EU IVDR Transition Toolkit

Ready for May 2022?

The IVDR EU 2017/746 entered into force in May 2017 with a five-year transition period.

You have the duration of this period to update your Technical Documentation to meet the requirements and comply with the Regulation before the Date of Application on **26 May 2022.**

Use our resources to support your transition

Conformity Assessment from a full scope EU IVDR Notified Body

At BSI, we rigorously review medical devices to ensure that they conform to the requirements of the European Directives and Regulations.

Supported by a dedicated IVD Team of Technical Specialists with an average of 20 years' experience, BSI provides CE certification under the EU IVDR.

More information is available on our website
www.bsigroup.com/ivdr

Start your application early

The transition to the EU IVDR requires you to plan and implement the new requirements, undergo a Conformity Assessment for your IVD medical device, and make any necessary adjustments before May 2022.

It is important for you to understand the EU IVDR before applying for Conformity Assessment to CE mark your device and place it in the EU market.

Use our Toolkit to access the resources you need for your transition

Your EU IVDR Transition Toolkit

Brochures, guidance and documents

- IVDR FAQs
- IVDR Readiness Review
- IVDR Training Courses
- IVDR Best Practice Guidelines
- Conformity Assessment Routes Guide

Your EU IVDR Transition Toolkit

White papers

- QMS for IVDs
- IVD Classification Rules
- Post-market Surveillance
- Risk management

Your EU IVDR Transition Toolkit

Webinars

- GSPR and the IVDR
- IVDR Application Process
- Conformity Assessment Routes
- QMS Requirements under the IVDR

Your EU IVDR Transition Toolkit

Training

- IVD to IVDR Transition
- Requirements of the IVDR for CE marking
- Implementation of the IVDR for CE marking

Talk to BSI today

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bsigroup.com/medical

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and start your journey with us