BSI/UK/1601/TR/0819/EN/GRP

Requirements and Implementation of the *In Vitro* Diagnostic Regulation

Training course

STAGE 1 2 3

Essential information about the course

The In Vitro Diagnostic Regulation details the requirements which manufacturers have to meet to sell In Vitro Diagnostic devices in the European Union. It replaces the In Vitro Diagnostic Directive.

This course introduces you to the key requirements of the IVDR. IVDs will now be classified according to their risk using a new rule-based system. The majority of IVDs will be subjected to independent assessment of their conformity to the Regulation by a Notified Body and will require third-party certification for the first time.

The course explores the four risk classifications and the conformity assessment routes for IVDs. It defines the Technical Documentation required, and the product safety and performance expectations, including requirements on clinical evidence, Post-Market Clinical Follow-up (PMCF) and Post-Market Surveillance (PMS). Traceability of devices through the supply chain and product labelling will be reviewed during the course.

The Regulation contains detailed requirements that need to be implemented, and will affect all IVD manufacturers, importers, distributors and EU Representatives. This course aims to offer guidance on implementation of the requirements stipulated in the IVDR into your business.

Please note: This course does not cover Medical Devices under the Medical Devices regulation (MDR EU2017/745).

Our course agenda

Day 1	**Day 2**
• What is an IVD? • CE marking approach for IVD's and an introduction to the key players in the IVDR • Classify IVD devices • Conformity assessment routes • Role of the General Safety and Performance Requirements as a basis for CE Marking • Technical Documentation and the Technical File • Product claims, labelling, UDI and EUDAMED • Requirements of performance evaluation • Post-market surveillance and Vigilance	• What is an IVD? • Background to EU and CE marking • Responsibilities • Placing on the market • Harmonized standards and common specifications • CE mark • Risk based Classification • Conformity assessment • Notified bodies and scrutiny

Day 3	Day 4
• Case study business case • GSPRs • Performance evaluation, clinical evidence and post market performance follow up • Post-market surveillance and vigilance reporting	• Case study regulatory strategy • Technical documentation • Product claims and labelling • EUDAMED and registration • Process validation and supplier control • Other Directives and Regulations • Case study: Product strategy Book today at **bsigroup.com/training**

Upon successful completion of your course, you'll receive an internationally recognized BSI certificate

Make sure the course is right for you

Who is this course for?

Manufacturers of In Vitro Diagnostic devices, in particular those who have not yet placed an IVD on the market in the EU, especially: Regulatory Affairs, Design and Development, Clinical Affairs Specialists, Quality Management, Quality Assurance personnel, and other Economic Operators including manufacturers, importers, distributors and authorized representatives who are new to, or have little familiarity with, the EU IVD market.

What will I learn?	What are the benefits?

• Identify devices that are within scope of the Regulation
• Understand the roles and responsibilities of the different Economic Operators identified by the Regulation
• Identify other key players and their obligations under the Regulation
• Identify key requirements concerning the following steps for conformity assessment:
  • Determine the risk class of IVD
  • Select conformity assessment procedure
  • Identify applicable General Safety and Performance Requirements (GSPRs)
  • Recognize key elements of Technical Documentation
  • Appreciate the importance of product claims, labelling, Unique Device Identification (UDI) and EUDAMED (The European Database on Medical Devices)
  • Identify requirements of clinical evidence
  • Post-Market Surveillance and updates
• Develop a strategy for regulatory compliance as stipulated by IVDR
	• Identify the key requirements of the In Vitro Diagnostic Regulation
	• Interpret and communicate the key requirements and expectations of the IVDR to your organization
	• Identify the next steps in planning of product realization and commercialization in conformity with the IVDR
	• Implement the requirements of the European In Vitro Diagnostics Devices Regulation
	• Execute robust and compliant performance evaluation and post market follow up studies
	• Guide and support other people and partner organisations affected by IVDR

• Recognize the roles and responsibilities of Economic Operators (legal manufacturer, Authorised representative, Importer and Distributor) and other Key Players (Notified Body, Competent Authority, significant subcontractors) under the IVDR • Explore the role of the Notified Body • Implement requirements concerning the following steps for Placing on the Market • Plan post-market activities required by IVDR • Impart knowledge concerning IVDR requirements into your organization, e.g. in projects for CE-marking	

Why invest in training from BSI?

We want to make sure you have the best learning experience possible. That's why we offer a range of training courses from beginner to expert. We create a positive learning environment so you retain the knowledge and acquire the skills that will continue to be of use beyond the course.

When you attend a BSI training course, our tutors are the best in the business. They're truly passionate about sharing their knowledge and ensuring you learn. Trusted experts with years of hands-on and business experience, they bring the subject matter to life with relevant and contemporary examples to enhance your learning.

Training delivered at your site could be a convenient and cost effective option, especially if you have multiple delegates. Talk to one of our experts to find out more.

Next steps with the BSI Academy

Want to learn more? You may be interested in:

Application of the IVD Regulation, IVD Directive to IVD Regulation Transition, Technical files and design dossiers for In Vitro Diagnostics (IVDs), Performance evaluation and clinical evidence for In Vitro Diagnostics (IVDs), Suite of ISO 13485 courses

BSI Group
Kitemark Court
Davy Avenue, Knowlhill
Milton Keynes, MK5 8PP

Find out more
Call: **+44 (0)345 086 9000**
Email: **training@bsigroup.com**
or visit: **bsigroup.com/training**