# Mediatri

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

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# Medistri's Application Areas for EO Sterilisation - Medistri

### **Medistri's Application Areas for EO Sterilisation**

Ethylene Oxide (also known as EO or EtO) Sterilisation technology is a low temperature gaseous process that is used to sterilise a variety of healthcare products. Through the use of a vacuum-based process, EO sterilisation penetrates the surfaces of your products. Medistri's EO Sterilisation infrastructure is built to save you time and scale your business.

EO Sterilisation is particularly beneficial for products that cannot be subjected to high heat or moisture, making it an ideal solution for many modern medical devices and pharmaceutical products. Here's how it works in practice for different types of products that are in their definitive package. **Surgical Kits & Single-use medical devices:** Surgical kits and single-use devices require thorough and consistent sterilisation. Medistri's EO processes guarantee sterility across all components, ensuring they are ready for safe use in critical surgical environments.

### Drug-Device Combination products: Drug-Device

Combination products, which combine pharmaceutical treatments with mechanical components, require a sterilisation method that protects both aspects. Medistri's EO sterilisation ensures that neither the drug formulation nor the device is compromised.

**Pharmaceutical Vials:** Pharmaceutical vials often contain delicate formulations that can be damaged by high heat or radiation. EO sterilisation offers a safe and effective solution for maintaining sterility without affecting the product's stability.

**Temperature-sensitive products:** For products that require careful handling due to temperature sensitivity, EO sterilisation at Medistri provides the perfect solution. By avoiding high heat, we ensure these products remain safe and effective for patient use.

#### **Products with integrated electronics and/or batteries:**

Products with integrated electronics and/or batteries are prone to damage from conventional sterilisation methods. EO sterilisation is non-corrosive and ideal for these sensitive components, ensuring functionality is preserved.

**Polymer-based products:** Polymer-based medical devices benefit from EO sterilisation, which protects their structure and function, ensuring that these critical devices perform as intended. ISO 11135 is the international standard that outlines the requirements for the development, validation, and routine control of Ethylene Oxide (EO) sterilization processes for medical devices. This standard ensures that the sterilization methods employed meet stringent safety and efficacy criteria, providing assurance that devices are free from viable microorganisms. At Medistri, adherence to ISO 11135 is integral to our EO sterilisation services, as it guides our practices in ensuring that temperature-sensitive products, implants, and other medical devices are effectively sterilised without compromising their integrity or performance.

At Medistri, we understand that every product is different, and that's why we tailor our EO sterilisation processes to meet the unique needs of each application area. From temperature-sensitive pharmaceuticals to complex drugdevice combination products, our expertise ensures sterility without compromising product quality. Medistri is your trusted partner for reliable and safe sterilisation.

To learn more about Medistri's Application Areas for EO Sterilisation, visit on our website <u>here</u> or directly contact our team at contact@medistri.swiss.

**Implants:** For implants, sterility is paramount. Medistri's EO sterilisation process guarantees the complete sterilisation of implants while maintaining the biocompatibility and structural integrity required for patient safety.

- The Medistri Team

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