CE marking Medical Devices with Software

Course Description

When it comes to creating, testing, and maintaining software, there are often grey areas. However, when your software applies to a medical device, the steps you take to define, classify, develop, and test your software become critical to both your business and patient health.

Achieving and maintaining a CE mark for your medical device software is essential to keeping your product marketable. For those organizations that are unsure how the medical device directives apply to their software, how their software is classified, and how to develop and maintain it with a CE mark in mind, this course will help you evaluate your software and processes so you can know what to do during the life-cycle of your software to meet the medical device directives and get on track.

Course Benefits

- Know what to do during software development and maintenance to meet the medical device directives
- Properly classify your software based on medical device directive parameters
- Effectively plan software risk management, development, testing, maintenance and problem resolution
- More efficiently achieve a CE mark for you medical device containing software
- Assess risks that may impact your software.

Learning Objectives

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

- Identify the relevant directives, standards, and guidance documents recommended to develop, maintain, and validate medical software according to the state of the art
- Determine if software is covered by an EU medical directive for CE Marking, and if so how you classify the software
- Apply concepts from the key software standards and guidance documents, including EN 62304, MEDDEV 2.1/6, and EN 60601-1
- Develop the basic knowledge necessary to evaluate software lifecycle processes and risk management to ensure that they are compliant with the medical directives.

Intended Audience

This course is intended for individuals or organizations involved in software within the medical device industry.

Course Duration

One day in-company training only.

Prerequisites

There are no formal prerequisites for this course.

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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