Your partner
in progress

European database on Medical Devices

Change is coming

What is EUDAMED?

The European Database on Medical Devices **EUDAMED** is the IT system developed by the European Commission as an integral part of MDR and IVDR implementation. It aims to enhance transparency about medical devices, including better access to information for the public and healthcare professionals, and enhancing coordination among EU Member States. The system will provide a living picture of the lifecycle of medical devices available in the European Union.

The EUDAMED Modules

The system integrates six modules to collate and process information on medical devices and manufacturers:

1. Actor registration
2. Unique Device Identification (UDI) and device registration
3. Notified Bodies and certificates
4. Clinical investigations and performance studies
5. Vigilance and post-market surveillance
6. Market surveillance

There is **EU guidance** on practices in the transition to full availability of EUDAMED for MDR and IVDR (MDCG 2021-1, MDCG 2022-12).

To stay up to date with EUDAMED development and timelines, please visit the dedicated **European Commission** webpage.

Amending Regulation (EU) 2024/1860 and EUDAMED gradual roll-out

On 9 July 2024, the amending **Regulation (EU) 2024/1860** regarding gradual roll-out of EUDAMED was published in the Official Journal of the European Union (OJEU) with immediate effect.

The objective of the amending Regulation was to further mitigate the risk of shortages of medical devices on the market and for EUDAMED this meant:

> Instead of waiting for all the modules to become available and be declared functional before their mandated use, a gradual roll-out of the EUDAMED database, will be implemented. This will make it mandatory to use those EUDAMED modules that are available for voluntary use once they are declared to be functional.

The amending Regulation makes the use of the respective EUDAMED modules mandatory, after a specified transition period, once a notice is published in the *Official Journal of the European Union* (OJEU) that the relevant modules are functional and meet the specifications.

Please refer to the **Q&A document** published by European Commission for additional guidance on the gradual roll-out of EUDAMED in the context of (EU) 2024/1860.

Actor registration module, UDI/device registration module, Notified Bodies/ certificates module and market surveillance module

On 27 November 2025 a notice was published in the *Official Journal of the European Union (OJEU)* that the following four modules (out of six) have been declared functional and meet the specifications for the Commission Decision **(EU) 2025/2371**:

- Actor registration
- Unique device identification (UDI) and device registration
- Notified Bodies and certificates
- Market surveillance

There is a 6-month transition period, and this means that the modules are mandatory to use from 28 May 2026.

The tables summarize the key dates and the specific requirements that apply to manufacturers and Notified Bodies as of those dates.

Guidance on Actor registration and Device registration can be found on the EC website **EUDAMED Information Centre**.

Key dates relevant to Manufacturers for modules declared functional

27 November 2025
Publication of the notice of module functionality in OJEU

27 May 2026
No later than 6 months after publication of the notice

Actor registration:
Economic operators must register themselves

UDI / Device registration:
Manufacturers must register their Regulation devices in EUDAMED before placing them on the market*

27 November 2026
No later than 12 months after publication of the notice

UDI / Device registration:
Manufacturers must complete registration of Regulation devices and legacy devices (unless the equivalent Regulation device is already registered) that were placed on the market before the mandatory use of the UDI/Dev module and that continue to be placed on the market also after the date.

*** Note:** for the purpose of the device registration in the UDI/Device registration module, the term 'placing on the market' refers to the instance when the first product of a given device (e.g. identified with the same UDI-DI) is placed on the market.

Key dates relevant to Notified Bodies for modules declared functional

27 November 2025
Publication of the notice of module functionality in OJEU

27 May 2026
No later than 6 months after publication of the notice

Notified Bodies/Certificates:
Notified Bodies shall start using EUDAMED to enter information regarding withdrawal and refusal of applications and regarding certificates (certificates issued, including amendments and supplements thereto, and suspended, reinstated, withdrawn or refused certificates and restrictions imposed on certificates) on an on-going basis.

27 May 2027
No later than 18 months after publication of the notice

Notified Bodies/Certificates:
Notified Bodies shall complete submitting all relevant certification and associated information on MDR/IVDR devices that manufacturers registered in EUDAMED and for which the NBs issued certificates prior to the module becoming mandatory.

What do manufacturer's need to do?

From 28 May 2026 all manufacturers are required to register as Actor in the Actor registration module and obtain a Single Registration Number (SRN), where applicable, before placing a device on the European Market*.

