Medistri.SA

Providing Sterilisation & Laboratory Services for the World's Most Innovative Healthcare Companies.

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# Introduction to EO Sterilisation Validation - Medistri

## 🚀 Introduction to EO Sterilisation Validation

Prior to beginning routine EO sterilisation, a product with a sterile claim needs to complete a validation process to ensure the Sterility Assurance Level claimed is met according to ISO 11135.

✔ Sterilization is the process of eliminating or reducing the number of microorganisms. It is a critical step in the manufacturing and packaging of medical devices and pharmaceuticals to ensure safe for use for patients. EO sterilization is a commonly used method of sterilization in the medical and pharmaceutical industries. It is a low-temperature process that uses ethylene oxide gas to penetrate and sterilize the surfaces of medical devices. EO sterilization is particularly effective for sterilizing heat-sensitive and porous materials, such as glass-based, plastic and textile-based medical devices. Additionally, EO sterilization does not leave behind any residue and is not known to cause any adverse effects on the materials of the medical devices, making it an industry-preferred choice.

During the EO sterilization process, medical devices are placed in a sealed chamber and exposed to EO gas at a controlled temperature and pressure. The EO gas penetrates the surfaces of the medical devices and comes into contact with any microorganisms present. After sterilization, the EO gas is removed from the chamber through a process called aeration, which ensures that any residual EO gas is eliminated and the medical devices are safe to handle.

👉 Examples of medical devices that are commonly sterilized using Medistri's EO Sterilisation Infrastructure include:

- Pharmaceutical vials
- Pharmaceutical syringes
- Implantable devices
- Surgical instruments
- Diagnostic equipment
- Endoscopes
- Catheters
- Stents
- Pharmaceutical Cartridges

It is important to note that not all types of products or packaging designs can be sterilized using EO sterilization, that's why a product with a sterile claim needs to complete a validation process to ensure the Sterility Assurance Level claimed is met according to ISO 11135.

Medistri specializes in ethylene oxide sterilization validations, thanks to our contract sterilization infrastructure, we work with our customers through the entire process from protocol generation to final report completion. Ensure that your team will be notified and regularly updated with the detailed outcomes of all stages of your validation project. How do you validate ethylene oxide sterilization at Medistri?

✔ Steps to an EO Validation at Medistri:

0 — Preparation of the Validation protocol
1 — Preparation of Process Challenge Device
2 — Preparation of Bioburden Sample
3 — Preparation of Sterility Sample
4 — Preparation of Residual Sample
5 — Load Preparation
6 — Validation Cycles
- (1) Short-Cycles
- (4) Half-Cycles
- (2) Full-Cycles

7 — Final Validation Report

👉 Medistri's final EO Sterilisation Validation Report is generated to:

- Document a review of the validation data.
- Confirm the acceptability against the approved protocol for the sterilisation process.
- Approve the process specification according to ISO 11135.

🎯 To learn more about Medistri's EO Sterilisation Validation services, visit on our website atwww.medistri.swiss or directly contact our team at contact@medistri.swiss.

- The Medistri Team

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Medistri's EO Sterilisation Validation: https://www.medistri.swiss/servicesubpage/sterilisation-validation