

**Course Title:**

## Standalone Software Under the Medical Devices Directives

Product ID: N137

Duration: 40 mins

SME: Steve Marshall

**Course Description:**

This course provides a detailed introduction to standalone software for medical devices.

It covers the following topics:

- Definition of standalone software
- EU requirements for software running on medical devices
- Software as a standalone medical device
- How the recent FDA draft guidelines on mobile medical apps complement the EU requirements
- EU MEDDEV guidelines for standalone software
- Expected developments in the MDD recast

At the end of this course there is a brief question and answer section.

### Watch the Course Trailer:

**Learning Objectives:**

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

- Comprehend the regulatory framework related to standalone software as medical devices
- Participate in the evaluation compliance process with regulations related to standalone software

**Who Should Enroll:**

Development managers and engineers who wish to update their knowledge about regulatory requirements related to standalone software, regulatory and quality managers involved in compliance issues related to standalone software, and executive management employees who wish to oversee compliance-related aspects of standalone software as medical devices are all welcome to participate in this course.

**Related Resources:** Yes

**Prerequisite Knowledge**

Participants should have sound work experience related to medical device software compliance.

The following course is strongly recommended:

- Understanding Software Validation (ID 227)

**Price:**

**Premium:** €120.00.- **Basic:** €160.00.-

**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.



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Online Training for Medical Device Professionals

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