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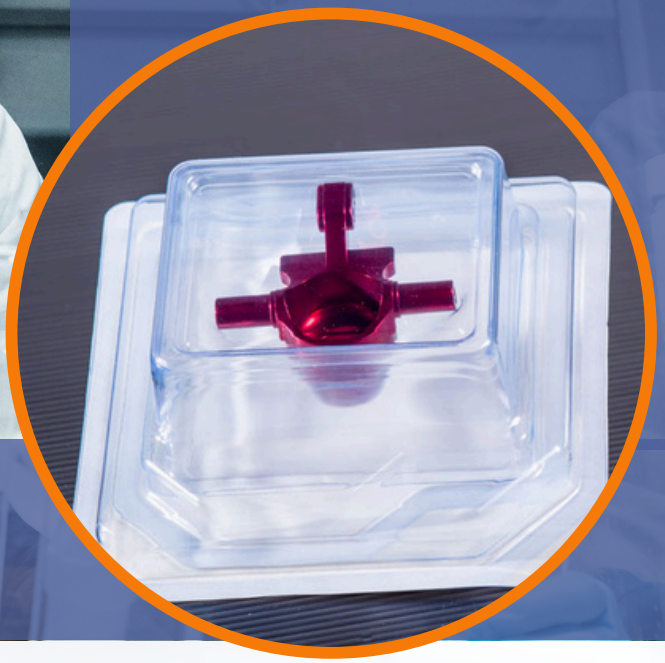


ON-SITE WORKSHOP

REQUIREMENTS AND GENERAL PRINCIPLES FOR THE PACKAGING AND STERILISATION OF MEDICAL DEVICES

Lisa Heilemann, Marcel Dörkes & Vincent Bornbaum

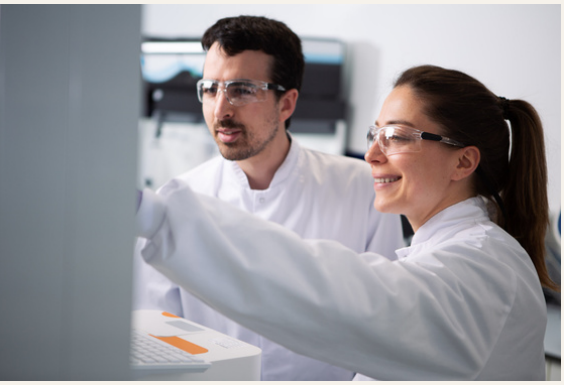
25th September 2025

8:30- 15:30 CET

with Lunch & individual Meet the Expert Sessions

WORKSHOP LOCATION VAN DER VALK HOTEL UTRECHT I WINTHONTLAAN 4 I 3526 KV UTRECHT, NETHERLANDS

SEMINAR LANGUAGE: ENGLISH



INTRODUCTION

The Medical Device Packaging & Sterilisation Workshop is a key event for professionals working in the medical device sector, offering a focused exploration of current standards, practical challenges, and regulatory developments. This workshop will provide a comprehensive overview of the requirements and best practices for the packaging and sterilisation of medical devices, with a particular emphasis on ISO 11607 and ISO/DIS 10993-7.

Participants will benefit from expert-led sessions covering packaging development, validation processes, and sterilisation methods including Gamma and Ethylene Oxide (EO). The programme also includes a detailed look at recent updates to ISO/DIS 10993-7, with practical examples and threshold calculations for EO residuals.

This workshop is an excellent opportunity to deepen your understanding of regulatory expectations, gain practical insights, and connect with peers and experts in the field.

WORKSHOP REGISTRATION

Register via the following link:
https://form.jotform.com/251883721659468

AGENDA

08:30 - 09:00 — **Welcome and introduction**

09:00 - 10:00 — **Packaging of medical devices – Development**

- Types and materials of sterile packaging systems
- Suitability of sterile packaging systems for different medical devices
- Requirements for the sterile packaging in relation to the use of the medical device
- Requirements for the development of sterile packaging systems (e. g. protective cap, fixation)
- Documentation according to ISO 11607

10:00 - 10:15 — **Coffee break**

10:15 - 11:15 — **Validation of sterile packaging according to ISO 11607**

- ISO 11607-2 qualification and validation of the machine and sterile packaging: Qualification & Validation
- ISO 11607-1 requirements for the medical device and material suitability: Material suitability, Transportation & Aging

11:15 - 11:30 — **Coffee Break**

11:30 - 12:30 — **Sterilisation Processes I**

Different Methods to sterilise medical devices

- How to find the right method
- Gamma Sterilisation according to ISO 11137
- Validation of Gamma Sterilisation Process

AGENDA

12:30 - 13:30	**Lunch**
13:30 - 14:30	**Sterilisation Processes II** • Ethylene Oxide Sterilisation ISO 11135 • Validation of EO Sterilisation • Upcoming changes and overview
14:30 - 15:00	**ISO/DIS 10993-7 Biological Evaluation of Medical Devices** – Ethylene oxide sterilisation residuals - Focus on Threshold Determination • Implemented Changes: An overview of the key changes in the standard and their significance for practice. • Determination of thresholds for EO and ECH residuals. • Exemplary Calculations for different devices
15:00 - 15:30	**Individual Meet the Expert Sessions**

ABSTRACTS

PACKAGING OF MEDICAL DEVICES – DEVELOPMENT

This session explores the fundamentals of sterile packaging systems, including material types and their suitability for various medical devices. Participants will gain insights into design requirements aligned with device usage, such as protective features and fixation elements. The session also covers essential documentation practices in accordance with ISO 11607, ensuring compliance throughout the development process.

