

Medical Device Sterilization

Course outline

October 1st and 5-7th, 2026

Important information

1. Before the course

The course literature is distributed as e-book 4 weeks before the training. To get the most out of the training it is highly recommended that you read this book and get well familiarized with the content. The actual amount of preparation needed depends on your previous experience with the various sterilization methods.

2. Online session

One week before the onsite training there will be a 1-day online training session where we will go through general requirements on the sterilization process, introduction to microbiology, bioburden estimation, use of biological indicators and the difference between 'test of sterility' vs 'test for sterility' – this is an important part of the training and attendance is required for the certification.

3. On-site session

This part consists of 3 days face-to-face training, at DGI-Byen, in Copenhagen. The agenda is found on page 3-4 of this document.

4. After the course

You have the opportunity to undergo an examination to verify your knowledge. The exam consists of eight questions that shall be answered with free text (there are no alternatives to choose from).

It is an open exam, so you can make use of the e-book, the training material and any other information while preparing the answers (please note that it is an individual test, meaning that no co-operation with other attendees should occur when preparing and submitting the answers).

Detailed agenda: see next page →

Course content

Day 1 Online - October 1st, 08.30-17.00

- 08.30 Course start - presenting trainers & attendees
- 08.45 Introduction to sterilization and overview of sterilization standards
- 09.15 General requirements for sterilization (ISO14937:2009) and the relation to the Quality Management System ISO13485:2016
- 10.00 Short break
- 10.30 Microbiology; microbial characteristics and their role for sterilization
- 11.00 Bioburden estimation. Microbiological methods - Part 1. Determination of population of microorganisms (ISO 11737-1:2018)
- 12.00 (Lunch break)
- 12.45 Test of sterility vs test for sterility, 11737-2 vs EU Pharmacopeia
- 13.30 Packaging for terminally sterilized medical devices – Requirements on materials, sterile barrier system and packaging systems (ISO 11607-1:2019)
- 14.15 Short break
- 14.35 Use of Biological Indicators (ISO 11138-1:2017)
- 15.30 Clean rooms
- 15.45 Test of sterility vs test for sterility, ISO 11737-2 vs EU Pharmacopeia
- 16.30 Wrap-up, information about the onsite training
- 17.00 End of day 1

Day 2 Onsite - October 5th, 09.00-17.00

- 09.00 Introduction and welcome (recap from the online day)
- 09.45 Microbial inactivation kinetics – Requirements for terminally sterilized device to be designated “STERILE” (EN 556-1)
- 10.30 Break
- 10.45 Radiation sterilization Part 1. Nature of ionising radiation and measurement of dose (ISO 11137-1, -3)
- 12.00 Lunch
- 13.00 Radiation sterilization Part 2. Dosimetry
- 13.45 Radiation sterilization Part 3. Establishing the sterilization dose (ISO 11137-2)
- 14.15 Break
- 14.30 Radiation sterilization Part 3. (Continued)
- 15.30 Exercise – Radiation dose setting
- 16.30 Review of exercise results
- 17:00 End of day 2

Day 3 Onsite - October 6th, 08.30-16.45

- 08.30 Radiation sterilization Part 4. IQ, PQ and Routine Control
- 09.50 Break
- 10.10 "Irradiation audit" – exercise
- 11.15 Exercise feedback
- 12.00 Lunch
- 13.00 Heat sterilization; ISO 17665 - Validation and routine control of sterilization by moist heat
- 13.45 Dry heat sterilization – EN ISO 20857:2013
- 14.15 Break
- 14.30 Exercise on ISO 17665
- 15.30 Feedback and review of exercise
- 16.00 Choice of material for terminally sterilized medical devices
- 16.45 End of day 3

Day 4 Onsite - October 7th, 08.30-16.45

- 08.30 Ethylene oxide – Validation and routine control of the sterilization process (ISO 11135:2014)
- 09.45 Break
- 10.00 Ethylene oxide ISO11135:2014 (continued)
- 11.00 Exercise – EO Sterilization Audit
- 11.45 Lunch
- 12.45 Exercise review and feedback
- 13.30 Cleanrooms & associated controlled environments (ISO 14644, Part 1–5)
- 14.15 Break
- 14.30 Introduction to Aseptic processing. Part 1: General requirements ISO 13408-1 (to some extent, Part 2-5 and EN 556)
- 15.15 Overview of recent development and changes in regulations and standards for medical device sterilization
- 16.00 Summary – closing remarks and information about the exam.
- 16.45 End of Day 4