Requirements and Implementation of the Medical Device Regulation

Training course

STAGE 1 2 3

Essential information about the course
Learn about the key requirements, concepts, and the overall process for CE marking under the Medical Devices Regulation (MDR). The CE mark gives access to a market with 500+ million people. All medical devices will need to undergo a conformity assessment procedure based on the MDR requirements to be placed on the EU market.

This course conveys key concepts and requirements of the European MDR, offering guidance on the implementation of the requirements. Learn to draw up a clear concept or project plan, and how to integrate the requirements into your business and your documentation. You should gain confidence and expertise to evaluate and implement more specific requirements of your own.

The Regulation will affect all medical device manufacturers, importers, distributors and EU Representatives. Suppliers and subcontractors will also be affected, as well as manufacturers of some devices without a medical purpose (for example, devices used for esthetical body modification or contact lenses that change eye colour without correcting vision).

The MDR focusses on device safety and performance, emphasizing pre-market requirements, conformity assessment, quality management aspects, Post-market surveillance (PMS), transparency and traceability. The requirements will also affect (supply chain) audits and governmental control; introduce new partners to interact with, and increase communication needs and obligations (for example: contracts, reporting, documentation, and publication of information).

Please note: This course does not cover In Vitro Diagnostic devices under the IVD Reegulation.

Our course agenda

Day 1	**Day 2**
• Introduction to CE marking and European legislation, and general obligations under the MDR • Scope of the MDR • Determine risk class of device • Select conformity assessment procedure • Amend and maintain a QMS • Identify applicable safety and performance requirements • Assemble Technical Documentation • Apply conformity assessment procedure and assign unique identifications • Complete Declaration of Conformity (DoC) and affix CE mark • Post-market surveillance (PMS)	• General obligations • Scope of the MDR • Determine risk class and applicable 'NBOG' codes • Select conformity assessment procedure • Amend and maintain QMS • Identify applicable safety and performance requirements

Day 3	Day 4
• Continuation of applicable safety and performance requirements • Technical documentation best practice • Apply conformity assessment procedure	• Assign Unique Identifications • Complete DoC (Declaration of Conformity) and affix CE mark • Post Market Surveillance (PMS) • Review of course 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?

This course is especially suitable for RA, QM, and QA professionals who need to implement the MDR; Anyone concerned with certification or active in projects for CE marking; Employees working for organizations that partner with Medical Device manufacturers e.g. as subcontractor, crucial supplier, OEM, authorized representative, importer, distributor, auditee.

What will I learn?	What are the benefits?
• Communicate the key requirements and concepts within the Regulation • Reference aspects and evaluate if and how your company is affected by the MDR and to what extent • Explain the structure and administration of the Regulation • Recognize partners of manufacturers affected by the Regulation • Describe the key steps of a conformity assessment • Explain the main impacts on the QMS relating to the MDR • Recognize the requirements for PMS and updates • Evolve a strategy for regulatory compliance as stipulated by MDR • Implement requirements concerning conformity assessment • Fulfil technical documentation requirements • Plan post-market activities required by MDR	• Understand the key requirements and concepts of the MDR • Communicate the impact of the key requirements introduced by the MDR to your organization • Implement the requirements of the European MDR • Guide and support other people and partner organizations affected by MDR • Set up and update required documentation • Take the necessary steps for your organization to meet the MDR requirement • Maintain compliance to MDR and other/future documents related to Medical Device legislation • Systematically explore and implement more detailed and updated provisions (e.g. common specifications (CS), delegating and implementing acts, standards)

• Put into effect your knowledge of implementation of MDR 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 MDR Regulation, Medical Device Directive to Medical Device Regulation Transition, Technical files and design dossiers for MDR, Clinical evidence for Medical Devices, 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**