Medical devices CE marking

Course Description

BSI's "Medical Devices CE Marking" three day course is designed to provide participants with the knowledge to assist their companies in getting products to market more quickly.

Management personnel responsible for all aspects of CE marking medical devices as well as internal and external auditors will benefit from this course. Participants will gain knowledge of the requirements of the Medical Device Directive and the CE Marking approach. Participants will be able to provide leadership for their organizations when placing medical devices on the market in the European Union.

Learning Objectives

On completion of this training, participants will be able to:

- Explain the European CE Marking approach and its legal and operational basis
- Explain the structure and purpose of the medical devices directive
- Implement the EU risk classification criteria for medical devices
- Identify the conformity assessment routes and quality assurance requirements for the various risk classes
- Describe the role of the essential requirements as the basis for CE Marking, including the use of standards
- Explain the importance and role of clinical data
- List labelling requirements
- Identify the regulatory significance of risk management and process validation
- Identify the necessary steps required for post market surveillance for different risk classes
- Interpret the criteria for reporting adverse incidents under the vigilance system
- Define the manufacturer's regulatory responsibilities, including reporting of changes to products and QMS system to the Notified Body
- Identify technical documentation requirements
- Identify the relevance of recent changes to the medical device directives
- Conduct internal and external audits for compliance with the directives.

Intended Audience

- Regulatory, quality, design, development, manufacturing, marketing managers and personnel
- Organizations preparing 'own branding' or 'private labelling' of devices
- Potential internal auditors and others who need an in-depth knowledge of the requirements of the medical devices directives.

Course Duration

Three days.

Prerequisites

Participants should have experience with or basic knowledge of quality management systems for the medical device industry or experience of the manufacture, design, marketing or use of medical devices.

How will I learn?

We use accelerated learning techniques that encourage interaction and collaboration, keep the course varied and put your learning in context. Our tutors are the best in their field and will make sure your learning needs are met. Choose between public or in-company courses tailored to your business – whatever delivers the most positive and successful outcome for you.

Where will I learn?

We deliver five star learning at first class venues. Each venue has been selected to provide the best possible learning environment so you can maximize your learning experience.

Who are we?

As an EU Notified Body, our expertise is in auditing to the requirements of the Directives. Our tutors are skilled in transferring knowledge contained within each standard to help you embed excellence within your organization. With over 65,000 clients in 150 countries worldwide, you can trust BSI to help you perform better, reduce risk and grow sustainably.

Why train with us?

We've trained and audited thousands of businesses using the same standards so we can genuinely benchmark performance. And we can take you from beginner to certification quickly then support you with follow-up courses and webinars – and all this for the price of your course.

Did you know?

Our tutors are active practitioners in their subjects, ensuring the latest developments are fully understood. We are the leaders in medical devices regulatory expertise with over 200 BSI Medical Device product and regulation experts around the world.

Next step:

To book this course, call one of our dedicated training experts on +1 800 862 6752 or book online at bsigroup.ca/training

In-company Training

Discuss your product development in confidential surroundings by opting for bespoke in-company training.

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