

Course Title:

Pathways to CE Marking under the In Vitro Diagnostics Directive

Product ID: N168

Duration: 50 mins

SME: Sue Spencer

Course Description:

This course provides an in-depth review of all aspects of the in vitro diagnostic regulations in Europe including their classifications, which conformity assessment routes are applicable, how to consider the essential requirements and what the post market surveillance requirements are to keep in vitro diagnostic devices safe on the European market.

The course is based on the requirements of the current directive 98/79/EC. However, since the new draft regulation has already been published, a specific course is developed to outline the potential future requirements.

Watch the Course Trailer:

Learning Objectives:

Upon successful completion of this course, learners will be able to

- apply the current applicable classification rules for IVD devices in Europe
- choose the right conformity assessment route
- comply with the applicable essential requirements for the specific IVD devices
- develop a post market surveillance plan for the IVD devices.

Who Should Enroll:

Regulatory associates and regulatory managers, quality assurance associates and managers, production managers, design and development engineers, regulatory body personnel.

Related Resources: Yes

Prerequisite Knowledge

An understanding of the GHTF principles for IVD devices will greatly help as pre-requisite knowledge to this course.

Price:

Premium: €111.00.- **Basic:** €148.00.-

Course Format:

All WMDO professional online training courses are fully interactive and contain audio, video, graphic animation, online quizzes and include all necessary course materials. Trainees receive a minimum of 60 days of unlimited access in which to complete each course depending on course length and complexity. (See individual course descriptions for details). Courses include handouts, case studies, working documents and other useful links. After successful completion of your course, you will be able to download your WMDO Certificate of Completion for your training records.

Online courses are cross-browser compatible and require internet connection (minimum 300kbs) and Adobe Flash Player installed (Free download available at: <http://www.adobe.com/products/flashplayer>).

Premium Account Holders:

Premium account holders enrolling in this course will receive complimentary email access to subject matter experts for any questions, clarifications or feedback they may have concerning this course and its contents, including free automatic course updates for 1 full year.