The EU IVDR Date of Application is approaching

Are you ready for the May 2022 deadline?

The In Vitro Diagnostic Regulation (IVDR) EU entered into force in May 2017 with a five-year transition period. Manufacturers have the duration of the transition period to update their Technical Documentation to meet the requirements and comply with the Regulation before the Date of Application of the IVDR in May 2022.

Conformity assessments from a full scope EU IVDR Notified Body

BSI The Netherlands (2797) is a leading Notified Body; we 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 is able to offer CE certification under the EU IVDR.

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

Use our resources to support your transition.
It is important that you 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.

Use this toolkit to access the key resources you need to prepare for your transition.

Your EU IVDR Transition Toolkit

- **Brochures and guidance documents**
  - IVDR FAQs
  - IVDR Readiness
  - Conformity Assessment Routes
  - IVDR Training
  - IVDR Best Practices Guidelines

- **Whitepapers**
  - QMS for IVDs
  - IVD classification
  - Post-market surveillance
  - Risk management

- **Webinars**
  - Conformity Assessment Routes
  - IVDR application process
  - GSPR and the IVDR
  - QMS requirements under the IVDR

- **Training**
  - IVD to IVDR transition
  - Requirements of the IVDR for CE marking
  - Implementation of the IVDR for CE

For more information on these and our full range of IVDR training courses, visit our website: [www.bsigroup.com/ivdr](http://www.bsigroup.com/ivdr)

Talk to BSI today
Call: 1 800 862 4977
Visit: [bsigroup.com/medical](http://bsigroup.com/medical) and start your journey