mandatory key attributes attached to the UDI-DI.

Some attributes are common to various regulations; others are specific to EUDAMED.
Some of these attributes are listed in the introduction to the regulations. However, the mandatory attributes (excluding conditional data) used in the "Devices" module and most commonly encountered, have been extracted in the following table.

Attribute	Subject to change after publication	Comments
General		
UDI-DI device code	No	
Entity issuing UDI-DI coding	No	Example: GS1
Code Nomenclature	Yes	EUDAMED list
Device brand name	Yes	Several languages available
Reference / Catalogue number	No	
Marking		
Quantity of device	No	
Usage unit UDI-DI	Yes	If the unit of use is different from the base unit, the UDI-DI code / entity issuing the UDI-DI codification must be mentioned.
Type of UDI-PI	Yes	Examples: "Batch number"; "Serial Number"; "Expiration date" as defined on the label in its PI section.
Use		

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Markets		
Device status	Yes	Several possible values " On the EU market " ; " Not intended for EU market " ; " No longer placed on the EU Market ".
Country	Yes	1 country at least when "on the EU market" is selected
From (date)	Yes	
To (date)	Yes	
First country of sale EU	Yes	
Clinical size		
Substances		
Storage conditions		
Warnings		

A comparison of the attributes of the regulatory bases quickly reveals a wide divergence in the attributes required and in their definition. In this sense, each regulatory base is unique and cannot be derived from a universal model.

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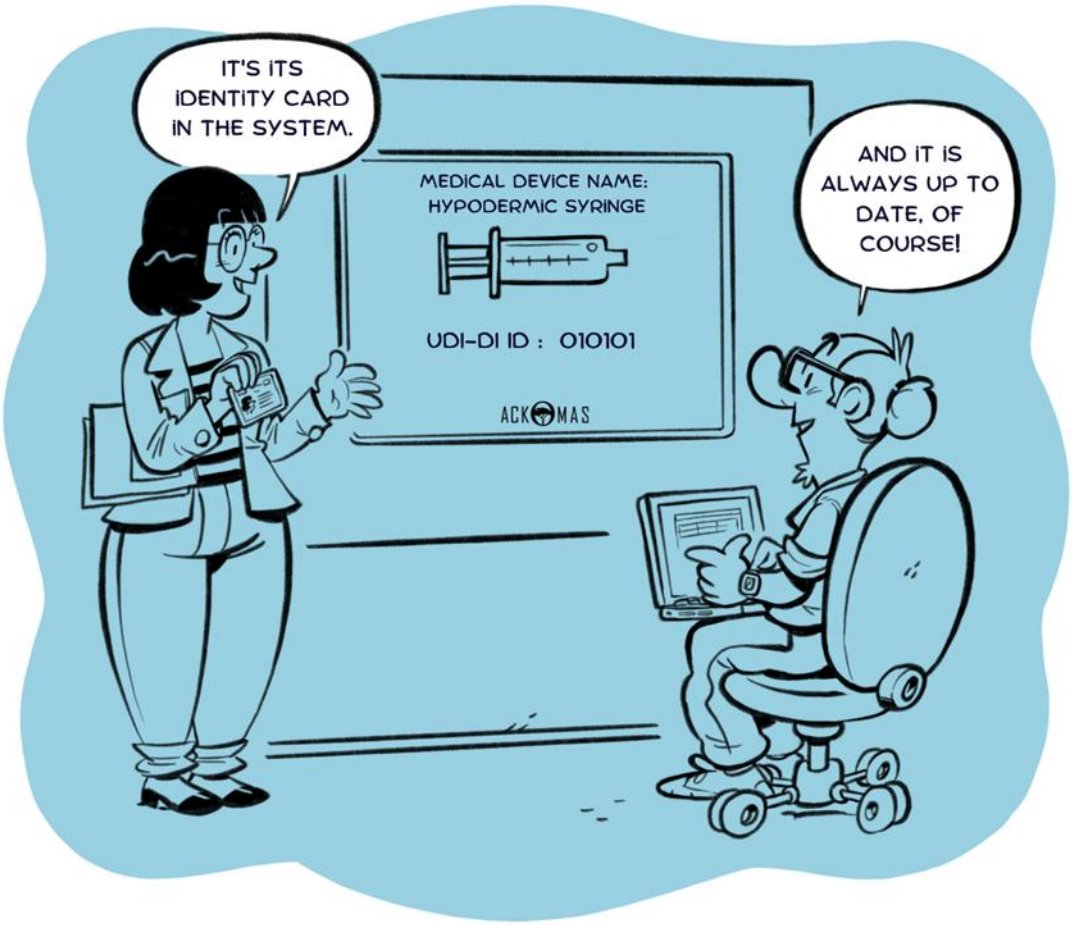

6 HOW TO IDENTIFY YOUR MEDICAL DEVICES IN EUDAMED

The creation of a data model requires several elements to be taken into account. The list of these elements may vary from one company to another, but certain criteria are common to all companies.

Regulations 2017/745 and 2017/746 set out the rules for mandatory changes UDI-DI codification, and in so doing supersede possible recommendations from codification entities.

6.1 Quantifying (counting) medical devices by market

- Identify the medical devices distributed in each geographical area concerned by regulations,
- Determine the volume for each zone in order to estimate the workload involved in collecting the information.

6.2 Checking the correct use of the UDI-DI code in EUDAMED

A UDI-DI must be affixed to the device itself (and its unit of use if applicable), to its packaging or to the medical device's minimum sales unit, and higher packaging levels (excluding logistics units) must have their own UDI.

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The following questions may arise:

- Is my device's UDI used for different primary packaging: for example, separate primary packaging for different markets or different brand names?
- Are grouping boxes of different capacities used (10-product boxes, 20-product boxes, etc.)?
- Do several different grouping boxes intended for different markets (FR, DE, IT, ES...) contain identical cases?

The aim of this research is to identify all the hierarchical product marketing models in the company, in order to create the right data model.

An analysis of the data model is essential, as it can have major consequences for logistics and product identification.
Implementing an incorrect data model will have major consequences for logistics and product identification.
There are profound differences in the rules between EUDAMED and GUDID.

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7 SPECIAL CASES TO BE APPREHENDED

The EUDAMED database contains a wealth of product and market information not found in databases such as GUDID. This has a major impact on registration rules and on the data model to be used for declarations, as well as on the company's logistics management.

7.1 Which barcode for which destination?

AIDC ("Automatic Identification and Data Capture") and HRI ("Human Readable Interpretation") - the regulations refer to "UDI carrier" - lay down the principle that the barcode and its plain text transcription (of the chosen attribution entity) must appear on

- Device label,
- The device itself and,
- All higher packaging levels.

However, if there are space constraints on the unit of use, they must appear on the immediate upper packaging.

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In addition, for individually packaged and labeled Class I and IIa single-use devices, they may appear on the highest level of packaging, unless the user does not have access to this level of packaging.

7.1.1 An unlabeled Unit of Use (UoU) code

The unit of use is assigned so as to associate the use of a medical device with a patient when the UDI does not appear on the unit device (at its level of use), for example when several units of the same device are packaged together. Example: box of catheter plugs.

