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## EO Sterilization and Treatment: A Comparative Overview - Medistri

### EO Sterilization and Treatment: A Comparative Overview

EO Sterilization and EO Treatment represent distinct processes. EO Sterilization refers to a validated procedure that ensures sterility in compliance with regulatory standards, while EO Treatment suggests an invalidated approach. To avoid ambiguity, it is advisable to use precise terminology such as "non-validated EO procedure", as only a validated EO Sterilization guarantees the required sterility assurance.

Ethylene oxide (also known as EO or EtO) is a low temperature gaseous process widely used to sterilize a variety of healthcare products, such as single-use medical devices. Through the use of a vacuum-based process, EO can efficiently penetrate surfaces of most medical devices and its lower temperature makes it an ideal process for a wide variety of materials.

Using EO as a sterilization method is important because it effectively eliminates harmful microorganisms while being compatible with heat- and moisture-sensitive medical devices, ensuring product safety and regulatory compliance across a wide range of materials, such as:

- Pharmaceutical vials.
- Temperature-sensitive products.
- Products with integrated electronics.
- Products with integrated batteries.
- Polymer-based products.
- Implants.
- Surgical Kits.
- Single-use medical devices.
- Drug-Device Combination products.

The sterilisation process is carefully monitored and controlled to ensure that the product is not damaged or compromised during the process.

In contrast, EO Treatment is used primarily during research and development (R&D) or for pre-testing purposes. This is a non-validated process that allows manufacturers to test their products and adjust sterilization parameters before full validation. While EO Treatment plays a key role in product development, it does not meet the same regulatory standards as validated EO Sterilization.

The equipment used for the EO Sterilisation is designed to maintain precise conditions of temperature, humidity, and gas concentration to ensure that the process is effective and safe.

**1. Preconditioning:** The product to be sterilized is placed in a sealed chamber and exposed to a controlled humidity and temperature to prepare it for the sterilisation process.

**2. Sterilisation:** The EO gas is introduced into the chamber, and the product is exposed to the gas for a specific period of time. The gas penetrates the product and kills any microorganisms present.

**3. Aeration:** After the sterilisation process is complete, the chamber is vented to remove the EO gas. The product is then aerated for a specific period of time to remove any residual gas and reduce the levels of EO to safe levels. At Medistri, samples of the items are tested for Endotoxin/LAL, Residuals & Sterility in our in-house laboratory to confirm that the sterilization process was effective.


At this moment, this process is called EO Treatment - the products weren't validated by the Medistri's Laboratory team.

In order to consider a safe and validated EO Sterilization, the product should be tested to ensure that it has been effectively sterilised and that the levels of EO are within safe limits.

Validated EO Sterilization undergoes rigorous testing to meet international regulatory standards such as ISO 11335, which governs the development, validation, and control of the EO sterilization process. This validation ensures consistent sterility across batches of products, providing regulatory compliance and product safety.

ISO 11335 is the international standard that details the development and validation of a process for sterilizing medical devices using ethylene oxide. It provides guidance on how to validate the sterilization process. Once the process as a whole has been validated, the medical device manufacturer, regulatory bodies, and end users can be confident that the final product is sterile.

Validated Ethylene Oxide Sterilization offers a reliable guarantee of sterility through stringent validation procedures, whereas Non-validated Ethylene Oxide Sterilization, or EO Treatment, presents uncertainties regarding effectiveness and safety. Ensuring clear differentiation and proper validation is vital for maintaining high standards of product safety and regulatory compliance.

 To learn more about Medistri's EO Sterilization and Treatment, visit on our website [here](#) or directly contact our team at [contact@medistri.swiss](mailto:contact@medistri.swiss).

- The Medistri Team

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