VALIDATION OF STERILE PACKAGING ACCORDING TO ISO 11607

This session provides a structured overview of the qualification and validation processes for sterile packaging systems and sealing equipment in line with ISO 11607-2. It also addresses the requirements of ISO 11607-1, focusing on material suitability, transportation simulation, and ageing studies. Participants will gain practical insights into ensuring packaging integrity and compliance throughout the product lifecycle.

STERILISATION PROCESSES I

This session introduces the various sterilisation methods available for medical devices and provides guidance on selecting the most appropriate technique. A particular focus will be placed on Gamma sterilisation, including its validation process in accordance with ISO 11137. Participants will gain a practical understanding of method selection and regulatory requirements for effective sterilisation.

ABSTRACTS

STERILISATION PROCESSES II

This session focuses on Ethylene Oxide (EO) sterilisation in accordance with ISO 11135, covering key aspects of process validation and regulatory compliance. Participants will also receive an overview of upcoming changes to the standard, with practical insights into how these updates may impact current sterilisation strategies.

ISO/DIS 10993-7 BIOLOGICAL EVALUATION OF MEDICAL DEVICES

Ethylene oxide sterilisation residuals - Focus on Threshold Determination

In this session, the latest changes to the ISO/DIS 10993-7 standard for the Ethylene oxide sterilisation residuals of medical devices will be covered in detail. Focus will be drawn to the implemented changes as well as the impact on the determination of thresholds to be used for the residual analysis.
Exemplary calculations will be discussed for different medical devices.

SPEAKERS

LISA HEILEMANN

Lisa Heilemann completed a Master's degree in Biological Sciences in 2016. Since then, she has conducted validations of medical devices in accordance with ISO standards 19227, 11135, 11137 and 11607 for cleaning, sterilisation and packaging at Eurofins Inpac. Her core areas of focus include packaging and transport validation, ageing studies, gamma and EO sterilisation, regulatory processes, and quality management. As a long-term employee of the validation and quality assurance department, she has excellent qualifications. Since 2021, she has been one of two heads of validation. As of 2025, she has taken on the role of sole Head of Validation. Since 2022, Lisa Heilemann has been a member of the DIN standards committee for the packaging and sterilisation of medical devices, where she shares her expertise and skills with other experts.

VINCENT BORNBAUM

Vincent Bornbaum studied medical engineering at Hochschule Pforzheim. During his studies he gained experience in the development and testing of endovascular protheses.
For his bachelor‘s thesis, he developed an annealing process for cardiovascular stents.
Since 2025 he has been part of the Microbiological and Validation service at Eurofins Steripac.

SPEAKERS

MARCEL DÖRKES

Marcel has an academic degree (MSc) in molecular biology and an advanced toxicological expertise by further training. Marcel has been working in the field of evaluating the biological safety of medical devices since February 2018 and is now the Head of Medical Device Consulting in Germany. Marcel Dörkes' expertise includes the biological safety assessment of medical devices and related toxicological issues including strategy planning, chemical characterization procedures and overall biological risk assessments. Marcel is member of ISO TC 194 and involved in several working groups including ISO 10993-1, ISO 10993-17 and ISO 10993-18.

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REGISTRATION FEE: € 195 VAT EXCLUDED
WORKSHOP LANGUAGE: ENGLISH
ON SITE WORKSHOP

THE PRICE INCLUDES: PARTICIPATION IN THE WORKSHOP, LUNCH AND REFRESHMENTS.
YOU WILL RECEIVE CONFIRMATION, PAYMENT AND INVOICING DETAILS BY EMAIL AFTER SUBMISSION.
THE REGISTRATION FEE IS PAYABLE IN ADVANCE BY BANK TRANSFER.

Registration link | https://form.jotform.com/251883721659468

GENERAL TERMS AND CONDITIONS:

IN THE EVENT OF CANCELLATION BEFORE AUGUST 20, 2025, 50% OF THE FEE WILL BE REFUNDED. CANCELLATIONS RECEIVED AFTER THIS DATE WILL NOT BE REFUNDED.

EUROFINS MEDICAL DEVICE SERVICES RESERVES THE RIGHT TO CANCEL OR CHANGE THE PROGRAMME, SPEAKERS, DATE OR VENUE. IF THE EVENT HAS TO BE CANCELLED, REGISTRANTS WILL BE NOTIFIED AS SOON AS POSSIBLE AND WILL RECEIVE A FULL REFUND OF FEES PAID. EUROFINS MEDICAL DEVICE SERVICES IS NOT RESPONSIBLE FOR AIRFARE, HOTEL OR OTHER EXPENSES INCURRED BY PARTICIPANTS.

ONE STOP-SHOP SOLUTION FOR YOUR MEDICAL DEVICE NEEDS

CONSULTING
CE, FDA, ROW Regulatory Submission
QA/RA Management • Technical Documentation
Quality Management System • Training
Design Validation • Usability/Human Factor
Biocompatibility & Preclinical Safety (Biological Evaluation - Toxicological Risk Assessment)
Clinical Evaluation • PMS/PMCF/PSUR
ISO 13485 Certified • Certified auditors

TESTING
Biocompatibility & Toxicology
Cleaning & Reprocessing Validations
Chemical & Physical Analysis
Distribution & Package Integrity • Electrical Safety
Human Factors & Usability
Microbiology & Sterility • Mechanical & Functionality • Viral Safety

STERILE PACKAGING
Cleaning • Assembly •
Packaging (Materials & Design) •
Sterilisation • Validations •
Documentation •
Procurement Management

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