



# Package for PRODUCTION/PURCHASING

## Regulation (EU) 2017/745

REF. E-MDR-F-09 – E-LEARNING

EUROPEAN REGULATIONS

### COURSE DESCRIPTION

The Production/Purchasing package is composed of 5 modules and has been designed specifically to present, in an interactive format, the main obligations of the Production and Purchasing Departments to ensure compliance with Regulation (EU) 2017/745.

### DURATION

150 minutes, including 95 minutes of lessons and 55 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 the Production/Purchasing Departments

### EDUCATIONAL GOALS

- Understand the regulatory framework for medical devices
- Identify the requirements that apply and their impact on the Production/Purchasing Departments' activities

### PREREQUISITES

Familiarity with the MD sector

### COURSE CONTENT

1. Overview of Regulation (EU) 2017/745
2. EUDAMED & UDI
3. General Safety and Performance Requirements
4. Technical Documentation
5. 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.

### 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 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 5 modules (*final quiz/success criteria >= 80%*). When trainees pass the final 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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