BSI/UK/1600/TR/0819/EN/GRP

Implementation of the *In Vitro* Diagnostic Device Regulation for CE Marking

Training course

STAGE 1 2 3

Essential information about the course

The In Vitro Diagnostic Devices Regulation (IVDR 2017/746) is the legislation detailing the requirements which manufacturers have to meet to place in vitro diagnostic devices on the market in the European Union.

The Regulation contains detailed requirements that need to be implemented, and will affect all IVD manufacturers, importers, distributors and EU Representatives.

The IVDR focusses on devices to be safe and effective, emphasizing pre-market requirements, conformity assessment, post-market-surveillance (PMS), and traceability.

This course aims to offer guidance on implementation of the requirements stipulated in the IVDR into your business.

Our course agenda

Day 1	**Day 2**	**Day 3**
• 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	• 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/en-IL/medical-devices/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?

The course is especially suitable for:

- RA, QM, and QA professionals who will be implementing the IVDR within their organisations
- Personnel concerned with certification or active in projects for CE-marking, including R&D scientists, production personnel, project management.
- Staff in contact with IVD Device manufacturers at companies which are partners to manufacturer, e.g. as subcontractor, crucial supplier, OEM, Authorized representative, importer, distributor, auditee

What will I learn?	What are the benefits?
• Develop a strategy for regulatory compliance as stipulated 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	• Take the necessary steps for your organization to meet the IVDR requirement • 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

Prerequisites - you are expected to have the following prior knowledge:

Participants must have an understanding of the requirements in the IVDR, for example conveyed through our IVDD to IVDR transition course, or the 1-day Requirements of the IVDR training course.

Participants would benefit from an understanding of European In Vitro Diagnostic Device legislation, or some experience in pre-or post-market activities within the EU.

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:

Requirements of the IVDR
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)
Risk Management for medical devices
Process validation
MDR courses

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