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EUDAMED registration deadlines are approaching: Is your company ready?

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EUDAMED Registration deadlines: Get your company ready

What is EUDAMED?

It is the EU database under MDR (Regulation 2017/745) and IVDR (Regulation 2017/746) to centralize information on medical/IVD devices.

Purpose: to enhance transparency, improve device traceability, and strengthen post-market and regulatory oversight.

Who Needs to Register?

Economic operators: manufacturers, system/procedure pack producers, authorised representatives (for non-EU manufacturers), importers.

All devices placed on the EU market must have their UDI and device data submitted to EUDAMED. Legacy devices (those certified under the previous Directives) also have specific submission obligations.

What Modules Make Up EUDAMED?

Six interconnected modules and a public portal:

1. **Actor Registration:** For registering economic operators and obtaining SRN. Live since December 2020.
2. **UDI/Device Registration:** For registering devices & device identifiers. Live since October 2021; mandatory phase approaching.
3. **Notified Bodies & Certificates:** Manages CE certificates and notified bodies' data. Partially available.
4. **Clinical Investigations & Performance Studies:** Under development; will record studies and investigations.
5. **Vigilance & Post-Market Surveillance:** Under development; will record incidents and actions after devices are on the market.
6. **Market Surveillance:** Under development; will support monitoring compliance, inspections, and non-conforming products.

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What Data is Needed for the UDI Module?

Key "core" data fields to submit with each UDI-DI (as per MDR/IVDR Annex VI & user guides) include:

- Basic UDI-DI: Groups of devices with same intended purpose, risk class, essential design/manufacture.
- UDI-DI: Device version/model.
- Manufacturer / company name & address; SRN: Single Registration Number.
- Trade name, model / Catalogue number / Reference number
- Risk class of device
- Nomenclature code: EMDN.
- Key attributes: Sterile? Single-use? Contains latex, animal tissue, etc.
- Device status: Marketed, discontinued, recalled, etc.

How to Register UDIs in EUDAMED?

- **Manual entry (GUI/web interface)**: Small device portfolio; entering one UDI-DI at a time (<25 UDIs).
- **Bulk uploads (XML/structured files)**: Medium portfolios; faster than manual; need to follow EUDAMED schema **(25-50 UDIs)**.
- **Machine-to-Machine (API)/automated exchange**: Large portfolios, regular updates; reduces errors **(>50 UDIs)**.

What is available right now?

In accordance with the transitional provisions set out in Regulation (EU) 2024/1860 amending the medical devices regulations, the mandatory use of each module will start 6 months after it is declared functional following an independent audit, and the publication of a Commission notice to that effect in the Official Journal of the European Union.

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Current timelines for mandatory UDI registration and rest of modules – July 2025

2024				2025				2026				2027
Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1

Deliver end user full technical documentation for M2M first 4 modules

Notice(s) publication in the OJEU for Actor, UDI /Devices, NBs &Certificates and Market survillance

Notice publication in the Official Journal (OJEU) for vigilance

End of all transition periods for devices registration

Onboarding activities for the modules declared functional. Training material available

Increase commucation and onboarding activities

MVP Audit on 4 Modules

MVP Audit Vigilance

Mandatory use of Actor, UDI/Devices, NBs & Certificates, MSU

Mandatory use of Vigilance module

CI/PS Analysis & Development

European Commission

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Your Fast-Track to EUDAMED Compliance

A fully managed service by Asphalion that simplifies your EUDAMED submissions: no license, no subscription, no hassle.

Aspha EudaMate

EUDAMED COMPLIANCE AT SCALE

Aspha EudaMate M2M tool cuts the workload by ~75–80%

AsphaEudaMate is a Machine-to-Machine (M2M) upload tool integrated into the EUDAMED Data Exchange (DTX) system. This option allows automatic data exchange between an external backend system and EUDAMED backend services (including bulk exchange).

With this customized Asphalion-built application, **our team can connect directly to the EUDAMED DTX service** and, using a simple completed spreadsheet, upload all your UDIs in bulk in a single step, without the need to manually enter any data into the EUDAMED interface.

- **Machine-to-Machine (M2M) Massive upload tool**
- **End-to-end support: from spreadsheet to XML upload**
- **No need for expensive external tools**
- **Fully compliant with EUDAMED data structure**
- **Fixed-price packages tailored to your UDI volume**
- **Optional discounted data entry and validation services**
- **No recurring fees nor subscription — updates only when needed**
- **Designed and operated by MedTech regulatory experts**

How much time can you save with Aspha EudaMate?

# UDIs	Manual GUI	Aspha EudaMate	Time Saved (h)	Time Saved (workdays)	% Saved
100	16.7 h (≈2.1 d)	4.3 h (≈0.5 d)	**12.4 h**	1.6 d	**74%**
500	83.3 h (≈10.4 d)	17.7 h (≈2.2 d)	**65.6 h**	8.2 d	**79%**
1,000	166.7 h (≈20.8 d)	34.3 h (≈4.3 d)	**132.4 h**	16.5 d	**79%**
10,000	1,667 h (≈208 d)	334 h (≈41.8 d)	**1,333 h**	166.6 d	**80%**

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Need help?

Contact our team to guide you through SaMD/MDSW requirements, FDA submissions, and readiness for the new AI Act.

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