



WORLD MEDICAL DEVICE ORGANIZATION

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Online Training for Medical Device Professionals

Course Title:

Steps to CE Mark

Product ID: 162

Duration: 52 mins

SME: Carole Stamp

First Released On: 02/17/2011

Course Description:

This course walks learners through the different steps of the path to CE-mark including classification system and routes to CE-mark based on an efficient quality system and adequate technical file.

Watch the Course Trailer:

Learning Objectives:

Upon successfully completing this course, learners will be able to:

- Illustrate the CE-mark process and its major components
- Understand how classification systems under the medical device directive work
- Determine how manufacturers decide which CE-mark route is appropriate for a particular device
- Recognize the importance of a well-designed quality system
- Comprehend technical files and the differences with STED as a global system

Who Should Enroll:

Professionals new to the medical device industry, including inventors, managers, CEOs, or business professionals needing to understand the elements of the CE-mark process are all encouraged to participate in this course.

Related Resources: Yes

Prerequisite Knowledge

The following material is required:

- Understanding what constitutes a medical device
- How to determine if a product is considered a medical device
- Understanding the different phases of the medical device lifecycle

Price:

Premium: €115.00.- **Basic:** €154.00.-

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.