YOUR DATA COMPLIANCE PARTNER

ACKOMAS

SEMINAR BVMED
11.12.2025

BVMed AKADEMIE

ABOUT US

ACKOMAS is a leading IT software provider:

- Specialized in **regulatory data management and compliance**
- Team with an experience of **more than 15 years** in the pharmaceutical and medical device industries
- Leading M2M software solution for **UDI data submission** to European **(EUDAMED)** and international regulatory databases.

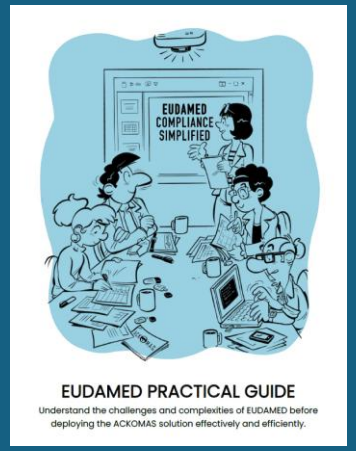
Member of:

- **MedTech Europe**
- **GS1 Healthcare** + **GS1** (Germany, France, Italy..)
- **ISPE** (International Society for Pharmaceutical Engineering)

ABOUT US

Active participation in international **working groups**

Free practical guide on EUDAMED and UDI submission



https://www.ackomas.com/eudamed-guide-download/

+15 webinars organized with our international institutional partners

ABOUT US

Active participation in international **working groups**

Free practical guide on EUDAMED and UDI submission

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

https://www.ackomas.com/eudamed-guide-download/

+15 webinars organized with our international institutional partners

WEBINAR OUTLINE

1. EUDAMED: Context
2. Module Overview
3. Data Models
4. Special Cases
5. BfArM Session
6. Options for UDI registration
7. Feedback: JOIMAX
8. Data Governance and Quality
9. Next Steps
10. Summary / Q&A

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WEBINAR OUTLINE: CONTEXT

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EUDAMED: CONTEXT

➢ **Regulations 2017/745 MDR, 2017/746 IVDR**

- introduces the UDI codification
- introduces the obligation of PRRC
- EUDAMED database

Goals:

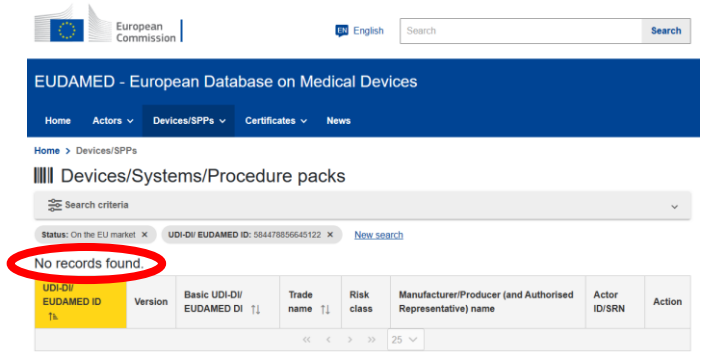
Ensure **security**, **traceability** and **transparency** of all medical devices placed on the EU market.

➢ **Amending Regulation 2024/1860 & Gradual Roll Out**

EUDAMED: CONTEXT

Non-compliance: what consequences and risks?

Consequence for legal manufacturers: Any medical device placed on the European Market, but **not registered** in EUDAMED, is considered **non-compliant**.



Business

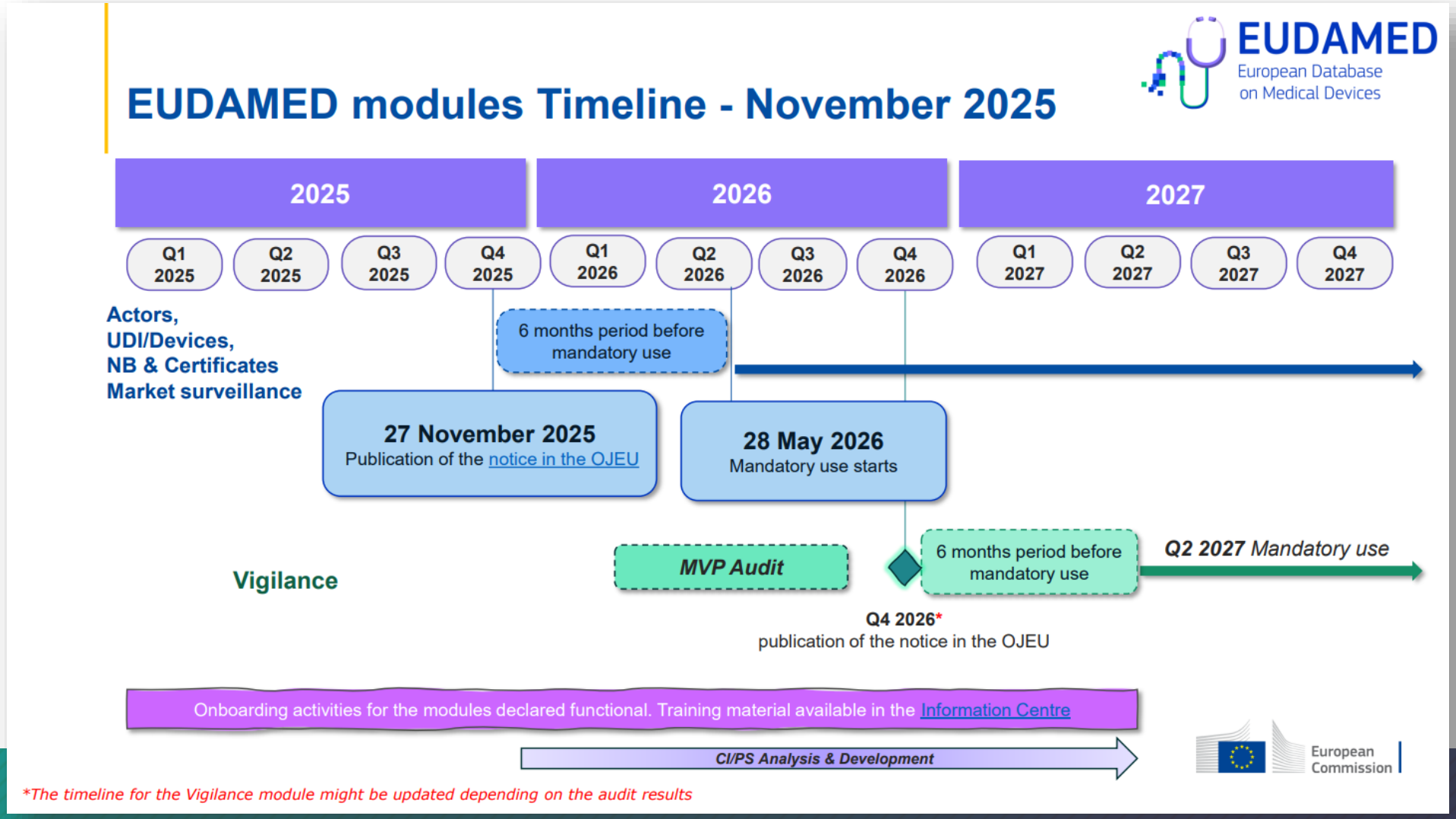
Unregistered device

No access to the European market

(Articles 10.7 & 29)

Breach of contract with distributor

EUDAMED: CURRENT TIMELINES



Accessible here

EUDAMED TIMELINES: UDI MODULE

__New__ products must be registered in EUDAMED __before__ placing them on the EU market

New devices placed on the market **on or after** 28 May 2026

28 May 2026 → **28 Nov 2026** → OJEU + 6 months

Deadline for registering all remaining __existing__ devices

(Existing) Devices placed on the market **before and still placed** on the market on 28 May 2026

28 May 2026 → **28 Nov 2026** → OJEU + 12 months

Master UDI contact lenses : obligation starting **7 November 2026** (MDCG 2014-14 Rev. 1)
Master UDI spectacle frames, spectacle lenses and ready-to-wear spectacles: obligation starting **1 November 2028** (MDCG 2025-8)

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WEBINAR OUTLINE: MODULE OVERVIEW

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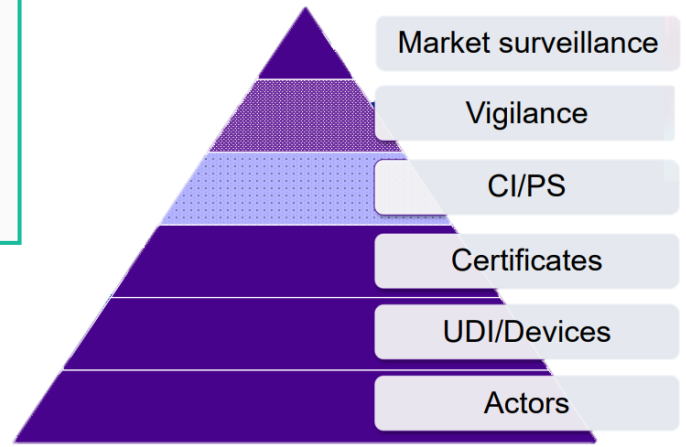
EUDAMED: MODULE OVERVIEW

6 EUDAMED modules:

Modules used by manufacturers :

- ACTORS — 28 May 2026 Mandatory use starts
- DEVICES — 28 May 2026 Mandatory use starts
- VIGILANCE & PMS — Q2 2027 Mandatory use *
- NB & CERTIFICATES — 28 May 2026 Mandatory use starts
- MARKET SURV. — 28 May 2026 Mandatory use starts
- CLINICAL INVESTIGATION / PERFORMANCE STUDIES — CI/PS Analysis & Development

! Interdependent modules !



Source: EC Stuttgart EUDAMED Workshop presentations

**expected* mandatory use for Vigilance & PMS (can be subject to change)

EUDAMED: STRUCTURE

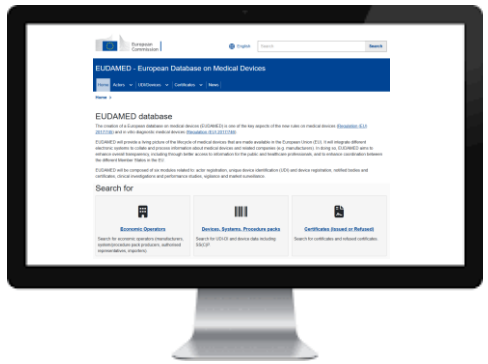
Who	What
MF – manufacturers	• Register as an actor
	• Register and update products (CE-marked)
	• Vigilance reports (upcoming)
PR – Producers of Systems/Procedure Packs	• Register as an actor
	• Register products
IM – Importers	• Register as an actor
	• Link themselves to non-EU manufacturers
	• Check within 2 weeks of placing a device on the market that the manufacturer correctly registered as actor in EUDAMED – Art. 30, MDR • Check device registration in EUDAMED before placing on the market – Art. 13(4) MDR
AR – Authorized Representatives	• Register as an actor and manage mandates
	• Verify that the manufacturer has complied with the registration obligations – Art. 11 MDR
SP – Sponsors of Clinical Investigations and Performance Studies	• Register as an actor (upcoming)
	• Register studies (upcoming)
	• Report deviation and completion (upcoming)
NB – Notified bodies	• Register certificates / CECP / SS(C)P
CA/DA – Competent/Designating Authorities	• Market surveillance

