

# bsi.

## ● European Database on Medical Devices

Be prepared for change

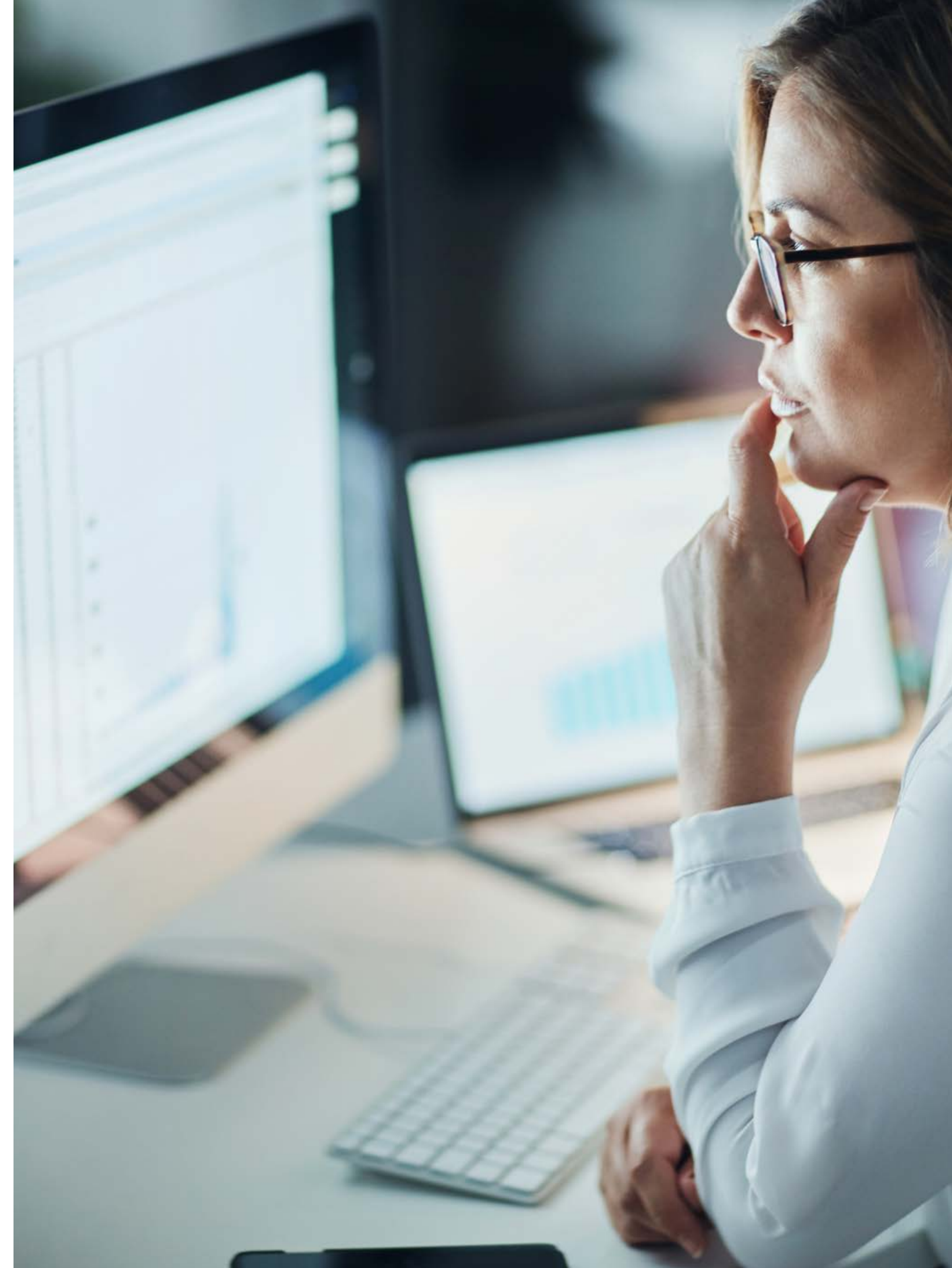
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### What is EUDAMED?

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.



