

**Course Title:**

## Electronic Instructions for Use of Medical Devices in the European Union

Product ID: N143

Duration: 50 mins

SME: Carole Stamp

First Released On: 04/20/2012

**Course Description:**

This course provides a detailed review of the European requirements for the electronic labeling of medical devices under directives 93/42/EEC (Medical Device Directive [MDD]) and 90/385/EEC (Active Implantable Medical Device Directive [AIMDD]). The contents of this course are based on the European regulation 207/2012: "On Electronic Instructions for Use of Medical Devices."

### Watch the Course Trailer:

**Learning Objectives:**

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

- Recall the context and background of electronic labeling
- Implement Instructions for Use (IFU) in an electronic format based on risk assessment
- Assess whether the conditions for providing IFUs in an electronic format are fulfilled

**Who Should Enroll:**

Regulatory affairs professionals in charge of labeling, developmental engineers and clinical research managers who contribute to the setup of medical device labeling, and quality managers and engineers who are responsible for change control of technical documents (including labeling) are all encouraged to participate in this course.

**Related Resources:** Yes

**Prerequisite Knowledge**

A strong grasp of the CE-marking process, essential requirements, the principles of the risk management process, and the logical links between essential requirements, risk management, clinical evaluation, and the outcome for labeling are all requirements for this course.

Knowledge of the general requirements for labeling that apply within the European Union is also required.

For more information on the topics above, please review the following courses:

- Labeling Requirements for Medical Devices in Europe (ID N133)
- Risk Management for Medical Devices in EU and US (ID ID 78, 83, 94 and N189)
- The European Union Regulatory System for Medical Devices (ID 145)

**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



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