EUDAMED: ACCESS TYPES

Different levels of access for different purposes

1. Public

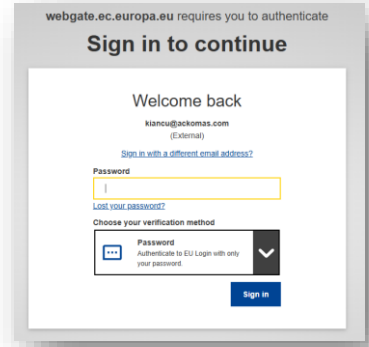
- For anyone who wants to search for publicly-accessible information (e.g. distributors, healthcare providers, patients, other authorities, everyone)
- No login necessary
- Information available to the general public on:
  - **Manufacturers** and other actors
  - **Products**
  - **Certificates**
  - **SSCP & SSP** (Summary of Safety and Clinical Performance) for higher-risk devices
  - Certain safety-monitoring data (**vigilance**): MIR and FSN — will come at a later stage
- Public API



Public website

2. Restricted

- For actors who will enter information
- User login required



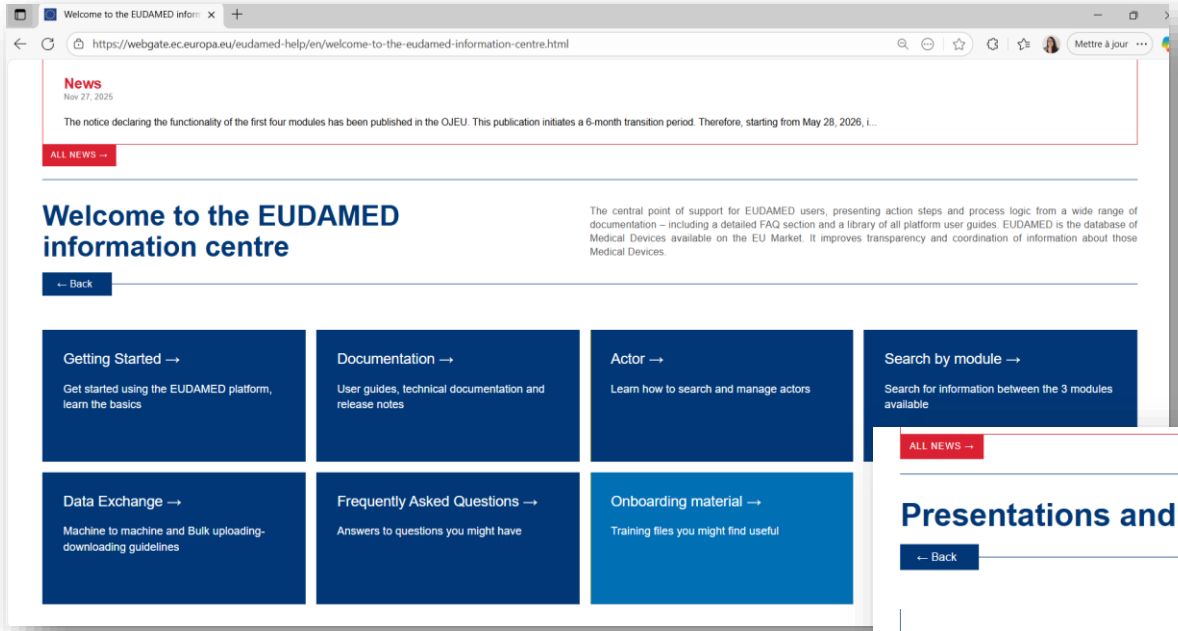
3. Playground

- Separate environment, access via dedicated webpage
- For actors who wish to test module functionalities
- User login required
- **Separate SRN** and **access request** necessary

4. Training

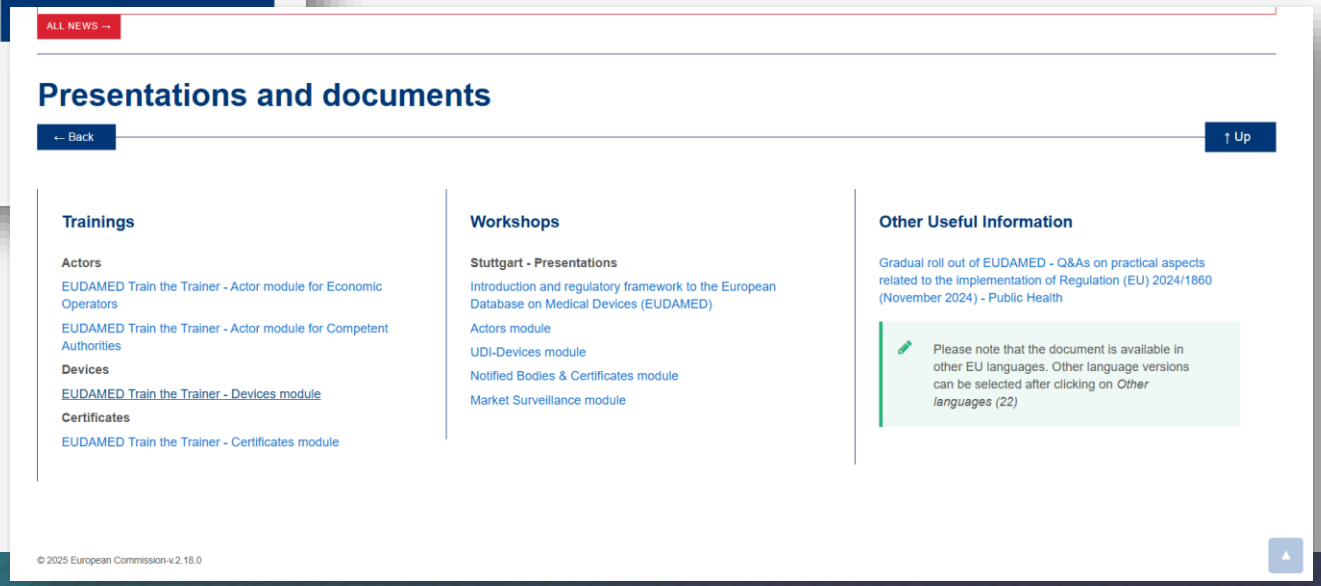
- For training purposes, mirror of Production (not yet available)

EUDAMED: INFORMATION CENTER



Welcome to the EUDAMED information centre

EC Presentations and documents



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EUDAMED: ACTORS

EUDAMED
European Database on Medical Devices

Modules used by manufacturers :

- **ACTORS** — 28 May 2026 Mandatory use starts
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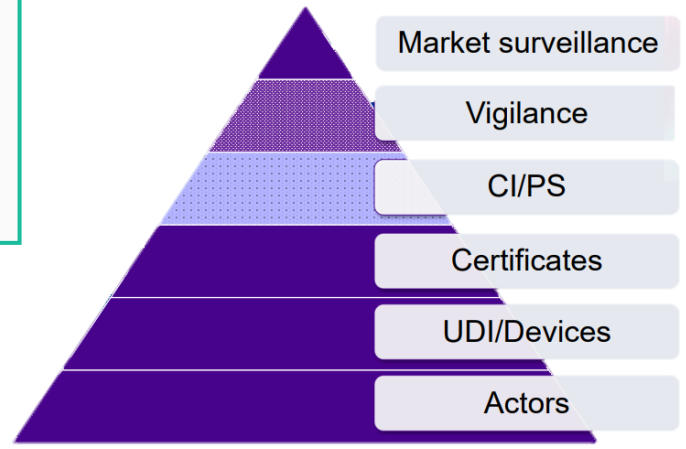
- VIGILANCE & PMS — *Q2 2027 Mandatory use**
- NB & CERTIFICATES — 28 May 2026 Mandatory use starts
- MARKET SURV. — 28 May 2026 Mandatory use starts
- CLINICAL INVESTIGATION / PERFORMANCE STUDIES — *CI/PS Analysis & Development*

! Interdependent modules !



Source: EC Stuttgart EUDAMED Workshop presentations

**expected* mandatory use for Vigilance & PMS (can be subject to change)

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EUDAMED: ACTORS

SRN = Single Registration Number

DE — Country ISO Code

MF — Actor Role

00000XXXX — Unique number (9 digits)

- MF — Legal Manufacturer
- AR — Authorized Representative
- IM — Importer

Actor ID = for other types of actors

- PR — System/Procedure Pack Producer (SPPP)
- CA / DA — Competent / Designating Authorities
- NB — Notified Bodies
- SP — Sponsors of CI/PS

DE — Country ISO Code

PR — Actor Role

00000XXXX — Unique number (9 digits)

Application ID = temporary request number

(before the application is validated, eg. APP000000XX)

EUDAMED: ACTORS

Actor Registration Process

Basic Concepts

EUDAMED
European Database on Medical Devices

Roles:

MF - Manufacturer

AR - Authorized Representative

IM - Importer

PR – System/Procedure Pack Producer

User Profiles *(User Management)*

Authorized Representative	Manufacturer	System/ Procedure Pack Producer	Importer
LAA	**LAA**	**LAA**	**LAA**
LUA	**LUA**	**LUA**	**LUA**
Verifier Verify 'Actor Registration request' and submitted mandates associated to their actor	**Mandate Manager** Manage its 'Mandates' (only for non-EU MF)		**Linker** Manage its "link with non-EU MF'
Viewer	**Viewer**	**Viewer**	**Viewer**

Local Actor Administrator (LAA) - Manage "Actor data" and "Actor notification email addresses"

Local User Administrator (LUA) – Manage 'User access' requests

[EUDAMED Train the Trainer - Actor module for EOs]

2 LAA strongly recommended:

- ***Prevents loss of access to EUDAMED***
- ***Facilitates role assignment to EUDAMED UDI module***

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EUDAMED: UDI/DEVICE

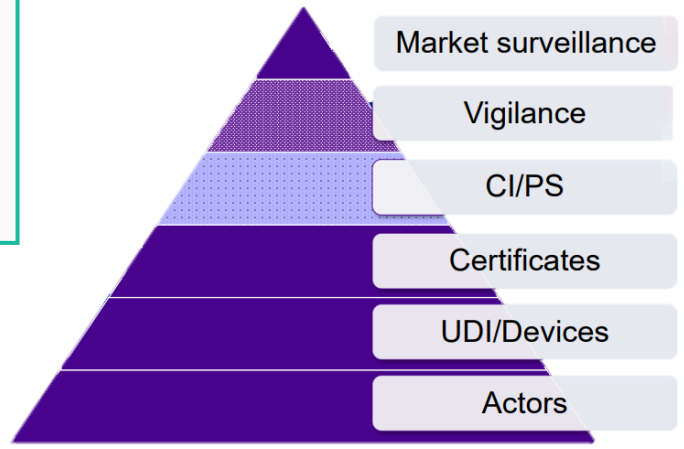
EUDAMED
European Database on Medical Devices

Modules used by manufacturers :

ACTORS	DEVICES	VIGILANCE & PMS
28 May 2026 Mandatory use starts	28 May 2026 Mandatory use starts	Q2 2027 Mandatory use*

NB & CERTIFICATES	MARKET SURV.	CLINICAL INVESTIGATION / PERFORMANCE STUDIES
28 May 2026 Mandatory use starts	28 May 2026 Mandatory use starts	CI/PS Analysis & Development

! Interdependent modules !



Source: EC Stuttgart EUDAMED Workshop presentations

**expected* mandatory use for Vigilance & PMS (can be subject to change)

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EUDAMED: UDI/DEVICE MODULE

Who registers UDI data?

2 LAA strongly recommended (Actor module)

- MF — Legal Manufacturer
- PR — SPPP

} **Obligation to register devices** — V P C

- AR — Authorized Representative
- IM — Importer

} Access limited to **Viewer** = **read-only** in regards to UDI data — V P C

- V — *"Viewer" (**by default** ⚠)*
- P — *"Proposer"*
- C — *"Confirmer"*

Distributors have no access via restricted page (no EUDAMED login). V P C

Notified bodies and competent authorities have Viewer access! (including access to discarded data) V P C

EUDAMED: UDI/DEVICE MODULE

UDI/Device

Central module in EUDAMED, connected to the other modules of the database.