From 28 May 2026 all manufacturers are required to register any devices and systems and procedure packs new to the market in the UDI and device registration module before the first individual unit of this device or system or procedure pack is placed on the European market*.

For any devices and systems and procedure packs already placed on the European market before 28 May 2026, the corresponding device registration in the UDI and device registration module must be done within 12 months from the publication in the OJEU, that is before 28 November 2026.

Submission of all the required device information into the UDI and device registration module would enable the manufacturer to comply with the device registration obligations as specified in Article 29 of MDR and Article 26 of IVDR. For certain devices, the UDI and device data will become visible to the public only once the Notified Body has entered the corresponding product certificate information in the Notified Bodies and certificates module.

*** Note:** for the purpose of the device registration in the UDI/Device registration module, the term 'placing on the market' refers to the instance when the first product of a given device (e.g. identified with the same UDI-DI) is placed on the market.

What do Notified Bodies need to do?

The main module to be used by the Notified Bodies is the Notified Bodies and certificates module and from 28 May 2026 they are required to submit the following information to EUDAMED:

- Certificates and changes to certificates, such as issued, amended, supplemented, restricted and re-issued
- Certificate decisions, such as cancelled, suspended, reinstated, withdrawn and refused
- Applications refused and withdrawn
- CECP notifications, and Mechanism for Scrutiny for MDR and IVDR
- Summary of Safety and (Clinical) Performance

For certificates issued in accordance with the MDR/IVDR before the mandatory use of the Notified Bodies and certificates module, the Notified Bodies have to register the related information in EUDAMED within 18 months after the publication of the notice of module functionality in OJEU, that is before 28 May 2027. This only applies to Regulation devices that need to be or are registered in the UDI and device registration module. Only the latest certificate version and, if applicable, the latest Notified Body decision taken in relation to that certificate version should be registered in EUDAMED.

Once BSI submits information to EUDAMED, certain aspects will be in the public domain to ensure transparency for the patient, healthcare professionals, health authorities and industry. To find out which kind of information will be public and which will remain confidential, please see the **EC Factsheet on MDR requirements for transparency and public information**. BSI will download data entered by manufacturers in the Actor registration and Device registration modules to verify alignment with the technical documentation (TD) submitted for review and facilitate successful uploads.

Manufacturers are responsible for ensuring that the information entered into EUDAMED is fully consistent with the TD submitted to BSI and with the details that will appear on the issued certificates.

Vigilence/post-market surveillance modules and Clinical investigations/ performance sudies module

Please refer to the **European Commission** website for the anticipated timelines on when these modules are expected to be declared functional and become mandatory for use.

What is changing?

One EUDAMED change type at a time

Currently, certificate changes can be combined and approved together to result in a revised certificate being issued. For example, a Legal Manufacturer address change (a certificate amendment) can be processed at the same time as a device is being added to the same certificate (a certificate supplement).

EUDAMED will only allow one type of change to be registered at a time. As such, in the example with the Legal Manufacturer address change and adding a new device, these certificate changes will need to be processed separately, and two certificate versions created, one for the amendment and one for the supplement. To accommodate this BSI is changing the way we are working to only allow one type of change to be approved at a time.

Certificate Revisions

Currently, the revision number specified on BSI MDR and IVDR certificates (MDR XXXXX R**YYY**) is updated at the time of certificate renewal only.

To comply with EUDAMED requirements, the revision number of the MDR and IVDR certificates will be updated with every update to the certificate.

Re-instatement of a Certificate after Suspension

Currently, when a certificate is re-instated after a period of suspension, a new certificate revision is issued with the suspension period highlighted on the certificate history page.

As EUDAMED does not allow upload of an updated certificate upon re-instatement of a certificate, BSI's re-instatement process will be changed to not issue a new certificate version. The suspension period for the certificate will be visible in EUDAMED.

Certificate and EUDAMED content approval process

Currently, the mock certificate approval process generates a mock certificate that is approved by the manufacturer prior to the Notified Body decision making step and the final certificate release.

As part of the EUDAMED implementation process, BSI is investigating the possibility of providing the clients with a certificate content form instead of the mock certificate. The certificate content form will detail the final content that will appear on the certificate and the manufacturer will be asked to approve the content before final certificate issue.

