Introduction to CE Marking for the In Vitro Diagnostics Directive

Course Description

This BSI one day course has been designed to introduce the In Vitro Diagnostics Directive (IVDD), the types of product covered by the Directive and the regulatory framework required for placing IVD products on the European market.

On completion of training, participants will be able to apply knowledge of the directive to the development of IVD products as well as their on-going maintenance to achieve continued regulatory compliance throughout the lifecycle of the product.

Learning Objectives

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

- Explain the European CE marking approach with respect to IVDs
- Describe the structure and scope of the IVDD
- Identify what is an IVD device
- Classify IVD devices and determine appropriate conformity routes
- Describe the role of essential requirements as the basis for CE marking including the use of standards and an awareness of the technical documentation to support compliance
- Describe the requirements for performance evaluation
- Identify the necessary steps required for post-market surveillance and the reporting of adverse incidents under the vigilance system.

Intended Audience

- Senior management
- Regulatory, quality, research, design, development, manufacturing, marketing managers and personnel
- Organizations preparing 'own brand' or 'private label' devices
- Distributors of IVDs.

Course Duration

One day.

Prerequisites

There is no prerequisite for this course but participants will benefit from a basic knowledge of medical device use or manufacture.

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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