- **Operational since 2021**
- **Multiple updates** (versions)
  - current version **Production: v 2.18**
  - current version **Playground**: **v 3.18**

Production Login

Playground Login

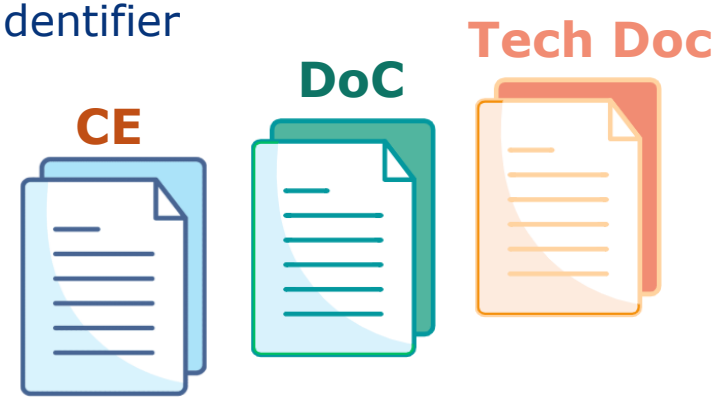
- Module that requires most time & effort in terms of **workload**. → **UDI registration**

EUDAMED: BASIC UDI-DI

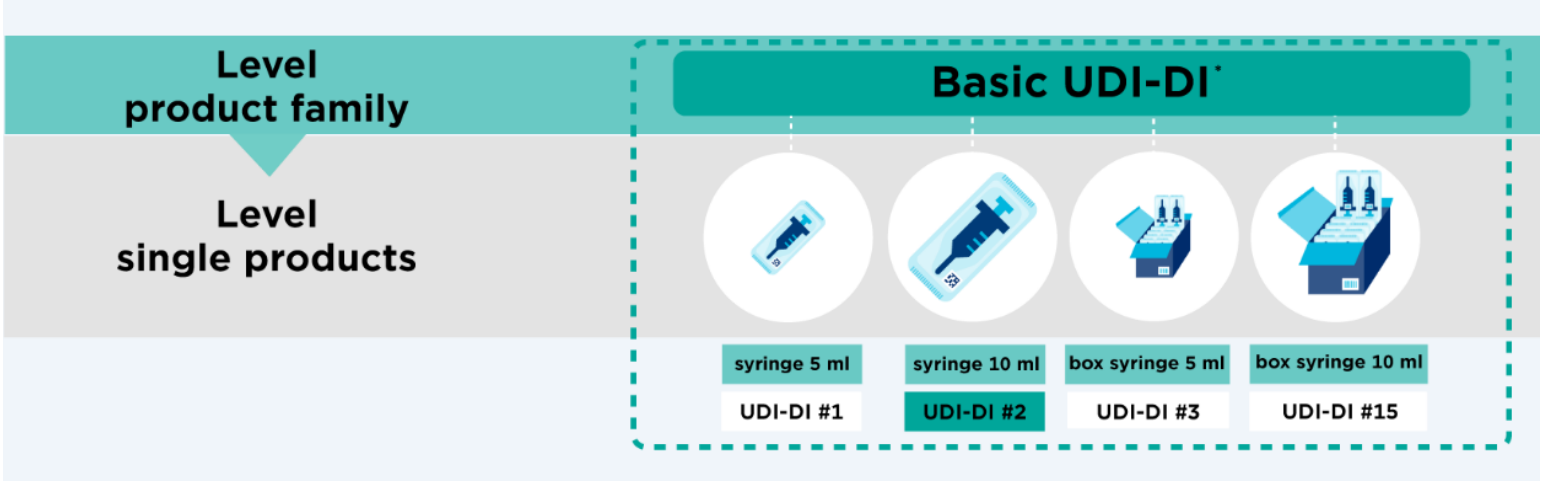
Basic UDI-DI = **e.g. GMN** (GS1) > "higher level" product family identifier

Manufacturer's responsibility to decide which devices are under one unique BASIC UDI-DI based on:

1) Same intended use
2) Same risk classification
3) Same essential design and manufacturing characteristics.



Source: GS1



EUDAMED: WHAT IS UDI?

- **UDI** = (device identifier) + (production identifier)

UDI-DI **UDI-PI**

- **UDI-DI** = eg. **GTIN** (GS1) → **static, model-related information** of the medical device registered in EUDAMED
- **UDI-PI** = **variable, production-related information** (e.g. batch, serial no., manufacturing/expiry date) → found on the label

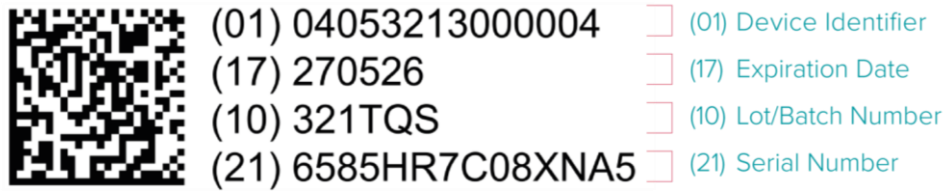
UDI-PI Rules (Part C of Annex VI, MDR 2017/745)

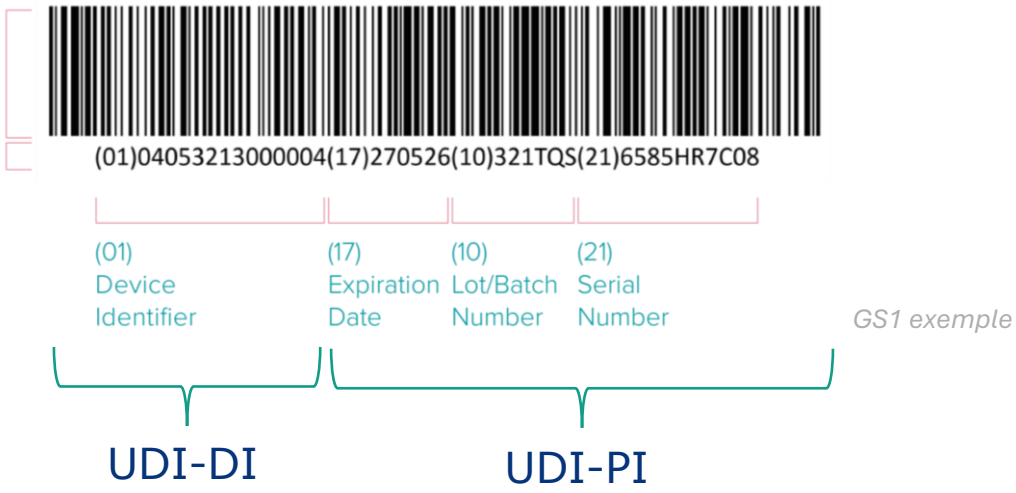
- If lot number, serial number, software ID, or expiry date is on the label → must be included in the UDI-PI.
- If manufacturing date is present together with other identifiers → it does not need to be in the UDI-PI.
- If manufacturing date is the only identifier → it shall be used as the UDI-PI.

Issuing Entities

EUDAMED: UDI & LABEL

Identifier	On Label	In Eudamed
Basic UDI-DI	**No**	**Yes**
UDI-DI (MUDI-DI)	**Yes**	**Yes**
UDI-PI	**Yes**	**No**





All data represented on the device **LABEL** and in **EUDAMED** have to be **consistent and coherent with each other**.

EUDAMED: UDI

- Assign **Basic UDI-DI** to the product families
- Assign **UDI-DI** or **Master UDI-DI** to devices

1 Unique device identification

- Assign **UDI-PI**
- Label **UDI** on **the devices**


(bar code or data matrix)

2 Label identification

- Register devices in **EUDAMED**

3 UDI Data registration

EUDAMED: SUMMARY

Module	What?	When in Eudamed?
Actors	Manufacturers, system/procedure pack producers, importers, authorized representatives who are new (new = from 28 May 2026 onwards)	Before first placing on the market
UDI/Device	Regulation (MDR/IVDR) CE-marked (or SPP) device placed on the market for the first time from 28 May 2026 onwards	Before first placing on the market
UDI/Device	Existing regulation (MDR/IVDR) or Legacy CE-marked or SPP device modified after 28 May 2026 onwards	Before first placing on the market
UDI/Device	Existing regulation (MDR/IVDR) CE-marked device or SPP (placed on the market before 28 May 2026) and still placed on the market after 28 May 2026 onwards (unchanged)	Registration until 28 November 2026
UDI/Device	Legacy CE-marked device (benefitting from transitional provisions) still placed on the market after 28 May 2026 and with no modifications	If no same* regulation device registered before 28 November 2026 → Legacy registration until 28 November 2026
UDI/Device	Regulation (MDR/IVDR) or Legacy CE-marked or SPP device no longer placed on the market before 28 May 2026	No registration, unless vigilance reporting

*Regulation device and legacy device have the same identification such as UDI-DI, and/or catalogue/reference number and/or trade name which follows from shared characteristics

EUDAMED: SUMMARY – PART 2

Module	What?	When in Eudamed?
UDI/Device	Old devices (products under previous directives)	No registration, unless vigilance reporting
UDI/Device	Custom-made devices (except class III implants)	No registration, unless vigilance reporting
UDI/Device	In-house manufacturing (healthcare facilities)	No registration, unless vigilance reporting
Certificates	New, modified and withdrawn certificates from 28 May 2026 onwards	As soon as the notified body makes the decision
Certificates	Certificates issued before 28 May 2026 with no modifications	Certificate registration by NB until 28 May 2027

Master UDI contact lenses : obligation starting **7 November 2026** (MDCG 2014-14 Rev. 1)

Master UDI spectacle frames, spectacle lenses and ready-to-wear spectacles: obligation starting **1 November 2028** (MDCG 2025-8)

EUDAMED: UDI TRIGGERS

When is it mandatory to create a new UDI-DI?

1. **New device creation**
2. **Major change of a device** - Part C of Annex VI, MDR 2017/745
3. **Device change due to *trigger* update in EUDAMED (EUDAMED rules)**

Data is as important as the device itself.

Did you know that:
+-50% all UDI data are *triggers*
→ see next section

Very important to **correctly submit data** to avoid risks associated to data formats in EUDAMED (non-editable attributes).

