



Technical Documentation

Regulation (EU) 2017/745

REF. E-MDR-MOD-08 – E-LEARNING

EUROPEAN REGULATIONS

COURSE DESCRIPTION

The Technical Documentation module presents the content of the Technical Documentation and the information in the documentation regarding post-market surveillance.

DURATION

23 minutes, including a 15-minute lesson and 8 minutes of quizzes



E-LEARNING

TECHNICAL PREREQUISITES

Computer and internet connection

METHODS USED

The module is composed of a lesson in the form of an **interactive video with voice-off** and **learning activities**. The module can be **accessed 24/7**. Reminders are sent to monitor knowledge acquisition and avoid a break in the learning curve.

TARGET TRAINEES

All individuals involved in the MD sector

PREREQUISITES

Familiarity with the Regulation's main definitions and general principles, and more particularly the General Safety and Performance Requirements (N.B. covered in the Overview and GSPR modules)

ACCESS

The CEISO ACADEMY platform can be accessed for a period of two months within two business days at most of approval of your order.

ADDITIONAL BENEFITS

Summary presentation of the regulation

Support materials **designed by experienced consultants-trainers**

Interactive lesson

Short modules that can be accessed as often as required and **autonomously**

As an option, you may select **Q&A sessions** with one of our consultants-trainers

EDUCATIONAL GOALS

- Familiarity with the Regulation's Annexes that set out the content of the Technical Documentation (TD)
- Familiarity with the requirements in terms of the TD content for the EU conformity declaration
- Familiarity with the documentation's elements on post-market surveillance

COURSE CONTENT

Assistance with navigation/Module objectives/Presentation of the course content

1. Prerequisites for the conformity declaration (Annex II)
2. Post-market surveillance (Appendix III)

EVALUATION METHODS

Course evaluation quiz
Satisfaction survey
Attendance certificate

This training is assessed based on each individual's acquisition of knowledge via a quiz at the end of the program (*success criteria* >= 80%). If trainees pass the quiz, they receive their training certificate, as well as the corrected quiz, by email.



Do you have a question? Contact us!

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