7.2 The proper use of packaging levels in EUDAMED

EUDAMED allows the management of multiple packaging levels, but strict rules apply: the hierarchical record must not contain duplicate UDI-DI codes in higher levels, so care must be taken with hierarchy identifications.

In addition, EUDAMED does not allow UDI-DI duplicates in higher-level declarations.

If, for example, the following hierarchy is declared:

- **Product UDI-DI "A"** in **case UDI-DI "B"** in **box UDI-DI "C",**

So you can't have a hierarchical statement like the one below for the same UDI-DI :

- **Product UDI-DI "A"** in **case UDI-DI "B"** in **box UDI-DI "D".**

In fact, UDI-DI "B" will be identified as a duplicate during the second registration and will be rejected in EUDAMED.

7.3 27 European countries to consider

In a hierarchical product declaration, the lowest product in the declaration dictates the countries of destination

As a result, a basic product using different cases for different countries of destination cannot be declared hierarchically.

7.4 Assemblies: SPPs, configurable devices, IVD kits

As a reminder, a set containing medical devices or *in vitro* diagnostic devices can be found under different terms in EUDAMED:

- "Procedure pack,
- "System",
- "Configurable device,
- "IVD Kit.

Confusion exists between these terms and is exacerbated when other regulations such as GUDID terms like "Convenience Kit" instead.

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7.5 Legacy Devices (MDD/IVDD) in EUDAMED

7.5.1 Definition of a "Legacy Device"

A legacy device is a medical device that was legally placed on the market under the previous European directives:

- 93/42/EEC (MDD or Medical Device Directive),
- 90/385/EC (active implantables), and
- 98/79/EEC (IVDD or *In vitro* Diagnostic Directive).

And, which benefits from the conditions associated with transition periods.

7.5.2 Legacy devices must be registered in EUDAMED

Legacy devices must be registered in the UDI/DEV module no later than 12 months after the date of publication in the European Official Journal, provided of course that they are still on the market on that date.
However, legacy devices do not need to be registered if the same device is already registered as an MDR/IVDR compliant device.

Note Bene: Devices for which modifications have been made to the regulation-compliant device, resulting in the allocation of a new UDI-DI, would not be considered as "the same device".

However, in the event that a vigilance action concerns the "Legacy device" and not "the same" MDR/IVDR compliant device, the "Legacy device" must be registered in the UDI/DEV module and referenced for the PMSV action to be entered in the VGL module.

Reminder. The dates for compulsory registration of medical device data in EUDAMED should not be confused with the transition periods for physical medical devices on the EU market.

7.5.3 Basic UDI-DI of the "Legacy device" during registration in EUDAMED

A "Legacy Device" cannot use the same Basic UDI-DI as the one used for the device under MDR/IVDR.
Similarly, there is a one-to-one relationship between the UDI-DI and the Basic UDI-DI of the Legacy device.

There are two alternative ways of assigning a basic UDI-DI to a legacy device:

- Use the existing UDI-DI of the "Legacy device", adding the prefix "B-" as a minimum, which is the most common case, or

Generate an EUDAMED DI if the "Legacy Device" has no existing UDI-DI, and use it with the "B-" prefix to build the Basic UDI-DI.

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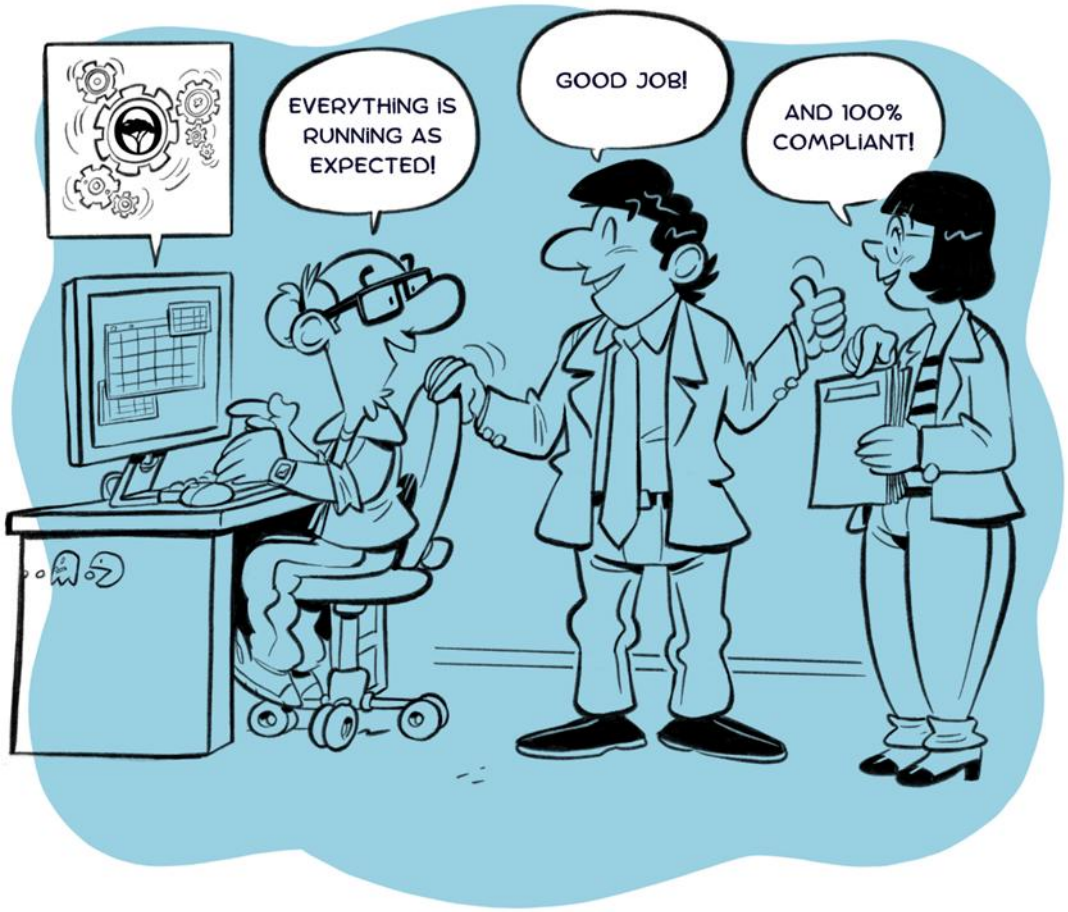

8 SHOULD EXCHANGES WITH EUDAMED BE AUTOMATED?

The volume of medical devices (MDs) is the main criterion: having few MDs means that manual or semi-automatic entry (loading XML files) into EUDAMED can be envisaged.

This criterion must be completed by

- The volume of major modifications to a DM (without change of commercial reference),
- The quality of the data and of the processing, which makes it more or less necessary to correct the data (when this is authorized or possible in EUDAMED).

All other cases require automatic data synchronization with EUDAMED ("machine to machine"). This not only enables data to be created and modified without having to worry about divergent formats or rules specific to EUDAMED.

Traceability and error handling are also features to be carefully investigated before choosing an architecture and a software solution.

