European Database on Medical Devices

Be prepared for change

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.
How will this work?

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

What do Notified Bodies need to do?

The use of the EUDAMED certificate module by Notified Bodies becomes mandatory at the end of the transition period once EUDAMED is declared to be functional via the publication of a Commission notice in the OJEU. Notified Bodies will be required to submit information related to applications, certificates and their changes, PSUR evaluation reports, SS(C)Ps etc. Notified Bodies may choose to submit this information ahead of the mandated deadline as modules of EUDAMED become available for voluntary use.

We have updated some of our operating processes/procedures to remain compliant and to interact with EUDAMED, and we would like to share these changes with you here.

EUDAMED timelines

Q3, 2026 - Q2, 2027
Independent Audit

Q4, 2027
End of 6 months transitional period. Eudamed becomes mandatory for modules 1,4,5 and 6

Q2, 2027
Eudamed achieves full functionality. Publication of a Commission Notice in the OJEU

Q2, 2029
End of 24 months transitional period. Eudamed becomes mandatory for modules 2 and 3

1 Minimum Viable Product (MVP) means that the system developed implements at least the minimum Medical Devices Regulations requirements and allows competent authorities and all stakeholders to comply with their legal obligations.
2 Publication of a Commission notice in the Official Journal of the European Union (OJEU). The full EUDAMED system (all 6 modules) is released.
3 The use of EUDAMED becomes mandatory as regards obligations and requirements related to Actors, Vigilance, Clinical Investigation and Performance Studies and Market Surveillance modules
4 The use of EUDAMED becomes mandatory as regards obligations and requirements related to UDI/Device and NB and Certificate

Q3, 2026 - End of the EUDAMED MVP development for all six modules

Q4, 2027 - End of 6 months transitional period. Eudamed becomes mandatory for modules 1,4,5 and 6

Q2, 2029 - End of 24 months transitional period. Eudamed becomes mandatory for modules 2 and 3

What is changing?

BSI Electronic Client Portal

We are changing how documentation is uploaded to the BSI Electronic Client Portal which is used by BSI clients to upload vigilance reports and technical documentation. The portal will include additional functionalities to allow manufacturers to upload individual documents as required for EUDAMED.

- Manufacturers will be able to submit SS(C)P documents against certificate number(s) while specifying the Basic UDI-DI(s) covered by the SS(C)P documents. Please do not submit translations of SS(C)P documents until BSI sends notification that uploads are starting to EUDAMED.
- Manufacturers will be able to submit a PSUR document against certificate number(s) while specifying the Basic UDI-DI(s) covered by those PSURs. PSURs for class III, implantable and class D devices should be submitted via the portal until EUDAMED is available for submission.

Manufacturers can access the instructions on how to submit these documents once they are logged in to BSI Electronic Client Portal.

To stay up-to-date with EUDAMED development and timelines, please check the dedicated European Commission webpage.
What is changing? – continued

MDR/IVDR Certificates - Four-date format

Moving forward, all BSI IVDR and MDR certificates will detail four dates:

- First Issue Date
- Current Issue Date
- Starting Validity Date
- Expiry Date

This change will be implemented for any MDR/IVDR certificates issued or re-issued henceforth. The four-date format is needed to align with the requirements when registering certificates in EUDAMED.

The table below shows a comparison of the current three-date format and the new four-date format:

<table>
<thead>
<tr>
<th>Three-date format on current MDR/IVDR certificates</th>
<th>Updated four-date format for future MDR/IVDR certificates</th>
<th>Explanation of the date</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Issued Date</td>
<td>First Issued Date</td>
<td>Date the certificate is first issued</td>
</tr>
<tr>
<td>Date</td>
<td>Current Issue Date</td>
<td>Date the current version of the certificate is issued</td>
</tr>
<tr>
<td>-</td>
<td>Starting Validity Date</td>
<td>Date the current version becomes effective</td>
</tr>
<tr>
<td>Expiry Date</td>
<td>Expiry Date</td>
<td>Date the certificate expires</td>
</tr>
</tbody>
</table>

MDR/IVDR certificates already issued MDR/IVDR certificates already issued with the three-date format continue to remain valid and will be converted to the four-date format when reissued (for any reason).

This change does not affect UKCA and EU Directive certificates, which will continue to use the three-date format.

Critical subcontractors and crucial suppliers

Current BSI issued quality system annex based MDR/IVDR certificates, such as Annex IX Chapter I & III certificates, include supplementary page(s) that list the critical subcontractors and crucial suppliers associated with the products covered by the scopes of those certificates. To allay any confidentiality concerns, MDR/IVDR certificates, moving forward will not include this supplementary information on subcontractors/suppliers. Instead, BSI will maintain this information within internal records.

There is no change to the process of approving any changes to critical subcontractors/crucial suppliers itself. Manufacturers must continue to notify BSI of any plans to make changes to their critical subcontractors and crucial suppliers during the certificate validity.

All quality-system based MDR/IVDR certificates issued or re-issued henceforth will not include the subcontractor/supplier information as described above. Current MDR/IVDR certificates already issued with this information continue to remain valid and will be transitioned to not having the subcontractor/supplier information the next time they are reissued (for any reason).

BSI will also implement the above principles to UKCA and EU Directive certificates moving forward to maintain a harmonised approach across all the legislations.

Other changes to BSI certificates and approval process

The changes below are anticipated to be implemented over the next few months before BSI starts submitting information into EUDAMED.

Before EUDAMED evolution

IVDR and MDR certificates revision number is updated at the time of renewal only

Mock certificate approval process generates a mock certificate that is approved by the manufacturer

After EUDAMED evolution

IVDR and MDR certificates revision number is updated each time a certificate is re-issued

Clients are provided with a certificate content form that details the final content that will appear on the final certificate and are asked to approve the content instead of a mock certificate

Next steps

Upon completion of these changes, BSI will start submitting the following information to EUDAMED when the relevant modules are available:

- Application refusals/withdrawals
- Certificates
- Changes to certificates
- Certificate cancellations/suspensions/reinstatements/withdrawals
- SS(C)P
- PSUR evaluation reports for class III, implantable and class D devices

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

If you have additional questions you can email us at: medicaldevices@bsigroup.com

Read more about our certification services on our website bsigroup.com/medical

Find us on LinkedIn