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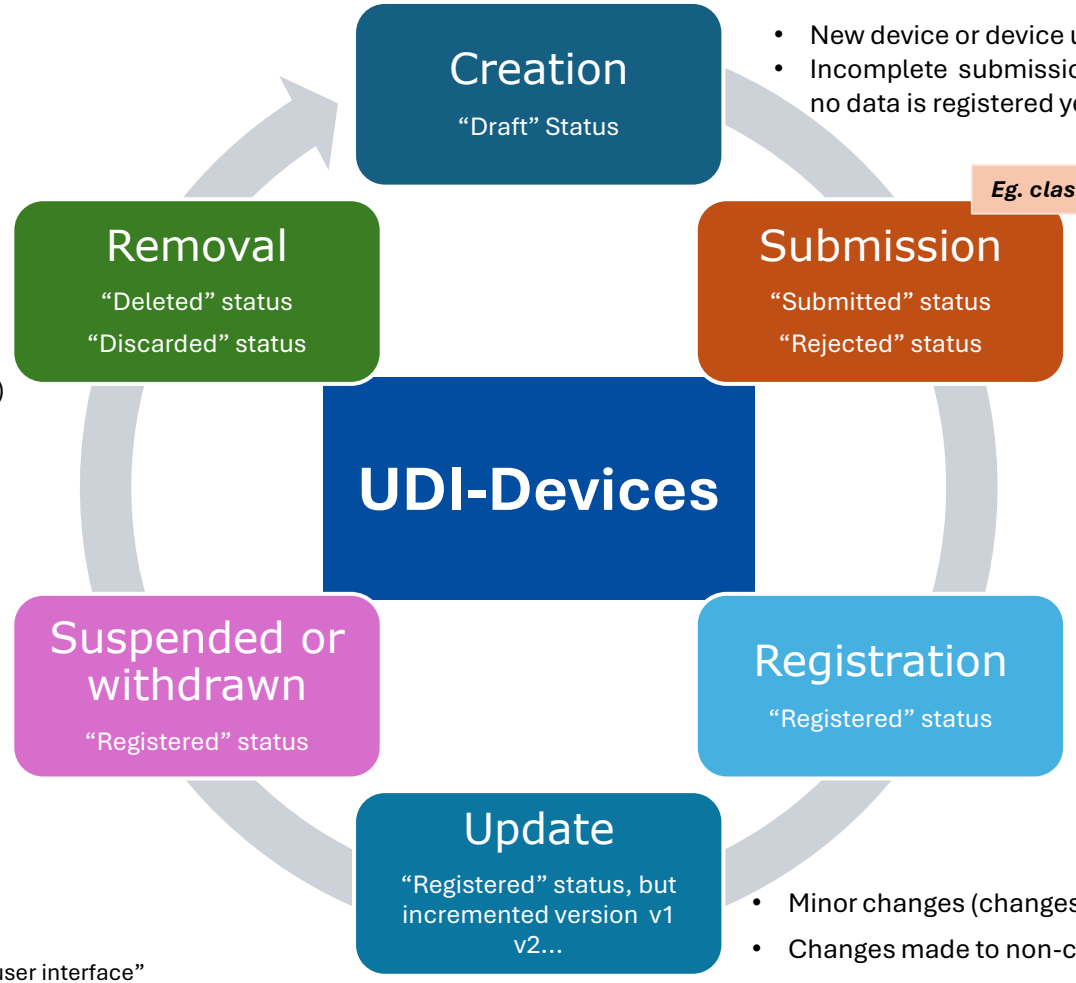
EUDAMED: UDI LIFECYCLE



- Changes of *Triggers* / data entry errors
  - ➢ If the data is still in "*Draft*", it is posible to completely remove it from the database = ***"Deleted"***
  - ➢ If already in *"Registered" status, the UDI data can be removed from the public database, but registration history remains in EUDAMED* = ***"Discarded"*** *

"*Discarded*" =

- UDI history remains in EUDAMED (restricted Access)
- Not visible anymore in the public database, only for supervising entities
- Possible to reuse the same UDI-DI for a new submission

- New device or device update of existing registered UDI
- Incomplete submission (creation or update in process) = no data is registered yet in EUDAMED

Eg. clases IIb implantables / III Annex – device certificate information

- EUDAMED submission finalized
- "Submitted" = pending Notified Body approval

The device will remain in "*Submitted*" status until the certificate is uploaded by the Notified Body

- Device remaines *"Registered"* , with the mention ***'no longer placed on the EU market'.***
- Device history remains in EUDAMED.

- Device is registered and available in the public database = **public data**

- Minor changes (changes to editable attributes)
- Changes made to non-critical attributes *(triggers)*

** Discard possible only if:*
"device is not referenced in any other item in EUDAMED"
"only possible manually from user with Confirmer profile from user interface"

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EUDAMED: ONGOING RESPONSIBILITY

UDI Data Update: Time to implement change in EUDAMED

Within **30 days** for device-related information (MDR/IVDR Annex VI, Part C section 5.8) – changes that don't require new UDI-DI

Within **1 week** for actor information changes (MDR Article 31/IVDR Article 28)

For new devices, data made available **immediately** before placing product on the market

Subsequent actor data accuracy checks (Art. 31 MDR/Art. 28 IVDR):

- Within **1 year** after initial submission
- Every **2 years** thereafter

Even if no changes, economic operators must **guarantee data accuracy**.

Data is as important as the device itself.

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EUDAMED: UDI DATA MODELS

Example:
MDR device data model

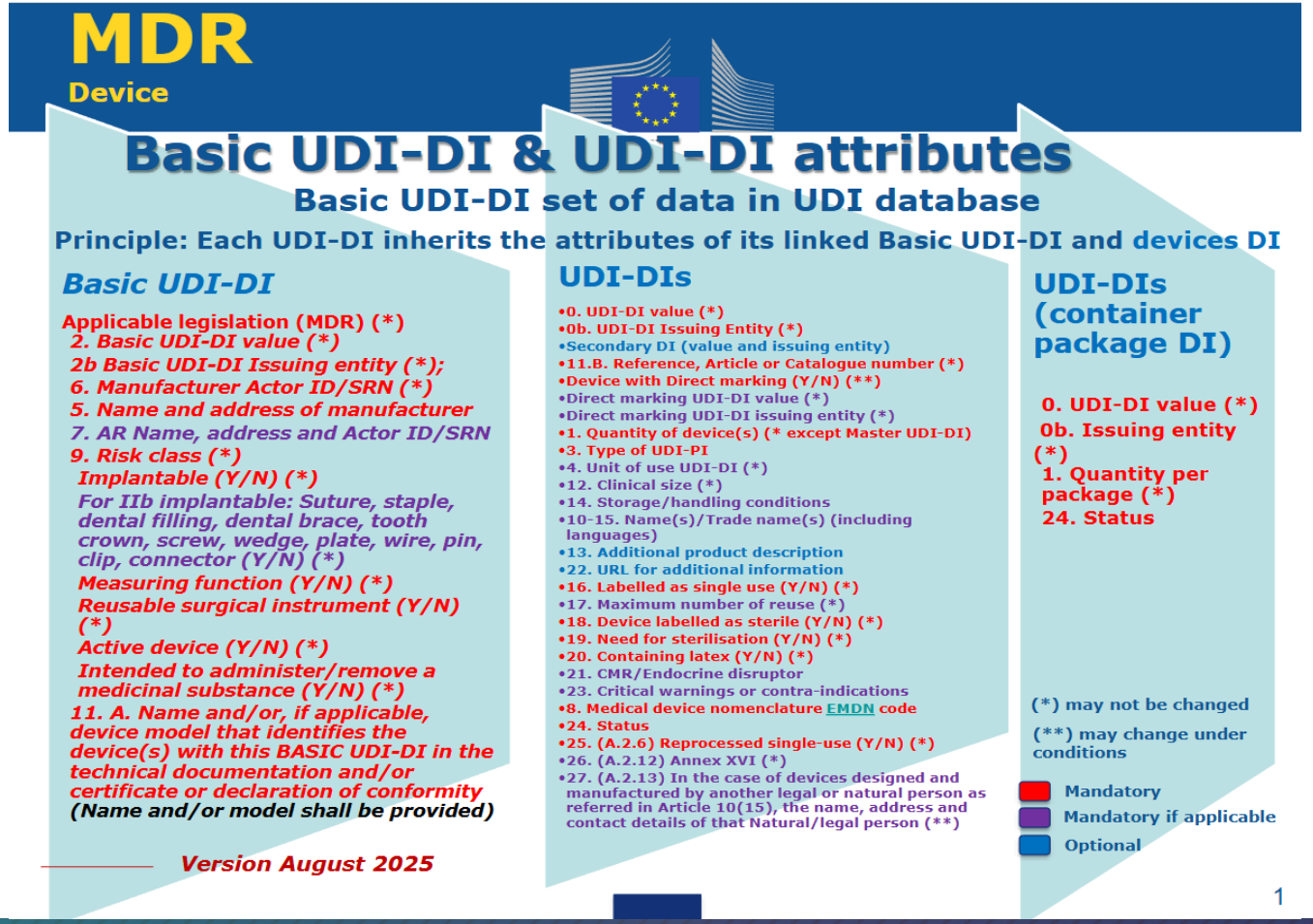
(*) = Triggers, data may not be changed

MDR DEVICES – SPP

IVDR DEVICES

MD / AIMD LEGACY DEVICES

IVD LEGACY DEVICES



WEBINAR OUTLINE: SPECIAL CASES

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EUDAMED: SPECIAL CASES

Special Registration Case: Products that <u>don't require</u> EUDAMED registration

Module	What?	When in Eudamed?
UDI/Device	**Old devices** (products under previous directives)	No registration, unless vigilance reporting
UDI/Device	**Custom-made devices** (except class III implants)	No registration, unless vigilance reporting
UDI/Device	**In-house manufacturing** (healthcare facilities)	No registration, unless vigilance reporting

EUDAMED: SPECIAL CASES

«Old Device»

✓ **CE certification under the following directives:**

- **MDD:** Dir. 93/42/CEE o **AIMDD** 90/385/CEE
- **IVDD:** Dir. 98/79/CEE
- or applicable norms before the directives

✓ Commercialized **in the EU** or put in service by the manufacturer **before the MDR/IVDR application dates** (*26/05/2021 for MDR, 26/05/2022 for IVDR*) **=>** No transition period

~~EUDAMED European Database on Medical Devices~~

« Regulation Device »

✓ **CE certification under the Regulations:**

- 2017/745 (**MDR**) or 2017/746 **(IVDR**)

EUDAMED European Database on Medical Devices

« Legacy Device »

✓ **valid CE certificate** or **declaration of conformity** under the directives (MDD, AIMDD, IVDD)

✓ Still placed on the EU market **after** the MDR/IVDR application dates

✓ Fills the required conditions for **transition periods** *(Art. 120 MDR or 110 IVDR)*

EUDAMED European Database on Medical Devices

* under certain conditions

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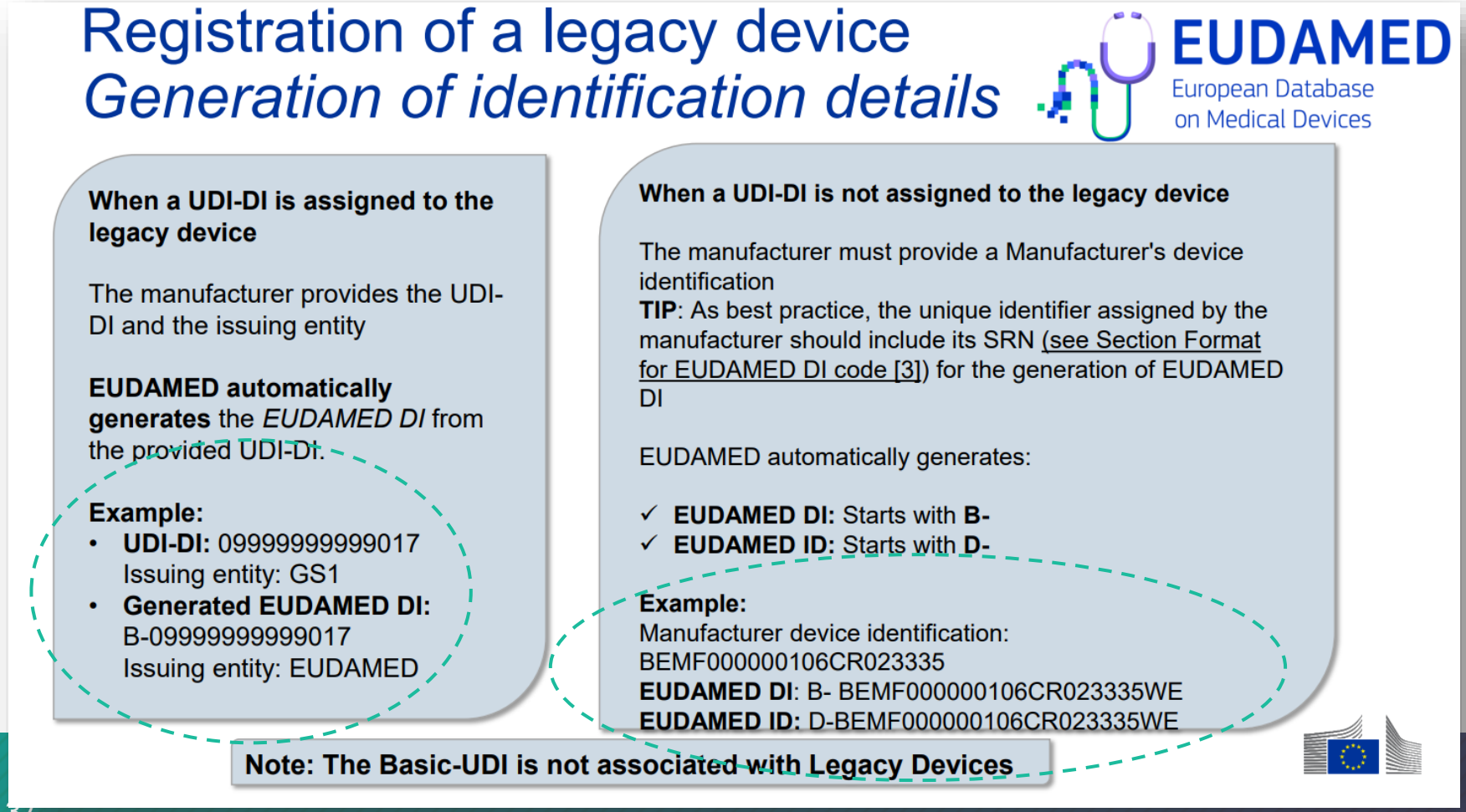
EUDAMED: SPECIAL CASES