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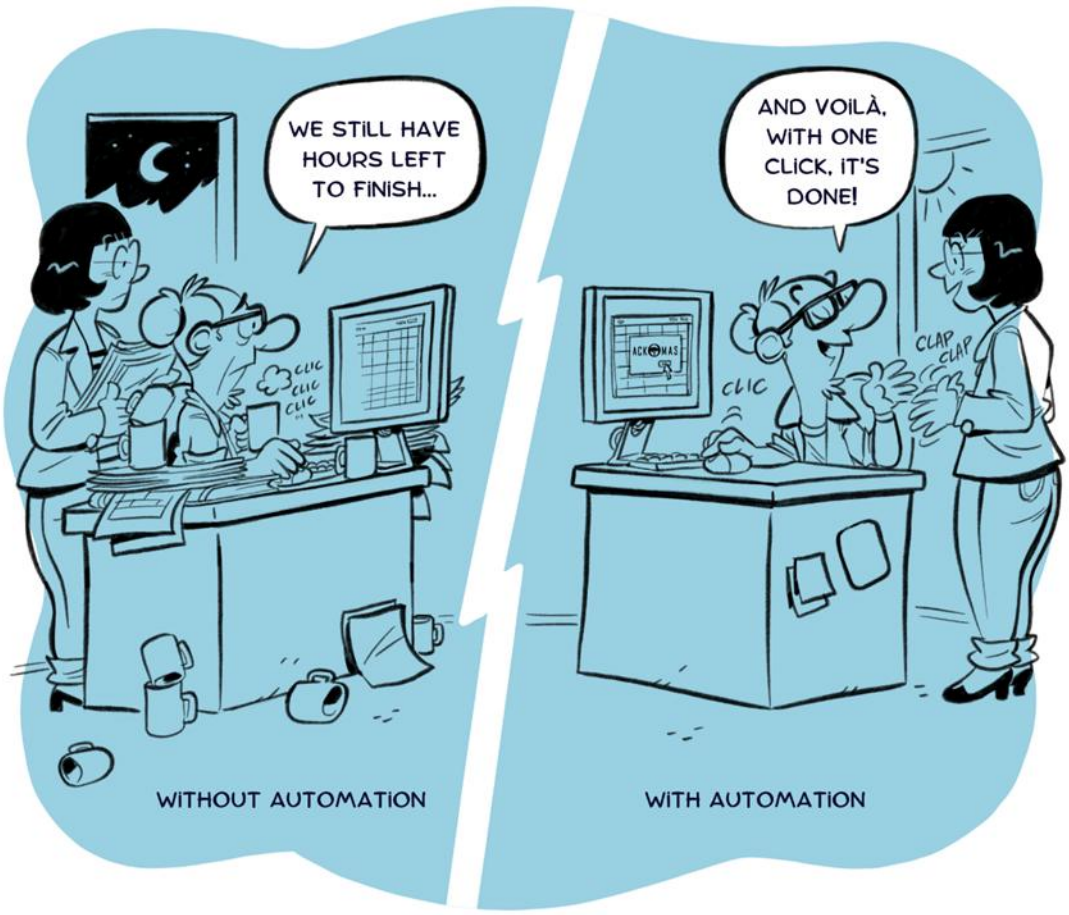

9 THE BENEFITS OF AUTOMATED EXCHANGES?

9.1 Alternative solutions

Several functional architectures are possible, depending on whether or not automation is required:

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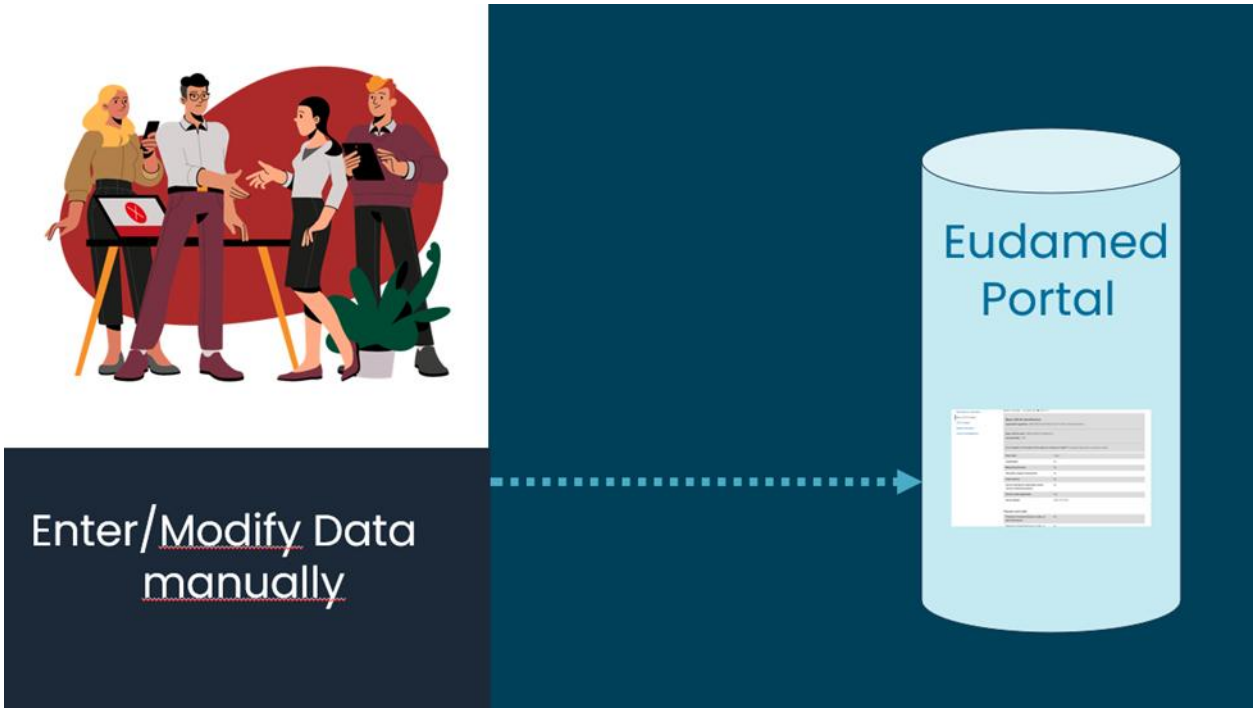
1. **Alternative #1**: Manually enter data directly into the EUDAMED database.



Data capture is the first option for medical device manufacturers marketing their products within the European Union.

The decision to choose such a solution, however rational, should be based on the 3 criteria mentioned above, starting with the low volume of product references sold.

The international marketing perimeter may also be an impediment to manual data entry in the long term, due to the ongoing multiplication of regulatory databases and increasingly complex rules in countries outside the EU.

A more subjective criterion is the availability of resources, particularly when data is not readily available in the manufacturer's information system or is of insufficient quality. It's fair to question the sustainability of a solution designed to mobilize a qualified resource for a low value-added data entry task.
The main objection heard to this criterion concerned the quality of the data expected. It is true that GUDID has set a poor example in this area, with many companies publishing data of insufficient quality (e.g., not updated on time). Current audits show that the American authorities are determined to remedy this situation.

Last but not least, this manual solution makes it impossible to trace data internally.

