



# Conformity Assessment Regulation (EU) 2017/745

REF. E-MDR-MOD-06 – E-LEARNING

EUROPEAN REGULATIONS

## COURSE DESCRIPTION

The Conformity Assessment module presents the procedures to assess conformity and the Technical Documentation's sampling principles in the framework of this assessment.

## DURATION

16 minutes, including a 10-minute lesson and 6 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, more particularly regarding market authorization, as well as classification and UDI rules (N.B. covered in the Overview, EUDAMED and UDI, Market Authorization and MD Classification 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.

## EDUCATIONAL GOALS

- Understand the conformity assessment procedures for medical devices according to Regulation (EU) 2017/745
- Understand the Technical Documentation's sampling principles in the framework of Medical Device conformity assessments

## COURSE CONTENT

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

1. Preamble
2. Conformity assessment procedures
3. Technical Documentation assessment via sampling
4. Quality Management System evaluation

## 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

## 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*  $\geq 80\%$ ). 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!

Email: [formation@ceiso.fr](mailto:formation@ceiso.fr)

Tel: +33 6 42 58 94 52