Special Registration Case: Legacy Devices

	Legacy	MDR/IVDR device
Device family identification	**EUDAMED DI** (no BASIC UDI-DI) Option 1. Assign **UDI-DI** to device (Issuing entity GS1, HIBCC, etc.) **EUDAMED DI** = «B-» followed by UDI-DI Option 2. Generate **EUDAMED ID** (Issuing entity = EUDAMED) **EUDAMED DI** = « B- » + Manufacturer code + key	**Basic UDI-DI** (Issuing entity GS1, HIBCC, etc.)
Device ID	**UDI-DI or EUDAMED ID** Option 1. Assign **UDI-DI** to device (Issuing entity GS1, HIBCC, etc.) Option 2. **EUDAMED ID** (Issuing entity = EUDAMED) **EUDAMED ID =** « D- » + Manufacturer code + key (generated from EUDAMED DI)	**UDI-DI** registered under Basic UDI-DI (Issuing entity GS1, HIBCC, etc.)
Certificate information	Provided by manufacturer in UDI/Device module	Provided by Notified Body in NB & Certificate Module
Link between product and product family	**Only one** EUDAMED ID associated to one EUDAMED DI	Multiple UDI-DIs can be under the same Basic UDI-DI

EUDAMED: SPECIAL CASES

Special Registration Case: Legacy Devices



EUDAMED Train the Trainer - Devices module (more information on Legacy)

EUDAMED: SPECIAL CASES

Special Registration Case: Master UDI


MDCG 2025-8

Guidance on the implementation of the Master UDI-DI solution for spectacle frames, spectacle lenses and ready-to-wear reading spectacles

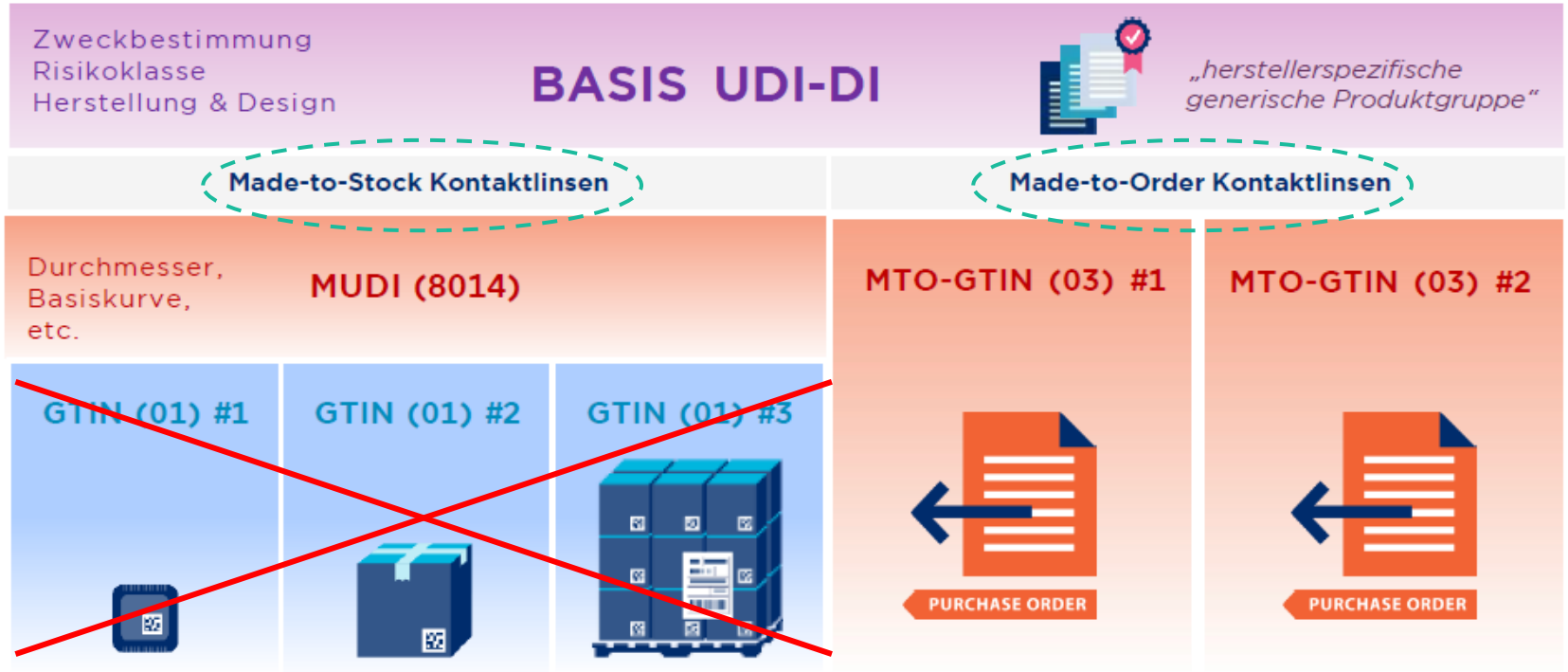
November 2025

Master UDI contact lenses › obligation starting **7 November 2026** (MDCG 2014-14 Rev. 1)

Master UDI spectacle frames, spectacle lenses and ready-to-wear spectacles › obligation starting **1 November 2028** (MDCG 2025-8)

EUDAMED: SPECIAL CASES

Special Registration Case: example of Master UDI for contact lenses



Source: GS1 Austria

WEBINAR OUTLINE

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2. Module Overview
3. Data Models
4. Special Cases
5. BfArM Session
6. Options for UDI registration
7. Feedback: JOIMAX
8. Data Governance and Quality
9. Next Steps
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UDI/DEVICE DATA REGISTRATION

DEVICE

3 ways to submit your data :

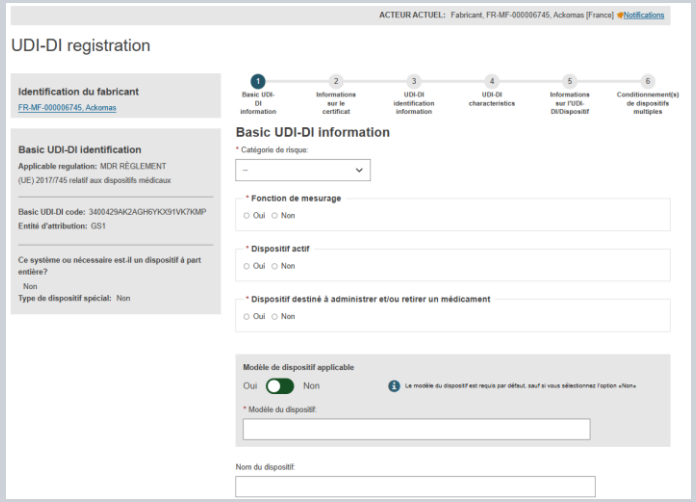
- **Manual input** directly on the platform
- **UDI Bulk upload** via XML files
- **Automatic link M2M**(1) via dedicated software

(1) « Machine to Machine » = automated data transfer to EUDAMED

UDI/DEVICE DATA REGISTRATION

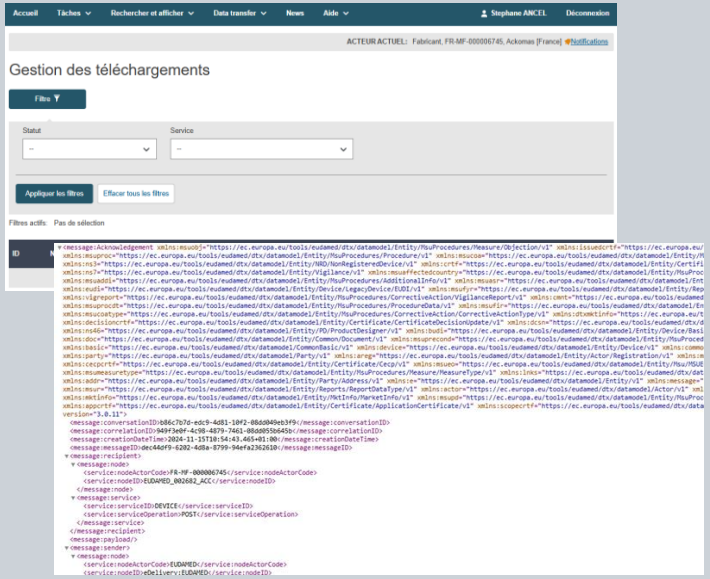
1

Manually via the EUDAMED web interface



2

Bulk upload via XML file



3

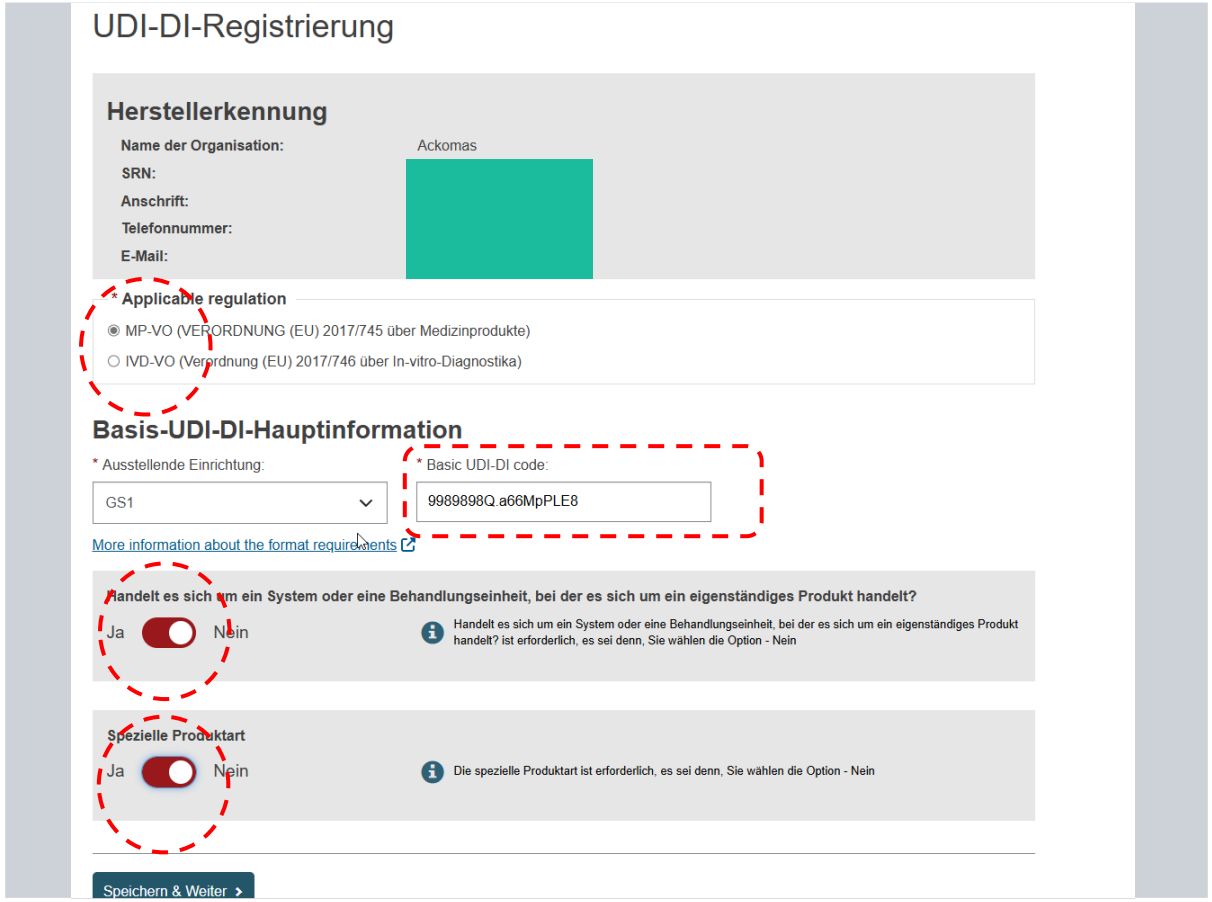
“Machine to Machine” Data transfer

EUDAMED solution

Automated bulk data transfer

MANUAL INPUT (EUDAMED WEBPAGE)