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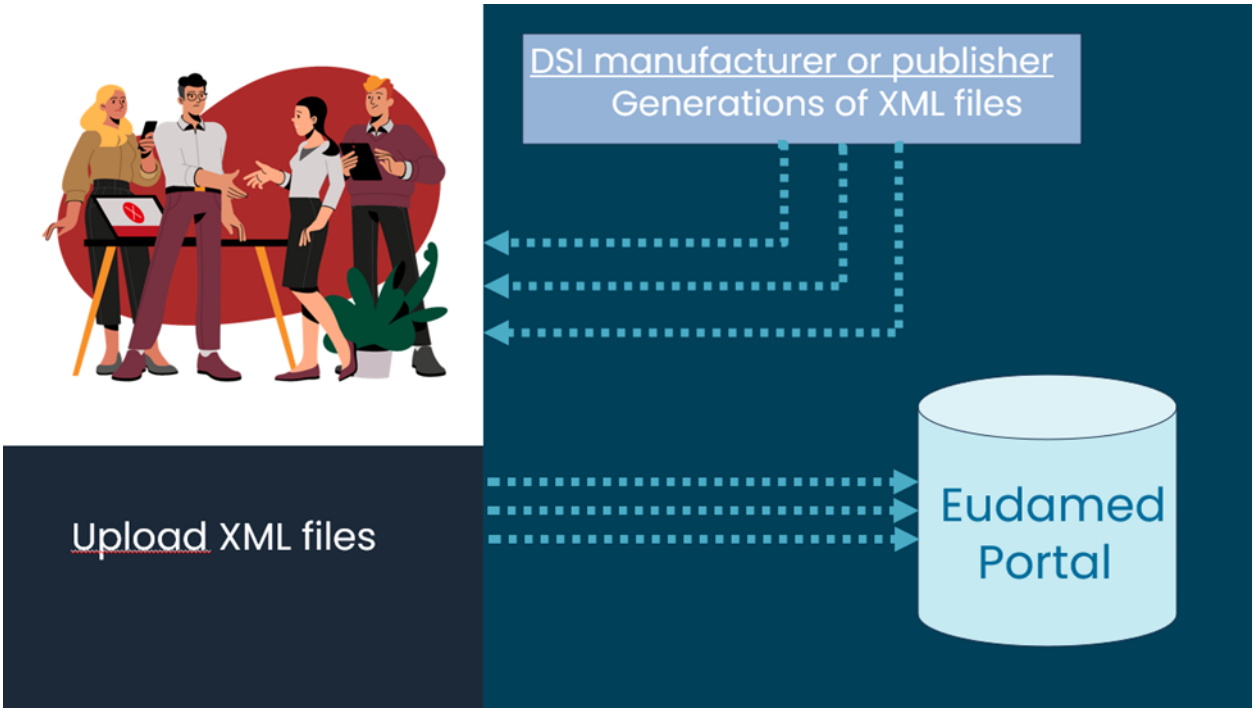
2. **Alternative #2**: Creation of XML files and loading into the EUDAMED database.



It is not possible to load Excel files directly into EUDAMED. This alternative requires the creation of XML files.

The creation of such files can be entrusted to the manufacturer's IT department or to a third-party service provider. It is possible to outsource work, but not the manufacturer's ultimate responsibility.

The manufacturer is responsible for loading the XML file into the EUDAMED database.
Given the large number of EUDAMED file formats, this semi-automatic solution really only concerns data creation in EUDAMED. Modifications, when authorized, are more easily managed manually.

This solution often places the burden of creating the XML file, and sometimes even publishing it, directly or indirectly on the IT department. It also generates a complex analysis of anomalies.

The generation of XML files will have to keep pace with EUDAMED version upgrades, which implies constant monitoring.

Each action, such as initial loading, adding UDI-DI, type of correction etc., is linked to a different XML file format. There are dozens of different XML file formats.

The XML solution has similar constraints to the manual solution, particularly in terms of traceability.

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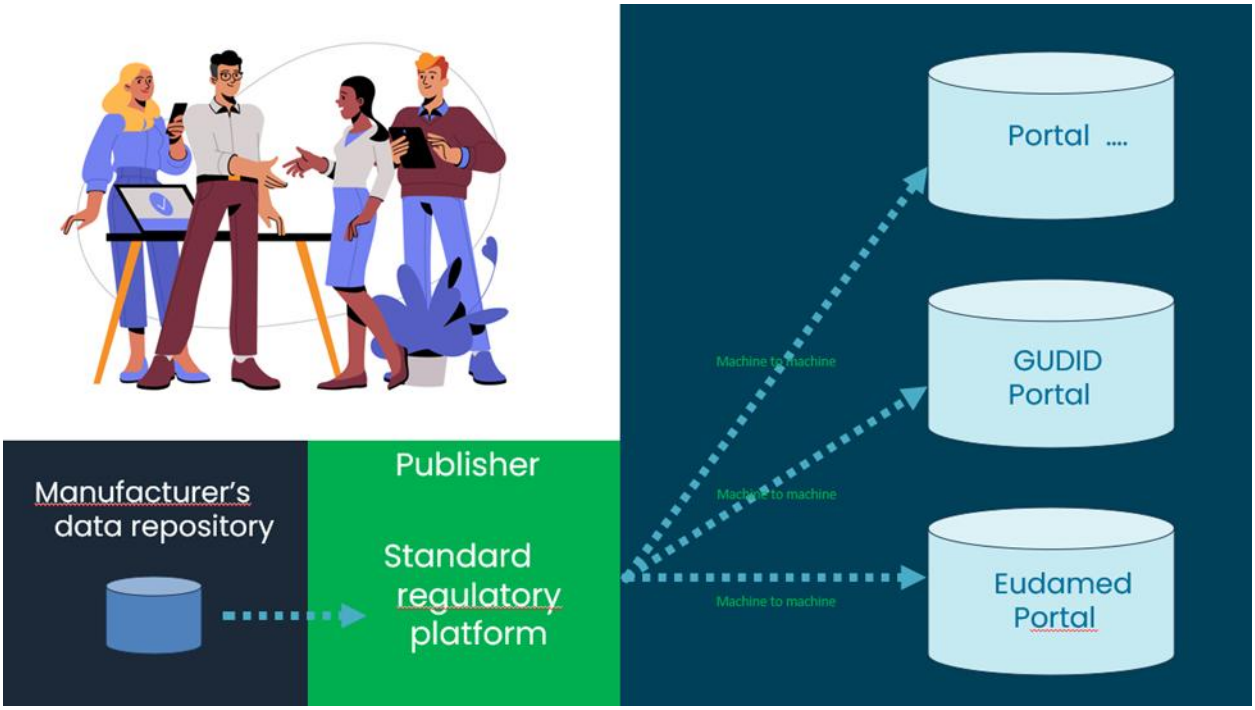
Please note that an XML file expected by EUDAMED **has nothing to do** with an Excel file (XLS) used to collect your data.

3. **Alternative #3**: Use an external regulatory solution and implement an interface between the customer's repository (stable enterprise data model) and this solution.



The platform editor automatically handles synchronization with the EUDAMED database for creation and modification. In this case, and only in this case, we speak of "machine-to-machine" exchanges.

The publisher also takes responsibility for changes in EUDAMED regulations, in the same way as for other regulations where applicable

The data models of the various regulations differ from one another, and the choice of one or more data models on the platform depends on the solution and therefore on the editor. The divergences between regulations, and also between players when a logistical extension is required, make a single model complex to administer, particularly when it comes to applying management rules to data
We can nevertheless encourage the few existing convergences, such as the one between EUDAMED and the Swiss regulatory database SWISSDAMED.

