



WORLD MEDICAL DEVICE ORGANIZATION

WMDO SA
Route de Denges 28C
1027 Lonay
Switzerland
Tel. +41 21 349 96 36
Fax +41 21 349 96 37
contact@wmdo.org

WMDO USA
3565 IDS Center 80
South 8th Street, Minneapolis
MN 55402, USA

Online Training for Medical Device Professionals

Course Title:

The Draft European IVD Regulation

Product ID: N181

Duration: 50 mins

SME: Sue Spencer

Course Description:

This course is designed to provide manufacturers with an overview of the major changes in concept and legislation of the latest draft proposal for IVD regulations in Europe (published in September 2012).

Watch the Course Trailer:

Learning Objectives:

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

- Understand the major differences between the current directive and the new regulation proposal
- Know what to expect once the new regulation comes into effect
- Start planning for implementing the new regulation requirements
- Embark on the necessary discussions with notified bodies in advance

Who Should Enroll:

Regulatory associates and managers, quality assurance associates and managers, production managers, design and development engineers, and regulatory body personnel are all encouraged to enroll in this course.

Related Resources: Yes

Prerequisite Knowledge

Familiarity with the current IVD Directive and EU regulatory system is required. These topics are outlined in the WMDO course "Pathways to CE-Marking Under the In Vitro Diagnostics Directive" (ID N168).

Price:

Premium: €114.00.- **Basic:** €152.00.-

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.