EUDAMED Webpage (UDI creation)



- Manual entry of data, attribute by attribute
- The information is structured on multiple pages
- It is necessary to complete the entire page in order to get to the next section of the form
- Additional fields can appear on the page depending on the type of product

Important to pay attention to the registration steps detailed in the user guides

MANUAL INPUT (EUDAMED WEBPAGE)

Advantages of manual entry

- Low IT investment necessary
- Readily available via web interface

🔍 **In short:**
Manual entry can be an option for low volumes of UDIs.

It can quickly become challenging to manage when the volume of UDI increases or the frequency of updates.

Limits of manual entry

- Risk of errors due to manual entry: data quality needs to be consistently checked
- Cost of personnel (time spent on manual entry)
- Very time consuming for larger volumes of UDI
- Necessary to set up internal data traceability and to manually document actions (requirement MDR/IVDR - see EUDAMED & QMS, MDCG 2021-19)
- Requires a significant time investment for understanding requirements
- Cannot perform bulk operations (changes to multiple UDIs at the same time)
- Not possible to duplicate data (copy data of existing UDI to create a new UDI)
- Support is limited to the EUDAMED help desk

XML FILE UPLOAD

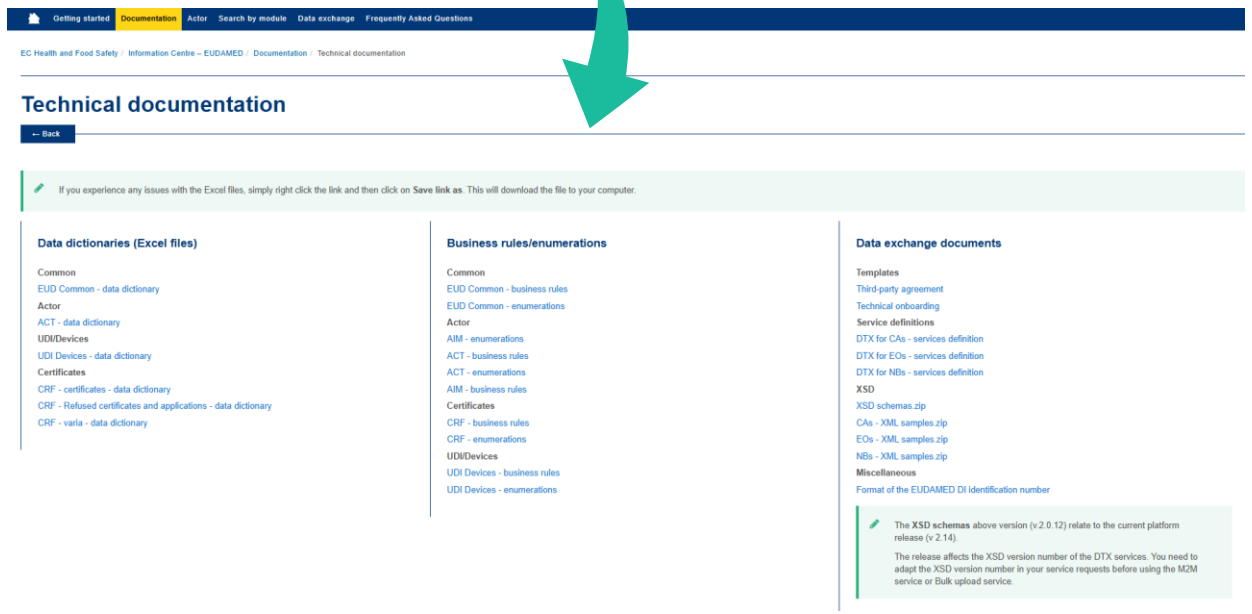
XML file

```
xmlns:appcrtf="https://ec.europa.eu/tools/eudamed/dtx/datamodel/Entity/Certificate/ApplicationCertificate/v
xmlns:sscp="https://ec.europa.eu/tools/eudamed/dtx/datamodel/Entity/SSCP/v1" version="3.0.11">
  <message:correlationID>APP-DTX-000049431</message:correlationID>
  <message:creationDateTime>2025-01-16T11:38:03.206+01:00</message:creationDateTime>
  <message:messageID>5bcd2978-5542-4b09-aa3f-d64e12f4e432</message:messageID>
▼<message:recipient>
  ▼<message:node>
     <service:nodeActorCode>FR-MF-000006745</service:nodeActorCode>
   </message:node>
  ▼<message:service>
     <service:serviceID>DEVICE</service:serviceID>
     <service:serviceOperation>GET</service:serviceOperation>
   </message:service>
 </message:recipient>
▼<message:payload>
  ▼<device:Device xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xsi:type="device:MDRDeviceType">
    ▼<device:MDRBasicUDI>
       <e:state>REGISTERED</e:state>
       <e:version>1</e:version>
       <e:versionDate>2025-01-16T11:31:47.275+01:00</e:versionDate>
       <budi:riskClass>CLASS_I</budi:riskClass>
      ▼<budi:modelName>
         <commondevice:name>DM Webinaire saisie données</commondevice:name>
       </budi:modelName>
      ▼<budi:identifier>
         <commondevice:DICode>3400422015Y01M15D1653BT</commondevice:DICode>
         <commondevice:issuingEntityCode>GS1</commondevice:issuingEntityCode>
       </budi:identifier>
```

XML generation requires IT knowledge

Necessary to be familiar with the EUDAMED technical documentation for XML file creation

Technical documentation

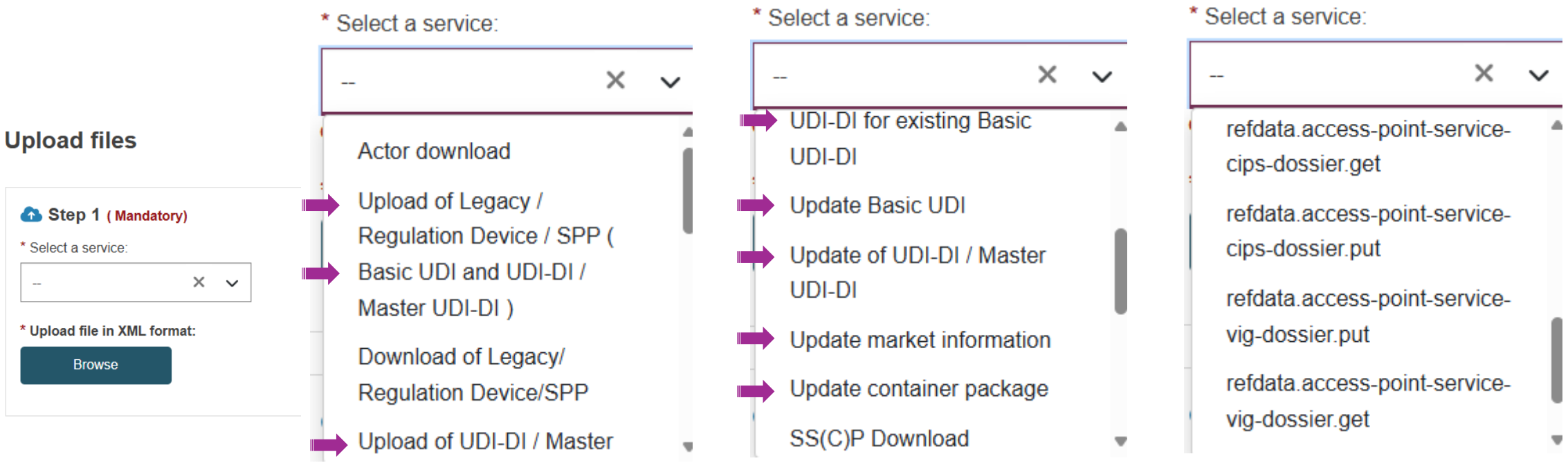


EUDAMED does **not allow** Excel spreadsheet file upload.

XML FILE UPLOAD

You first need to choose the type of upload !

If different submission types = separate XML files required

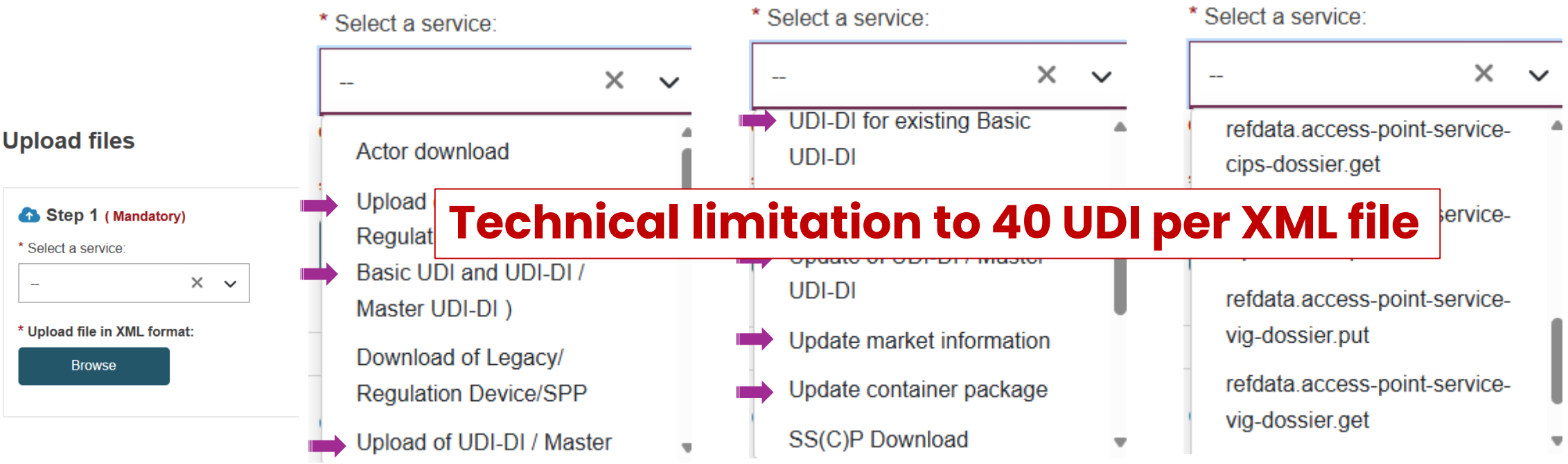


Necessary to understand the all different submission (service) types

XML FILE UPLOAD

You first need to choose the type of upload !