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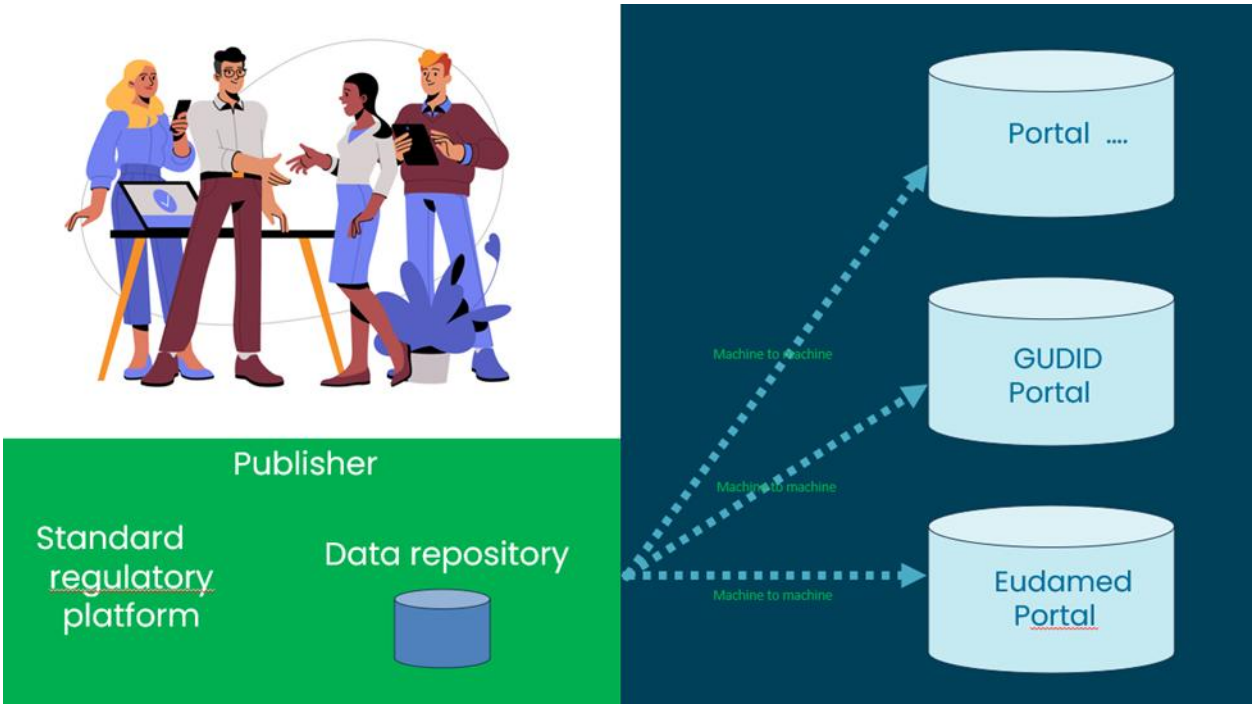
Naturally, the editor can either take charge of the interfaces (often referred to as APIs) between the manufacturer's information system (the repository) and the platform or leave this task to the editor. Among the points to consider when making this choice :

- The ability to keep a close watch on regulations and to carry out development work, which is rarely a manufacturer's main activity,
- Management of notifications and processing of anomalies on the editor's platform, which can then become a repository,
- Data validation in the manufacturer's information system (repository).

4. **Alternative #4**: the customer repository is outsourced to the publisher's platform.



In this case, the solution is based on both a standard and a customer-specific part. Its repository is specific to the customer. Specific developments may also be required to adapt the platform. In this case, specifications (URS) and qualification/validation of the specific system will be required.

Data can be collected by interface, by loading an Excel file or by direct input, and a workflow for validating data and preparing publications (for synchronization with the EUDAMED database in particular) must be taken into account.

5. **Alternative # 5** the customer develops his own EUDAMED (machine to machine) connector and, if necessary, wants compatibility with other regulations.

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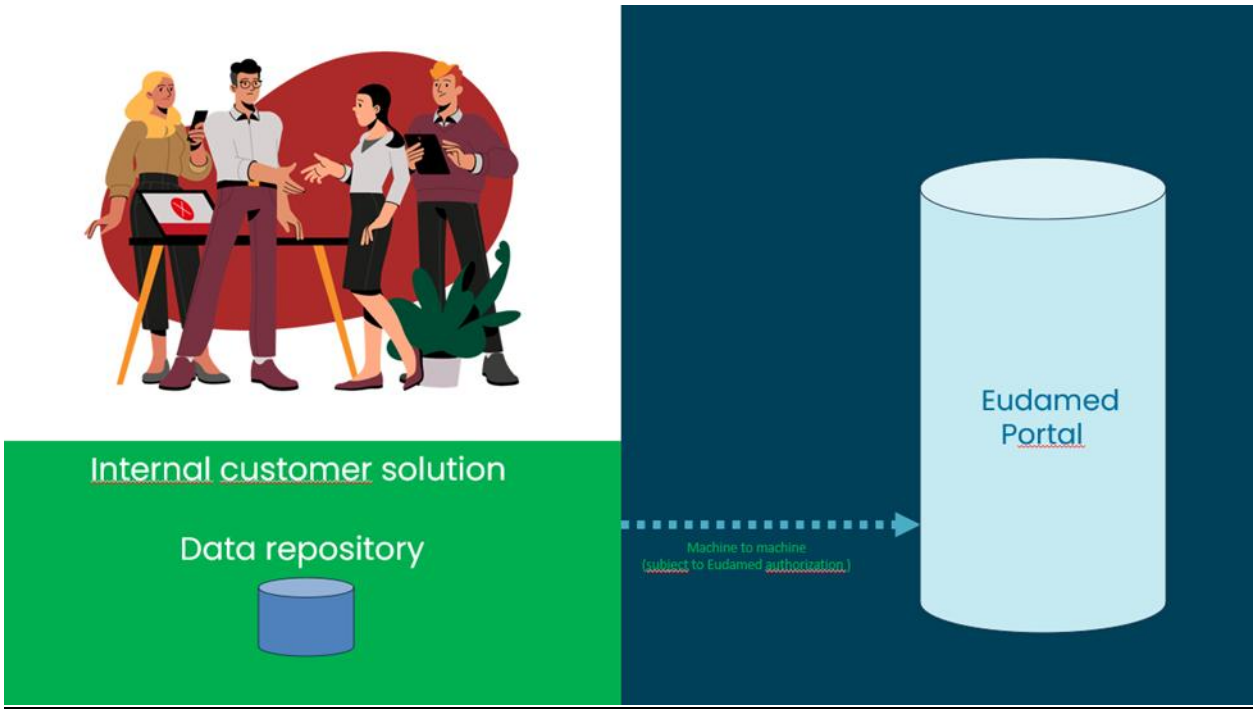

In addition to the constant regulatory and technical monitoring that implies regular updates of EUDAMED version evolutions, this alternative also relies on EUDAMED's authorization. However, it is not in the interest of EUDAMED's technical teams to multiply their contacts.

