Medistri.SA

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

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Introduction to EO Sterilisation - Medistri

🚀 Introduction to EO Sterilisation

The EO sterilization process has been employed by the health care industry to sterilize medical devices since the early 1940s. Although not as well controlled as the processes of today, the anatomy of the process itself remains remarkably similar to the earlier process designs.

At Medistri, whether you are a start-up or a large established company, you can track your products through the EO sterilisation process and have a clear overview of when your products are ready to leave our facilities. Medistri can ship your sterile products directly to your customers or to your distribution centre.

✔ You can also integrate the sterilisation of your products into your existing operational workflow, allowing you to simplify your supply chain management and streamline your logistics.

Ethylene oxide (also known as EO or EtO) is a low temperature gas process commonly used to sterilize a variety of healthcare products, such as single-use medical devices. The EO sterilization process is vacuum-based and can efficiently penetrate most medical device surfaces and its low temperatures make it an ideal solution for a wide range of materials.

Ethylene oxide sterilization consists of four primary variables:

- Gas concentration.
- Humidity.
- Temperature.
- Time.

EO is an alkylating agent that disrupts cellular metabolism and reproductive processes of microorganisms. EO penetrates breathable packaging, making contact with all accessible surfaces of the product to deliver the required sterility assurance level (SAL).

EO sterilisation is a popular method of sterilisation for medical devices and pharmaceutical products. It is important for companies to use EO sterilisation because it is effective against a wide range of microorganisms, including bacteria, viruses, and fungi. This ensures that the medical devices and pharmaceutical products are safe for patient use.

👉 In addition, there are regulatory requirements that companies must comply with when it comes to sterilisation. For example, the ISO 11135 standard provides guidance on the establishment and validation of an EO sterilisation process. Companies need to be aware of and address new standards and regulatory changes to ensure future compliance.

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At Medistri, the EO Sterilisation process goes as followed:

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.

4. Testing: The product is then tested to ensure that it has been effectively sterilised and that the levels of EO are within safe limits.

ISO 11135 is the international standard that details the development and validation of a process for sterilizing medical devices using ethylene oxide.

At Medistri, we follow the ISO 11135 for our EO Sterilisation process as it can help simplifying the production, ensures product consistency and safety, and promote global collaboration and compatibility. ISO standards can also help companies meet customer requirements, improve customer satisfaction, and comply with regulatory requirements.

ISO 11135 specifies the requirements for the development, validation, and routine control of an EO Sterilisation process in both industrial and healthcare facility settings. Also, it acknowledges the similarities and differences between the two applications and provides guidance on how to establish and validate an EO sterilisation process.

✔ At Medistri, we help companies meet their pharmaceutical quality standards as described in pharmacopeias and ensure that their products are pyrogen-free and safe for the intended purpose of use.

Medistri SA is equipped with 5 EO Sterilisation chambers each with capacities up to 16 palettes. Our chambers have been engineered to allow you to sterilise loads up to 200cm of height, allowing you to maximise the size of your final production loads, and reduce costs. Medistri can currently sterilise more than 73'000 palettes annually using its EO sterilisation infrastructure. And we're always working towards making this number larger.

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

- The Medistri Team

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