If different submission types = separate XML files required



Technical limitation to 40 UDI per XML file

Necessary to understand the all different submission types

XML FILE UPLOAD

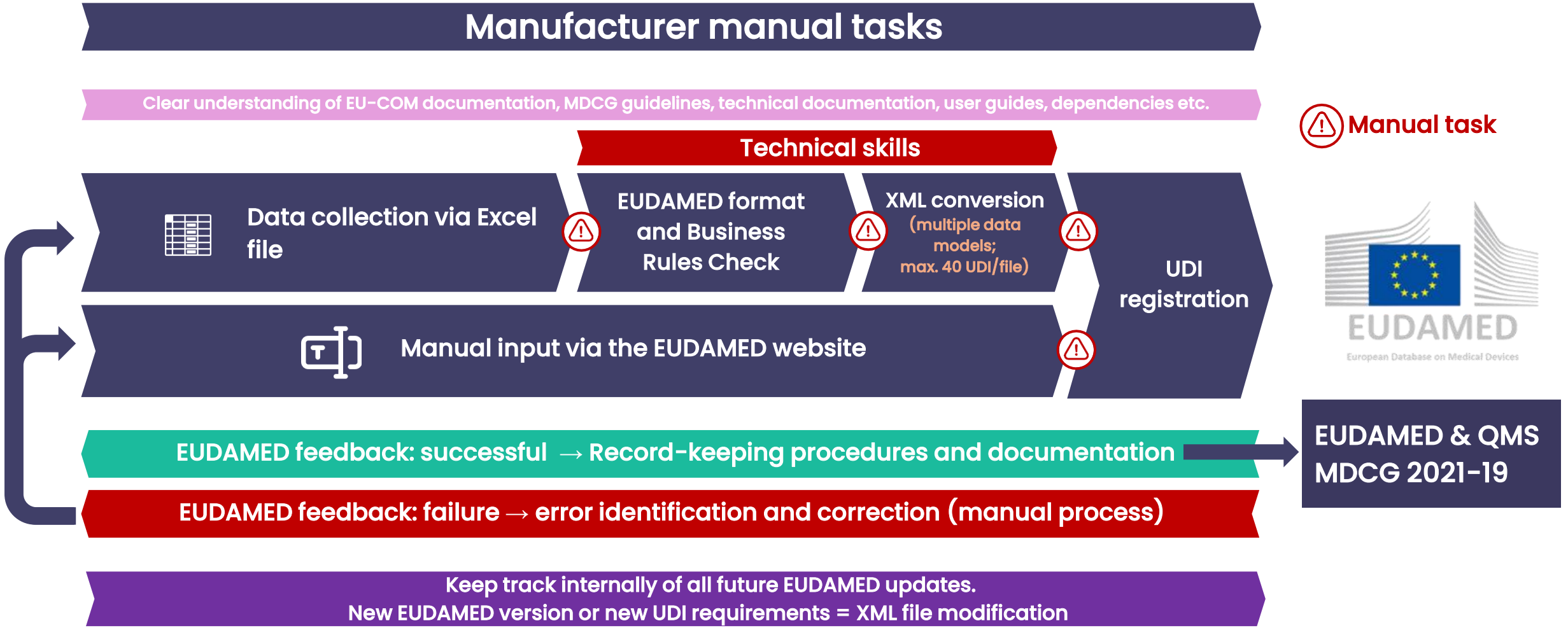
Advantages of XML

- No manual entry of UDI data

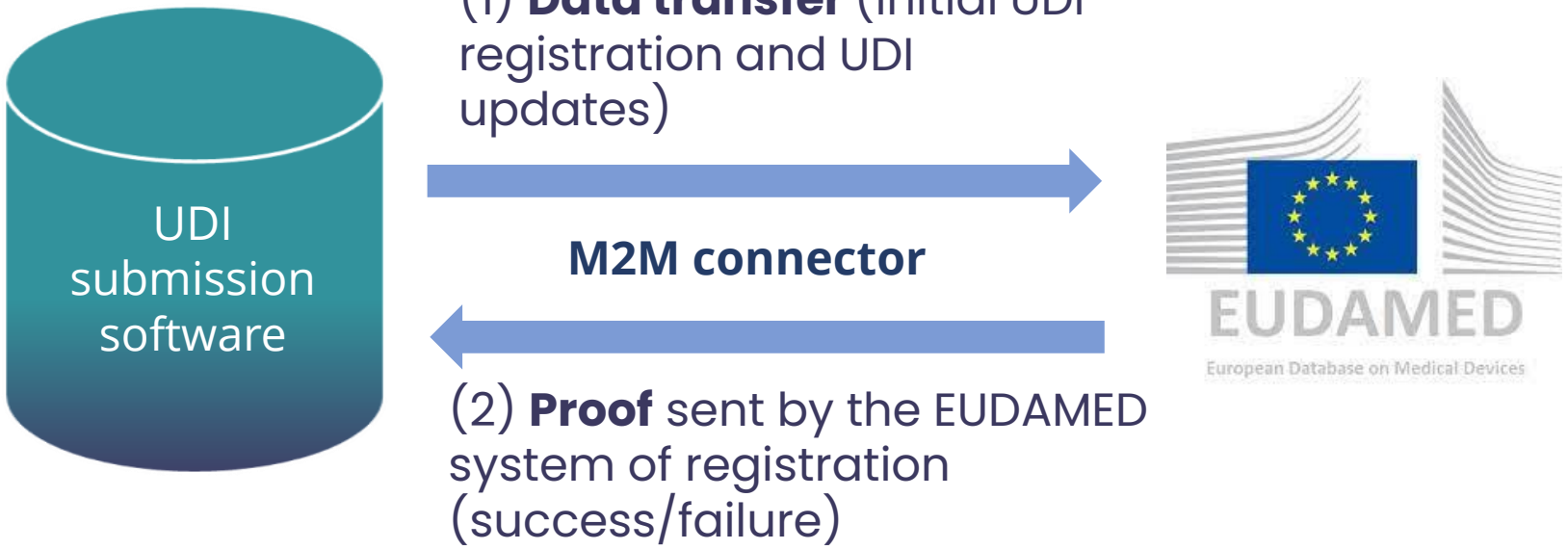
Limits of XML

- Technical limitation of 40 UDI per XML file
- XML file generation requires advanced technical IT understanding and skills
- In case of EUDAMED file rejection, necessary to be able to interpret error messages and fix the error = time consuming process
- In case of EUDAMED file rejection, no UDIs in the file will be registered in EUDAMED – everything will be rejected
- Upload of XML file is a manual action: potential source of error
- Necessary to set up internal data traceability and to manually document actions (requirement MDR/IVDR - see EUDAMED & QMS, MDCG 2021-19)

MANUAL/XML DATA UPLOAD SUMMARY



M2M DATA TRANSFER



M2M DATA TRANSFER: SUMMARY

EUDAMED updates = new software releases

Data collection via Excel file

Manual entry & data duplication

Connection to internal systems

Qualified provider ACKOMAS

EUDAMED Business Rules Check

UDI registration

EUDAMED confirmation

Customized project support + quality assurance tools + full traceability

Manufacturer tasks

Software tasks (Full M2M connector)

M2M DATA TRANSFER

Advantages:

- **Secured automated data transfer via qualified access point**
  - No waiting time for data registration
  - Full data traceability
  - Elimination of manual tasks
- **Registered proof** of all successful/failed data registration in EUDAMED
- Automated bulk submission of UDI data = **significant reduction of time** spent on manual entry
- **Elimination of errors** associated to manual entry or manual XML file upload

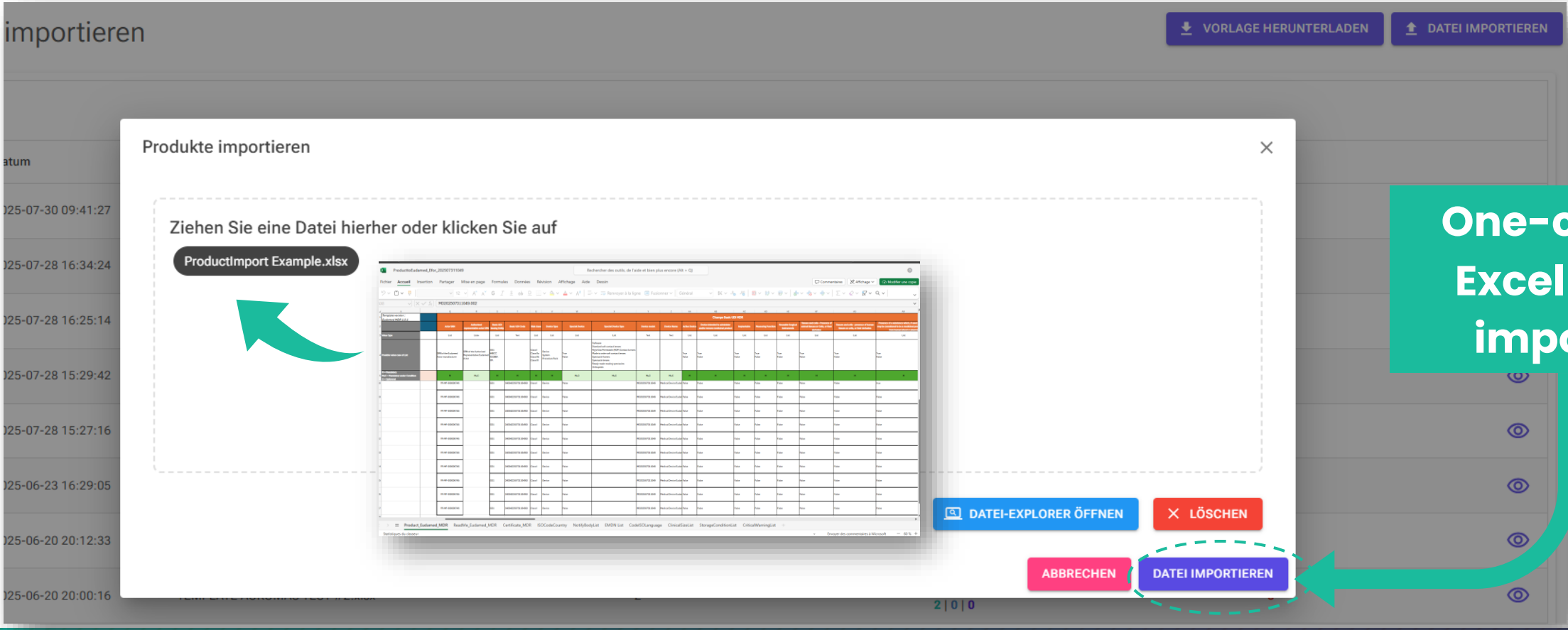
Challenges for setting up internal M2M access point (manufacturer-owned access point):

- **Technically complex:**
  - time-consuming and very costly IT project for internal teams
  - High level IT skills necessary

Challenges for choosing external M2M access point (3rd party solution provider):

- **Choosing the right provider and correctly evaluating:**
  - Quality of solution and service
  - Solution robustness
  - Solution reliability