Finally, it's worth pointing out that regulations take precedence over logistics: whether or not you can sell in a given territory depends on whether or not you comply with its regulations. Most EUDAMED rules are common to all European Union countries. There are more restrictive local rules, implicitly authorized by EUDAMED.

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9.2 How to make the right choice between these functional architectures

The choice of one or other of these functional architectures depends on the maturity of the industrial company and its available resources.

- Alternative #1 can only be chosen if the annual volumes of products and major modifications are not significant. Nevertheless, it should disappear with the multiplication of regulatory bases and the objectives of dematerializing exchanges with purchasing groups (GPO) and, more generally, with all players.

- Alternative #2 represents a real complexity in implementation, with a multitude of formats to be taken into account according to numerous criteria.

- Alternative #3 has the advantage over alternative #4 of working on a standard system, qualified and validated from a quality point of view.

- Alternative #4 can be envisaged when none of the company's systems is in itself a repository (multiple sources of information). The data model must be built in parallel with its governance

- Alternative #5 is rather theoretical, as it relies on authorizations from EUDAMED and involves a number of conditions to be met.

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10 DATA MODEL AND DATA INTEGRITY

10.1 Objective

This document describes the key principles underpinning data integrity compliance and provides a common understanding of current data integrity terms and expectations.

Data integrity is an integral part of the quality management system. It is important that the key principles of data integrity are clearly defined and understood by all associates.

The guidance document applies to all the company's products.

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10.2 Definitions and acronyms

10.2.1 Definitions

Duration	Definition
Raw data	Unprocessed and unaltered data in its original form
Processed data	Data derived from examination of raw data
Metadata	Data that describes the attributes of other data and provides context and meaning. This information generally describes the structure, data elements, interrelationships and other characteristics of the data. It also enables data to be attributed to an individual.
Certified copy	a copy of the raw data, checked for accuracy, legibility and completeness
Data format	The medium in which the information is presented
Data file	Electronic data presented in a type of file that can be read by a person or a system.
Data archiving	Permanent, long-term preservation of completed data and relevant metadata in their final form
Data backup	Regular copying of all relevant data, including raw data and metadata, is carried out, controlled and reported as appropriate to business process requirements.
Data integrity	The extent to which all data is complete, consistent and accurate throughout the data lifecycle.
Data life cycle	All phases in the life of data (including raw data), from initial generation and recording to processing (including transformation or migration), use, data retention, archiving/retrieval and destruction.
Basic data (clinical)	All information contained in original files and certified copies of original files relating to clinical results, observations or other activities in the context of a clinical trial.
Static data	Data that does not change after it has been recorded. This is a set of fixed data.
Dynamic data	Also known as transactional data, the information is modified as new updates become available.

10.3 Key concepts

Data integrity is based on a few key concepts that must be understood by everyone in the company:

- Risk management,
- Data governance,
- Data life cycle,
- Application of ALCOA principles,
- Compliance and appropriate validation of the IT system used for data management and storage.

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Regulations require that GxP data and records are complete, consistent, reliable and accurate, that their content and meaning are preserved, and that they are available and usable for the required retention period.

Regulated companies must have confidence in the quality and integrity of data used to make decisions impacting product quality and patient safety by ensuring that ALCOA principles are applied and maintained throughout the data lifecycle.

10.3.1 Risk-based approach

An appropriate risk management approach must be used to ensure the integrity of records and data. This requires appropriate controls to manage the risks identified in the context of the regulated process. The effort and resources devoted to controlling elements of the data lifecycle must be proportionate to the risk in terms of impact on patient safety and product quality.

Quality risk management is an iterative process used throughout the lifecycle of a computerized system, from design to retirement, and throughout the lifecycle of data, from creation to destruction. Data and record integrity risks must be identified and managed alongside other quality and safety risks, using a risk management approach based on process understanding.
Some documents and data may reside on more than one system during their lifecycle, and quality risk management activities should start at the business process level, above that of individual systems.

10.3.2 Data governance

Data governance is a term used to describe the set of measures (documentation and processes) that ensure that data is complete, consistent and accurate throughout its lifecycle.
Data governance ensures formal management of records and data. Data governance encompasses the people, processes and technology required for effective data handling.

Data governance provides the structure within which appropriate decisions on data-related issues can be made according to defined models, principles, processes and authority.

The main elements to be taken into account in order to implement an appropriate strategy are as follows:

- *documented justification,*
- *a definition of the sponsorship and executive governance process,*
- *emphasis on management responsibility,*
- *implementation of knowledge-sharing tools,*
- *the development of appropriate levels of training.*

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10.3.2.1 Organization and ownership

10.3.2.1.1 Management responsibility

Management has a responsibility, at all levels of the regulated business, to promote data integrity and to make staff aware of the relevance of data integrity and the importance of its role in protecting patient safety and our organization's reputation.

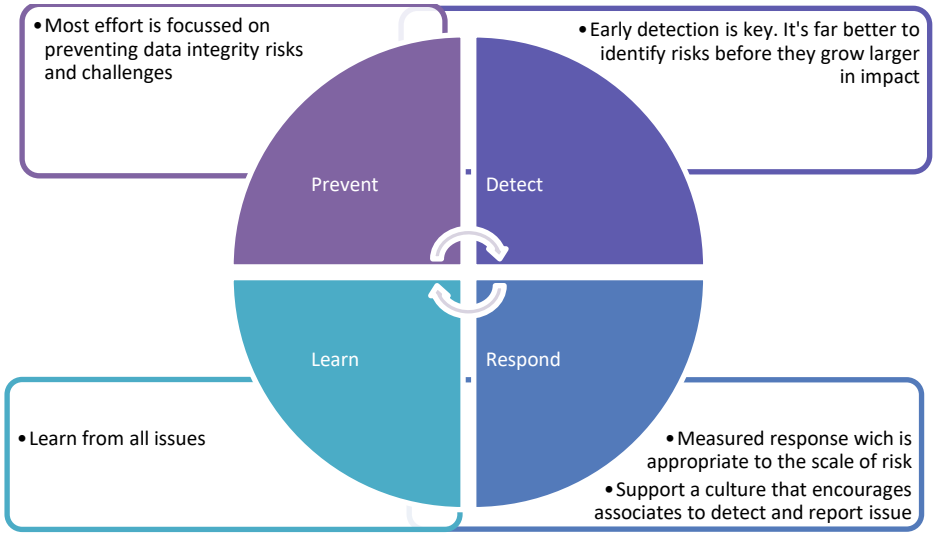
10.3.2.1.2 Education, communication and commitment

It is important to establish and maintain a culture that promotes data integrity. To this end, and as part of the GxP training program, the company's employees must be trained in the importance of data integrity, and in methods for detecting data integrity problems.

In addition, an appropriate working environment should be created, with open discussion and collective resolution of data integrity issues, rather than blaming others.

The main foundation of a high level of data integrity is knowledge and understanding of what data integrity is, how important it is to an organization, and the personal role of each employee in protecting it.

A proactive approach can be taken to controlling data integrity processes, focusing on prevention and early detection of potential data integrity risks. It is recommended to design and develop controlled processes by applying the following general principles:



10.3.2.1.3 Data ownership and responsibility

Data ownership and responsibilities must be defined to ensure appropriate accountability and responsibility for specific data, as well as integrity and compliance,
Data ownership must be defined for each stage of the data lifecycle and documented in the associated SOP or INS.