By Royal Charter



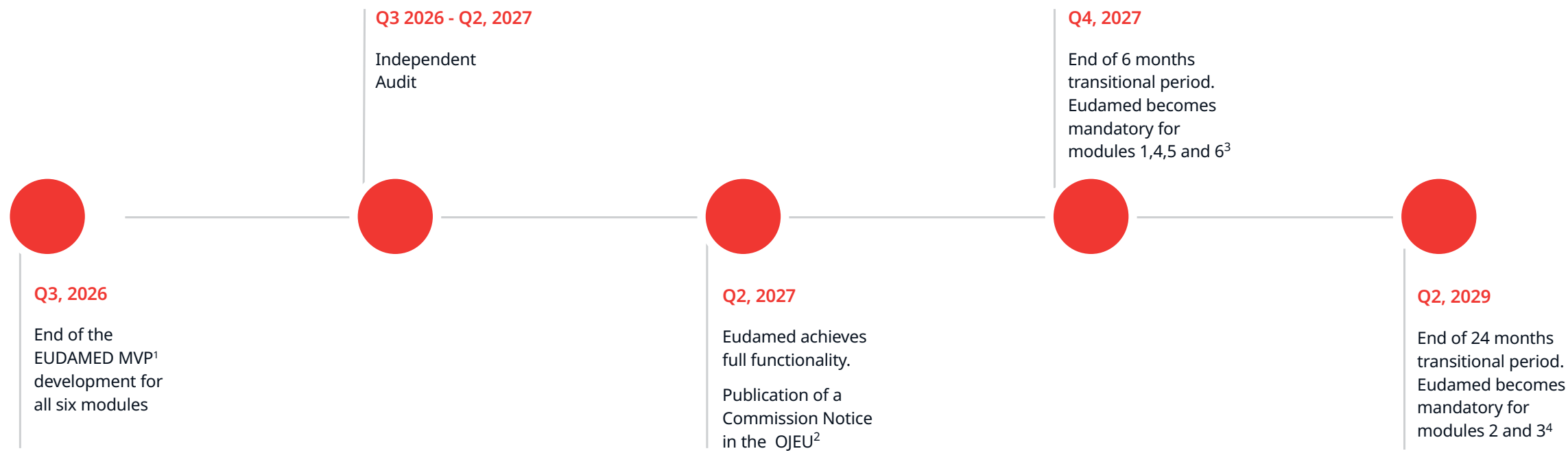
## How will this work?

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).

## EUDAMED timelines



<sup>1</sup> 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.

<sup>2</sup> Publication of a Commission notice in the Official Journal of the European Union (OJEU). The full EUDAMED system (all 6 modules) is released.

<sup>3</sup> The use of EUDAMED becomes mandatory as regards obligations and requirements related to Actors, Vigilance, Clinical Investigation and Performance Studies and Market Surveillance modules

<sup>4</sup> The use of EUDAMED becomes mandatory as regards obligations and requirements related to UDI/Device and NB and Certificate

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

## 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**.

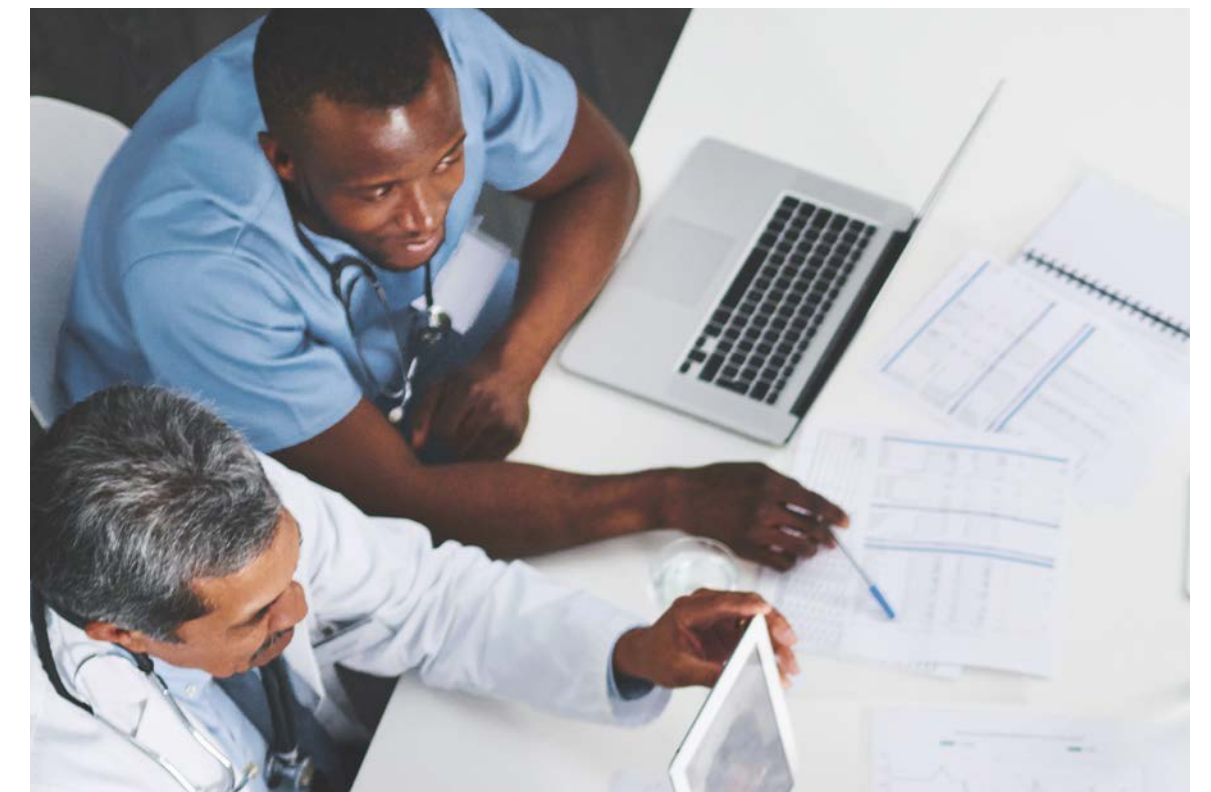
## What is changing?

### 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.





## 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:

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

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	After EUDAMED evolution
IVDR and MDR certificates revision number is updated at the time of renewal only	IVDR and MDR certificates revision number is updated each time a certificate is re-issued
Mock certificate approval process generates a mock certificate that is approved by the manufacturer	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**



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