BSI/UK/1657/TR/1119/EN/GX

Technical Documentation for the Medical Device Regulation (MDR)

Training course

STAGE 1 2 3

Essential information about the course

A required part of conformity assessment and CE Marking is the need for technical documentation which includes the collation of supporting information about your medical device. Technical documentation is maintained throughout the product lifecycle. Learn how to assemble this and other types of required information so you can CE Mark your device in Europe.

This one-day intensive course enables greater understanding of the key requirements for technical documentation for medical devices, in line with the European Medical Device Regulation (MDR) requirements in Europe. The aim of the course is to enable manufacturers to:

- Create robust technical documentation to demonstrate compliance to the MDR
- Better understand regulatory requirements and Notified Body expectation, to prevent unnecessary delays to the certification process

Our course agenda

- Technical documentation: Conformity assessment, overview and contents
- Interpret the MDR technical documentation requirements
- MDR Annex II:
  - Section 1: Device description and specifications, including variants and accessories
  - Section 2: Information to be supplied by the manufacturer
  - Section 3: Design and manufacturing information
  - Section 4: General safety and performance requirements
  - Section 5: Benefit-risk analysis and risk management
  - Section 6: Product verification and validation
- MDR Annex III Section 1: Technical documentation on post-market surveillance Information to be supplied by the manufacturer
- MDR Annex XIV:
  - Part A: Clinical evaluation
  - Part B: Post-market clinical follow-up
- MDR Annex IV: Declaration of conformity
- Guidance documents: Technical documentation structures

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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?

QA/Regulatory personnel involved in compiling technical documentation; product design personnel and those in research and development for medical devices intended for the European market.

What will I learn?	What are the benefits?
Upon completion of this training, you will be able to: • Confirm the technical documentation requirements as specified in the MDR and relevant guidance documentation • Interpret the MDR in relation to the technical documentation requirements • Define the process enabling the creation and maintenance of compliant technical documentation • Grasp how standards and guidance can be used to improve your technical documentation • Recognize what is expected by Notified Bodies for technical documentation during reviews and be better prepared • Recognize the documentation requirements during the product lifecycle and the post-market updates needed	This course will help you to: • Ensure auditable technical documentation meets regulatory requirements and demonstrates product safety and performance • Reduce delays to product certification by providing complete and compliant documentation • Reduce costs by reducing audit questions and nonconformities, thereby streamlining the certification process

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

You should have a basic understanding of European Medical Device Regulation (MDR).

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 Medical Device Regulation (MDR) Training Course

Implementation of the Medical Device Regulation (MDR) for CE Marking Training Course

Medical Device Directive (MDD) to Medical Device Regulation (MDR) Transition Training Course

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