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For processes supported by a computerized system,

- The business process owner is by default the owner of the data residing in the system, and therefore ultimately responsible for data integrity.
- The technical owner is responsible for the availability, support and maintenance of a system, and for the technical security of the data residing on that system.

10.3.3 Data life cycle

All phases of the data lifecycle, from initial data creation, capture and recording, through to processing (including transformation or migration), review, reporting, retention, retrieval and destruction, must be controlled and managed to ensure the accuracy, reliability and compliance of records and data.

GxP-relevant data has a well-understood and documented data flow throughout the data lifecycle, from creation to retention, based on risk management and understanding of the supported business process.

In addition, data ownership at each stage of the data lifecycle must be clearly defined and documented in the associated SOP or INS.

Retention periods for all GxP data (including dynamic data) must also be clearly defined and understood.

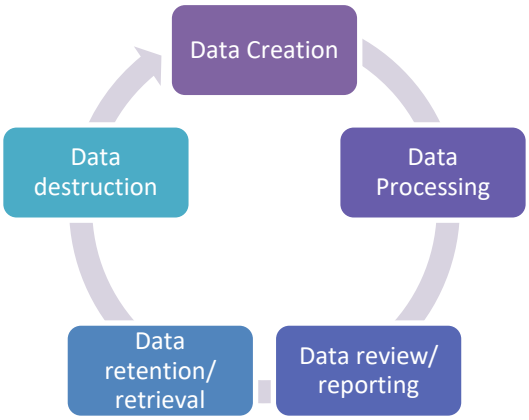

Figure1 : Data life cycle

10.3.3.1 Data creation

Data integrity may be compromised at the time of creation. If the original data is unreliable, its integrity cannot be guaranteed. Data creation must provide accurate data that is needed throughout the business process to make decisions based on that data.
Data can be created by entering new data, captured by the system from an instrument, device or other system, or captured manually.

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Data must be entered and saved at the time of the activity (simultaneously) and before moving on to the next activity in the process.

Data must be stored in the predefined location and format. When the same information is stored simultaneously in several locations or formats, the process/data owner must define where the main record is kept.

For processes supported by a computerized system, this information must be clearly identified in the SOP or INS.

10.3.3.2 Data processing

During this phase, data is processed to obtain and present information in the required format. Processing must be in accordance with defined and verified processes (e.g. specified and tested calculations and algorithms) and approved procedures.
Process data must not be manipulated to reach a more desirable end point.
The impact of data processing on product quality and patient safety varies according to the product and the business process. The rigor of the controls and checks required for the data processing stage must be determined by a documented and justified risk assessment.

10.3.3.3 Review of data/reports

During this phase, data is used to make informed decisions. The review, communication and use of data must be carried out in accordance with defined, verified processes and approved procedures.
Data review and reporting generally involve recording/reporting documents.

10.3.3.3.1 Data review

The review of the data (including review by a second person if required by regulations) must determine whether predefined specifications, objectives, limits or criteria have been met. The review must be based on a thorough understanding of the process (and, where applicable, the system) and its impact on product quality and/or decision-making, and the results and conclusions must be documented.
The data review and approval process must be described in a procedure.

The data review should include an examination of relevant metadata and GxP data audit trails, where applicable.

10.3.3.3.2 Audit trail Examination

Regulated companies must put in place a documented process for audit trail review, including second-person review. These reviews should be part of the usual data review/approval process and are usually carried out by the operational area that generated the data (e.g. clinical, laboratory, manufacturing).
The requirement for an audit trail review, including frequency, rigor, roles and responsibilities, must be based on a documented risk assessment that takes into account the business process and criticality of the data, the complexity of the system and its intended use, and the potential impact on product quality and patient safety.

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10.3.3.3.3 Data reports

Data communication procedures must guarantee the consistency and integrity of results.
Particular care is required when users can influence data reporting, e.g. compliance testing should be avoided.
Poorly conceived or defined processes, test methods and reports can lead to data reporting errors and erroneous decisions.
Summary reports are limited in that they may not contain all the data, and there is a risk that data issues will not be included, and therefore not examined. Where data summaries are used for reporting, they should be subject to documented verification against the original data.
Trends and appropriate measures can be used to identify and investigate potential data integrity problems.

10.3.3.3.4 Data distribution

Data must be accessible and distributed to authorized persons and other systems supporting the business process. Interfaces between business process systems must be designed and tested to signal failures, prevent data loss and enable recovery.

10.3.3.4 Data storage and retrieval

During this phase, data must be stored securely. Data must be easily accessible during the defined retention period, in accordance with defined and verified processes and approved procedures.
Applicable regulatory requirements, other laws and legislation, and the internal policies of regulated companies must be respected. This includes conservation and privacy requirements.
Data, including all original data and associated metadata necessary to maintain the content and meaning of GMP, must be defined and stored in a secure location with adequate physical and electronic protection against deliberate or inadvertent alteration or loss for the duration of retention. Access must be restricted to authorized persons, and adequate environmental protection against damage must be provided (e.g. against water and fire).
When a system is decommissioned or can no longer be supported, regulated companies need to consider how regulated data will continue to be stored and retrieved for the remainder of the retention period,

10.3.3.5 Data destruction

The data destruction phase involves ensuring that the correct original data is disposed of after the required retention period, in accordance with a defined process and approved procedures.

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10.3.4 ALCOA principles

ALCOA (and ALCOA+ or ++) is the acronym used to help us apply best practices in data management and integrity. All relevant data for GxP must comply with the following ALCOA++ principles throughout their lifecycle.

A	**ATTRIBUTABLE**	Ability to identify people or systems. Ability to identify the people who generated, modified or deleted the data. Possibility of identifying the person who processed the data
L	**LEGIBLE**	Data can be read out after recording. Ability to interpret data after recording
C	**CONTEMPORANEOUS**	Data is recorded at the time it is generated, or at the earliest possible date.
O	**ORIGINAL**	Data is kept in its original or certified (true copy) state. Data retain their content. Data retain their meaning
A	**ACCURATE**	Data reflect activity, measurement. Data verified (if necessary) The changes are explained
+	**COMPLETE, CONSISTENT, ENDURING, AVAILABLE**	All data is present and complete, none has been selectively omitted. Data is available at all times, to anyone who needs it to fulfill their role. Data is compatible, consistent and not contradictory. Data is retained and retrievable throughout its lifetime, in accordance with the retention period for the data type. Data must be stored throughout its lifecycle, and must be available for consultation when needed.
++	**TRACEABLE**	Data must be traceable throughout its life cycle. Any changes to data, context or metadata must be traceable, must not obscure the original information, and must be explained, if necessary. Changes must be documented as part of the metadata (e.g. audit trail).

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10.3.5 GxP system life cycle

GxP computerized systems can be involved in supporting a data lifecycle, as data can be passed from one system to another. To guarantee data integrity, all GxP computerized systems must be reliable and validated for their intended use.

The integrity of records and data must be integrated and maintained throughout all phases of the GxP system lifecycle, from design through project and operations to retirement.