EUDAMED: M2M EXAMPLE



One-click Excel file import

EUDAMED: M2M EXAMPLE

State	Last update	File name	Products created / updated / in error
✓	2025-03-04 16:57:32	Template Import MD_Eudamed_MDR data (Données M3 - DA) 040325.xlsx	9 / 2236 / 0
✓	2025-03-04 16:32:36	Template Import MD_Eudamed_MDR data (Données M3 - DA) 040325.xlsx	131 / 2105 / 9
✓	2025-03-04 15:45:12	Template Import MD_Eudamed_MDR data (Données M3 - DA) 040325.xlsx	683 / 1422 / 140
✓	2025-02-25 15:59:06	Template Import MD_Eudamed_MDR data (test DA).xlsx	1413 / 9 / 0
✓	2025-02-18 15:55:16	Template Import MD_Eudamed_MDR data (002).xlsx	0 / 9 / 0
✓	2025-02-18 15:50:38	Template Import MD_Eudamed_MDR data (002).xlsx	0 / 9
✓	2025-02-18 13:27:42	Template Import MD_Eudamed_MDR data (002).xlsx	0 / 9 / 1
✓	2025-02-18 11:36:45	Template Import MD_Eudamed_MDR data (002).xlsx	9 / 0 / 1
!	2025-02-18 11:26:56	Template Import MD_Eudamed_MDR data.xlsx	0 / 0 / 10

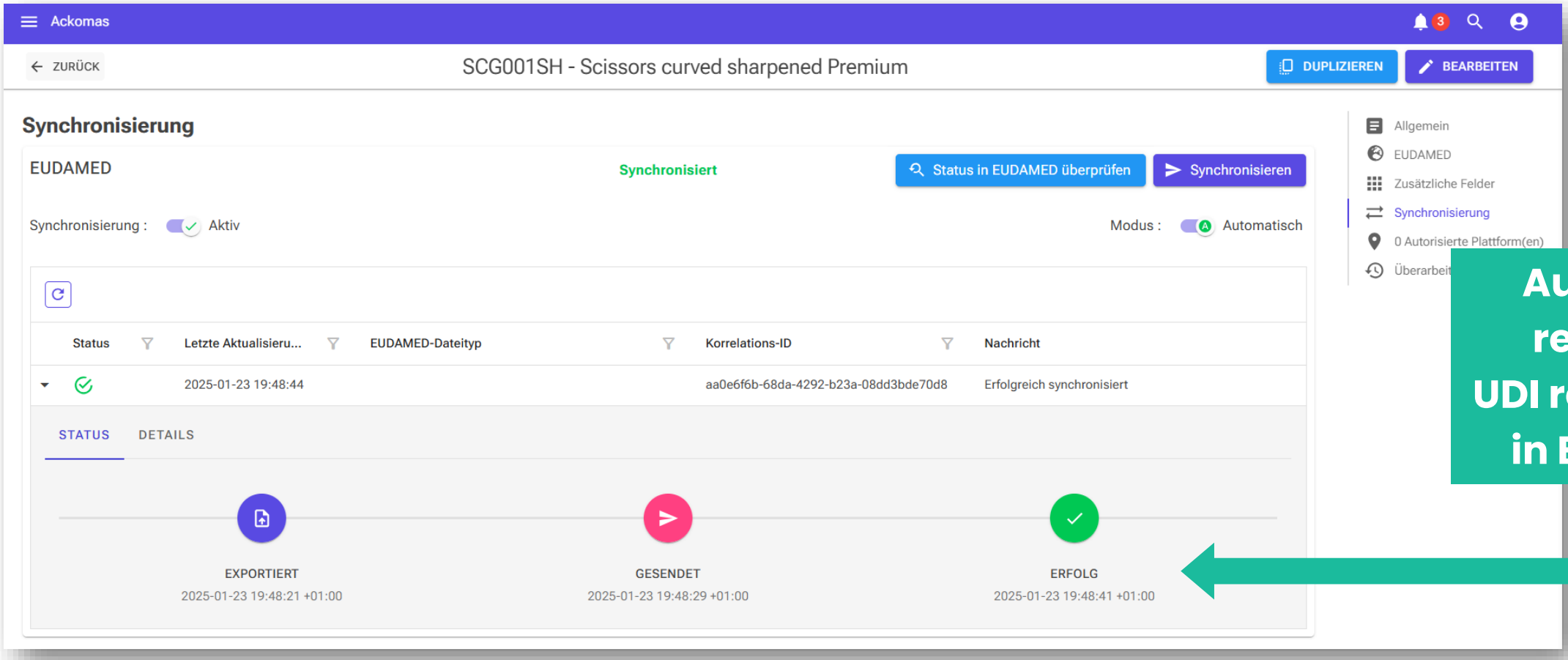
Clear UDI upload status

EUDAMED: M2M EXAMPLE

Blattname	Linie	Spaltenname	Zellenwert	Fehlertyp
Product_Eudamed_MDR	8	Identifier	3400420004683	Ungültiger Wert
Product_Eudamed_MDR	8	Identifier Type	GTIN	Ungültiger Wert
Product_Eudamed_MDR	8	Organism	I8	Ungültiger Wert
Product_Eudamed_MDR	8	Secondary UDI-DI		Pflichtfeld
Product_Eudamed_MDR	8	UDI-DI info same as product		Pflichtfeld
Product_Eudamed_MDR	8	UDI-DI Issuing Entity	AN8	Ungültiger Wert
Product_Eudamed_MDR	9	Identifier	3400420004690	Ungültiger Wert

Clear error identification

EUDAMED: M2M EXAMPLE



Automatic real-time UDI registration in EUDAMED

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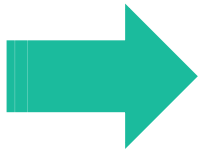
EUDAMED: DATA GOVERNANCE

EUDAMED centralizes critical medical device data

- All submitted data needs to be:
  - ✓ **Reliable** (accurate, up-to-date)
  - ✓ **Complete** (all required data is present)
  - ✓ **Traceable** (it is known **who** did **what**, **when** and **why**)
- Efficient data governance relies on:
  - ✓ **Clear roles** (RA, QA, IT, etc.)
  - ✓ **Documented processes**
  - ✓ **Suitable and reliable tools**

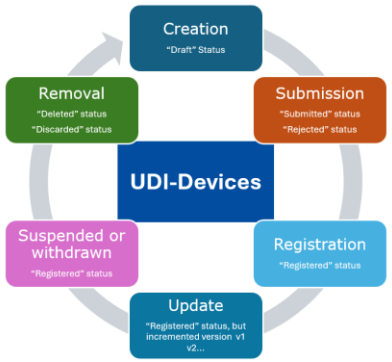


Goals:

- Avoid errors ensure compliance
- Facilitate audits and avoid findings.

FDA/GUDID feedback: audits revealed insufficient data quality → important not to repeat the same mistakes in EUDAMED.

EUDAMED: DATA GOVERNANCE



Data lifecycle: A structured approach

- Each UDI follows a cycle: Creation → Validation → Registration → Update → Archiving
- In EUDAMED:
  - ✓ Certain attributes are **not modifiable** once registered in EUDAMED.
  - ✓ Each modification generates a new version.
  - ✓ Certain actions (eg. deletion, discard) are **only manually possible** and **under certain conditions.**

Goals: Anticipate the impact of errors and data changes from the very beginning.
QI/QO/QP: Systems used for data management and submission need to be **qualified** in order to guarantee data exchance reliability with EUDAMED.

EUDAMED: DATA GOVERNANCE

Auditability, traceability, security: key requirements

- Data needs to be all all times **accessible**, **intelligible** and **justifiable.**
- EUDAMED requires:
  - ✓ Complete **action traceability** (who, what, when).
  - ✓ Secured access (user rights, role separation).
  - ✓ A durable, sustainable preservation of data and record history**.**

Upcoming audits: Supervising entities (competent authorities, notified bodies) can audit public data in EUDAMED → data as **key component** of audits/inspections.

EUDAMED: DATA GOVERNANCE

Good practices for ensuring data integrity

- Set up a data repository in alignment with EUDAMED: Single Point of Truth.
- Define clear rules and processes: who creates, who validates, who submits?
- Train teams for comprehensive EUDAMED understanding and for related tools.
- Plan data checks at regular intervals.

Data integrity is a **collective** mission, a **continuous** and **documented** process.

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NEXT STEPS

4. Start collecting your data (establish single point of truth).

3. Identify and understand the type and critical importance of each UDI attribute.

5. UDI submission to EUDAMED.

1. Determine total number of BASIC UDI-DI and UDI-DI to be registered in EUDAMED.

2. Evaluate available internal ressources and allocate them for EUDAMED integration → Select the **most suitable registration method**.

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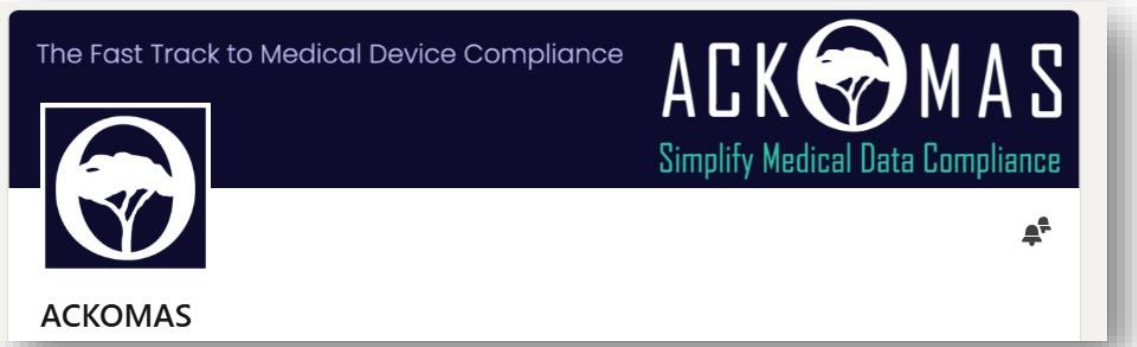
SUMMARY

EUDAMED will soon be mandatory: 28.05.2026

- ✓ The UDI/Device module requires **significant time investment**
- ✓ Gain a **clear understanding** of requirements for EUDAMED compliance
- ✓ The **clock is ticking**: only a few months remaining for understanding requirements, setting up internal processes and registering your data
- ✓ Choose the **right approach** and allocate the **right ressources** in a timely manner
- ✓ If in need of assistance, choose **reliable partners** who can assist you with EUDAMED requirements and UDI submission
- ✓ Don’t wait: **start now** your EUDAMED UDI project

FOR MORE ON EUDAMED & M2M UDI SUBMISSION



https://www.linkedin.com/company/ackomas/

Kristina Iancu

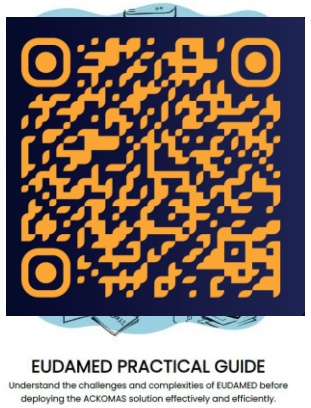
Regulatory Database Specialist

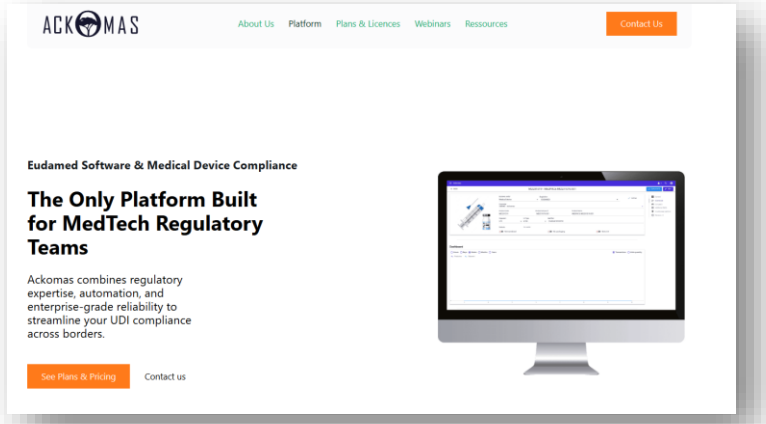
DACH Region

📍 **Strasbourg, France**

kiancu@ackomas.com

+33 6 85 99 64 78





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