



Package for DISTRIBUTORS

Regulation (EU) 2017/745

REF. E-MDR-F-02 – E-LEARNING

EUROPEAN REGULATIONS

COURSE DESCRIPTION

The DISTRIBUTORS' package is composed of 7 modules and has been designed specifically to present, in an interactive format, the main obligations of Medical Device distributors to ensure compliance with Regulation (EU) 2017/745.

DURATION

195 minutes, including 125 minutes of lessons and 70 minutes of quizzes



E-LEARNING

TECHNICAL PREREQUISITES

Computer and internet connection

METHODS USED

The modules are composed of lessons in the form of **interactive videos with voice-off** and **learning activities**. They 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, and more particularly MD distributors

EDUCATIONAL GOALS

- Understand the regulatory framework for medical devices
- Identify the requirements that apply and their impact on distribution activities

PREREQUISITES

Familiarity with the MD sector

COURSE CONTENT

1. Overview of Regulation (EU) 2017/745
2. Obligations of economic operators
3. EUDAMED & UDI
4. Market authorization
5. Classification of Medical Devices
6. Post-Market Surveillance & Vigilance
7. Quality Management System

ACCESS

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

EVALUATION METHODS

Course evaluation quiz
Satisfaction survey
Attendance certificate

This package is assessed based on each individual's acquisition of knowledge via a quiz at the end of each module (*practice quiz*) and one at the end of the 7 modules (*final quiz/success criteria* $\geq 80\%$). If trainees pass the final quiz, they receive their training certificate, as well as the corrected quiz, by email.

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



Do you have a question? Contact us!

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