Computerized systems supporting data integrity must be validated/qualified for their intended use, and controls must be implemented to meet ALCOA++ requirements.

This means that the following elements must be detailed as requirements and verified as part of the validation process:

- Audit trail functionality,
- User and administrator access rights management and segregation of duties,
- Compliance with ERES requirements,
- The ability to back up and restore data,
- Data transfer and processing capabilities.

10.3.5.1 Audit trail

GxP regulations require traceability of the creation, modification or deletion of regulated records and data.
Audit trail information must include the following:

- The identity of the person performing the action,
- In the case of a modification or deletion, details of the modification or deletion, as well as a record of the original entry,
- The reason for any modification or deletion of GxP,
- Time and date of action.

Within the enterprise, for GxP computerized systems, audit trail testing must be part of the validation activities in accordance with the defined models

Logical controls must be put in place for audit trail management, including limitations on the ability to disable, change or modify the function of audit trails. Procedural controls may also be required.

Audit trails should only be considered as part of a wider framework of controls, processes and procedures designed to achieve an acceptable level of record and data integrity.

There are three main types of data audit trail review:

- Examination of data audit trails as part of the review and verification of normal

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operating data,
- Examination of audit trails for a specific set of data during an investigation (e.g. data discrepancies),
- Review and verification of audit trail functionality (e.g. verification of audit trail configuration as part of periodic review). Audit trail review is currently part of the periodic review of the GxP computerized system.

The aim of audit trail review is to identify potential problems that could lead to a loss of data integrity. Such problems may include :

- Incorrect data entry,
- Modifications by unauthorized persons,
- Data are not entered at the same time,
- Data falsification.

10.3.5.2 Management of electronic documents and electronic signatures

To guarantee the integrity, authenticity, non-repudiation, availability and (where applicable) confidentiality of electronic records and signatures, automated procedural or system controls are implemented.
Automated controls are prioritized to minimize risk. However, if currently available technologies do not allow automated controls, alternative procedures or measures are considered.

10.3.5.3 Backup and restoration

Regular backups of all relevant data, including associated metadata necessary to maintain the content and meaning of GxP, must be made in accordance with a documented process to enable recovery in the event of system failure, data corruption or loss. The regulated company must ensure that the backup process is designed in such a way that regulated data is not lost or corrupted.
Data backups must be subject to controls equivalent to those on the original data, to prevent unauthorized access, modification or deletion. Backups should be kept in a physically separate and secure location. The data restoration process and technology must be based on the criticality of the data and the restoration time required, documented evidence must exist for restoration capabilities, and periodic testing must be carried out according to risk.

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11 LEXICON

- **ALCOA+**: a set of principles used to guarantee data integrity, particularly in regulated industries such as medical devices. ALCOA is an acronym that stands for :
    - Attributable: Data must be attributable to a specific person,
    - Legible: Data must be clear and legible,
    - Contemporaneous: Data must be recorded at the time it is generated,
    - Original: The data must be the original or a faithful copy.
    - Accurate: Data must be accurate and correct,

  ALCOA+ adds four additional criteria:
    - Complete: All necessary data must be included,
    - Consistent: Data must be consistent over time and between different systems,
    - Enduring: Data must be stored in such a way as to remain accessible and usable over time,
    - Available: Data must be easily accessible for audits and inspections.

- **Basic UDI-DI**: or Basic Device Identifier, is a key element of the medical device identification system in EUDAMED. It serves as an anchor point for grouping and

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identifying medical devices with similar characteristics. It should not be confused with the UDI-DI.

- **CE:** Conformité Européenne; the CE mark indicates that a product complies with European Union safety, health and environmental protection standards.
- **CECP**: Clinical evaluation and consultation procedure.
- **Class:** EUDAMED medical device classes are defined according to the level of risk associated with their use. The classification of a medical device determines the applicable regulatory requirements, including conformity assessment procedures and post-market surveillance obligations. A class I (MD) or class A (IVD) corresponds to low risk. EUDAMED and GUDID classifications are not identical for information purposes.
- **EUDAMED:** "European Database on Medical Devices".
- **DM:** Medical Device.
- **IVDD:** *In vitro* Diagnostic Medical Device.
- **FSCA**: Field Safety Corrective Action.
- **FSN**: Field Safety Notice.
- **MDCG**: Medical Device Coordination Group, which plays a key role in implementing European regulations on medical devices (MDR) and *in vitro* diagnostic medical devices (IVDR). Medical Device Coordination Group.
- **Actor ID**: Identifier similar to SRN (same structure) for registered actors not subject to article 31 MDR / article 28 IVDR).
- **INS**: Instructions.
- **IVD**: *In Vitro* Diagnostic Device.
- **IVDD**: *in vitro* Diagnostic Device Directive. It corresponds to the former European directives on *in vitro* Diagnostic Devices, such as 98/79/EC.
- **IVDR**: "*in vitro* Diagnostic Regulation". Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices.
- **MD**: Medical Device.
- **MDD**: Medical Device Directive. It corresponds to the old European directives on medical devices, such as 93/42/EEC or 90/385/EEC.
- **MDR**: Medical Device Regulation. Regulation (EU) 2017/745 on medical devices.

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- **ACT Module:** Actor Module. This module enables economic operators, such as manufacturers, assemblers, agents and importers, to register and obtain an actor ID or unique registration number (Actor ID/SRN).
- **CI/PS module**: Clinical investigations and performance studies module.
- **Module NB/CRF**: Notified bodies and certificates module.
- **MSU Module**: Market Surveillance Module.
- **UDI/DEV Module:** "UDI/Devices" module. This is the module in which Medical Devices are registered by the manufacturer or assembler.
- **VGL module**: Post-market surveillance and vigilance module.
- **M2M**: Machine to Machine. A machine-to-machine connection with EUDAMED enables automated data exchange with the EUDAMED database.
- **NB:** Notified Body.
- **PMSV**: Post-market surveillance or vigilance action.
- **PSUR**: Periodic Safety Update Report. The PSUR is a periodic safety update report to be submitted to EUDAMED by manufacturers of Class IIb and III medical devices, as well as certain Class D *in vitro* diagnostic (IVD) devices.
- **QMS**: Quality Management System.
- **Repository**: A data repository is a centralized base where all information on a company's master data, such as products, is stored. A SSOT (Single Source Of Thruth) is a type of repository that serves as a single reference for all other applications, guaranteeing data quality and consistency throughout the organization.
- **SOP**: standard operating procedures.
- **SPP**: System & Procedure Pack.
- **SPPP**: System & Procedure Pack Producer.
- **SRN**: Single Registration Number. Unique registration number (assigned to actors registered under article 31 MDR / article 28 IVDR).
- **SS(C)P**: Summary of safety and performance (clinical).
- **UDI-DI**: UDI device identifier (in accordance with article 27(1)(a)(i) MDR / article 24(1)(a)(i) IVDR). Not to be confused with Basic UDI-DI.
- **UDI-PI**: "UDI/Production Identifier". The UDI-PI identifies the production unit of a medical device. It can include information such as batch number, serial number, date of manufacture and expiry date.

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- **EU:** European Union.
- **XML:** eXtensible Markup Language. A markup language used to structure, store and transport data. XML is designed for data exchange between different systems.

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