As certain aspects will be in the public domain once BSI submits information to EUDAMED, BSI is investigating the possibility of implementing a EUDAMED content approval process where the data to be submitted to EUDAMED will be shared with the manufacturer for approval before registration in EUDAMED.

Next steps

BSI will issue further communications to our clients before we implement changes including submission of information to EUDAMED.

If you have additional questions, you can contact your Scheme Manager or email us at **BSI.EUDAMED@bsigroup.com**.

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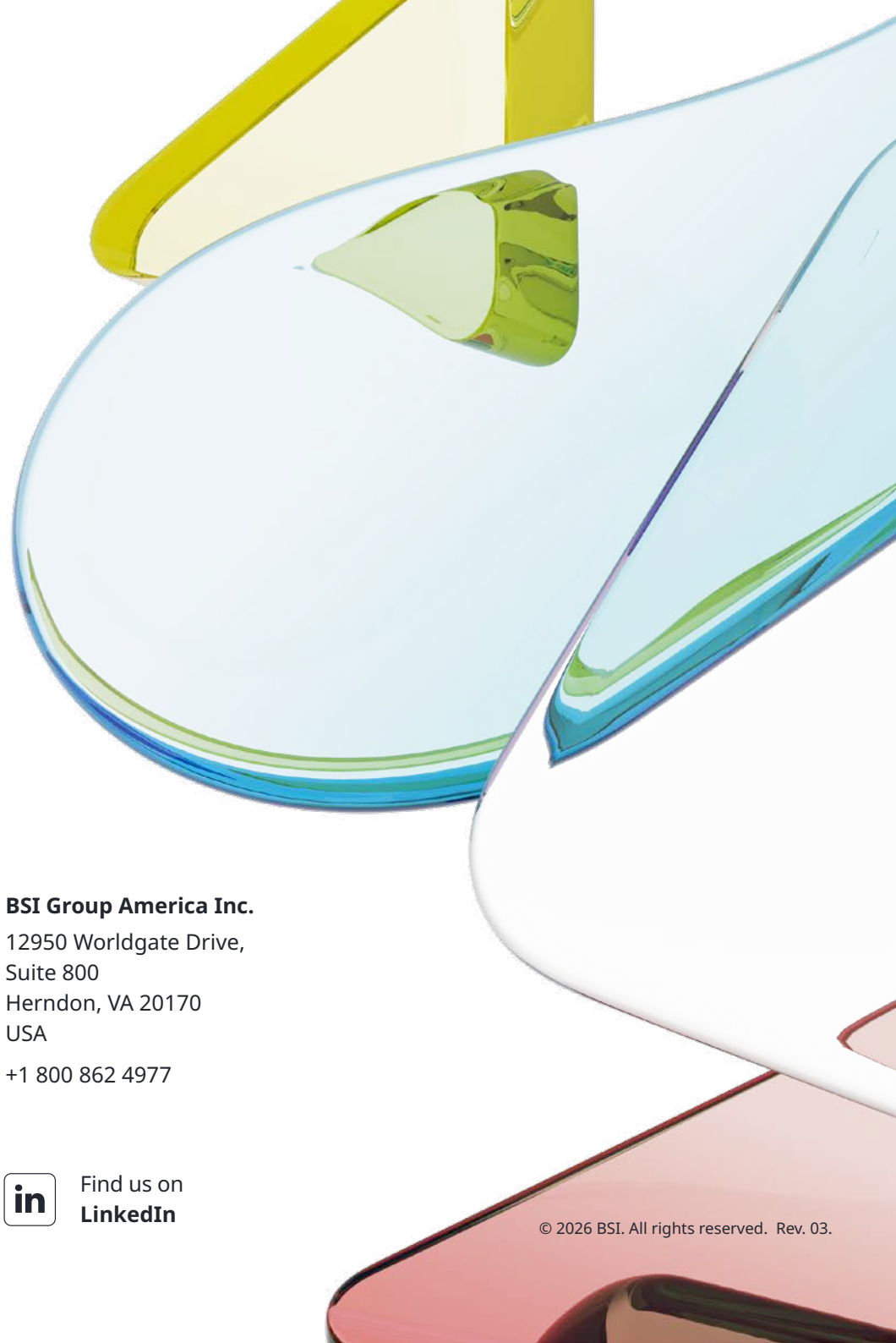

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