Medistri

Providing Sterilization & Laboratory Services for the world's most innovative healthcare companies.

From the Blog

EO Sterilization for Medical Devices

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At Medistri, we recognize that terminal sterilisation is a critical process step requiring uncompromising sterility assurance while preserving the integrity and performance of medical devices. Our EO sterilization services are designed to integrate into your development and manufacturing operations, delivering controlled, validated, and traceable processes aligned with regulatory expectations.

Medical device sterilization is essential to prevent infections and protect patient health. At Medistri, EO sterilization is performed in accordance with ISO 11135, ensuring that each process is rigorously developed, validated, and routinely controlled to achieve the required Sterility Assurance Level (SAL), while maintaining material compatibility and product functionality.

By combining the expertise of our laboratory, sterilization, and quality teams, we support manufacturers throughout the product lifecycle. With advanced technologies, modern processing infrastructure, and in-house analytical capabilities, we ensure that medical devices and components are sterilized efficiently, without compromising durability, performance, or development timelines.

Operational Transparency for Confident Planning
Whether supporting early-stage development or routine commercial production, our transparent sterilization workflows provide full visibility from receipt through release. Clear milestones and predictable lead times allow you to plan with confidence and remain focused on product development and market expansion.

Quality Systems Anchored in International Standards
At Medistri, EO sterilization is embedded within a certified quality management system and supported by continuous investment in infrastructure, validation practices, and technical expertise to meet evolving regulatory and industry requirements.

ISO 11135 provides the reference framework governing the development, validation, and routine control of EO sterilization processes for healthcare products. By applying this standard rigorously, we ensure that risks are controlled, processes remain reproducible, and products released from our facilities meet the highest expectations for safety, reliability, and regulatory compliance.

By following ISO 11135, we ensure that all products sterilized at our facilities are safe, reliable, and fully compliant with international quality and regulatory standards.

To learn more about Medistri's EO Sterilization services for medical devices, please visit our website here or contact our team at contact@medistri.com.

— The Medistri Team

#Medistri

Infrastructure Designed for Complex Medical Devices
Low-temperature EO sterilization for temperature-sensitive products
Compatibility with diverse materials and complex device geometries
Support for multiple packaging systems and load configurations
Defined aeration and controlled product release post-processing
Scalable capacity for development, validation, and routine volumes
Efficient and reliable turnaround times within a validated framework

EO Applications Across a Broad Device Portfolio
Medistri provides EO sterilization solutions for a wide range of medical devices and components, including:

- Temperature-sensitive medical devices
- Devices with integrated electronics or batteries
- Polymer-based devices and components
- Implants
- Surgical kits and procedure packs
- Single-use medical devices
- Metallic surgical instruments
- Ceramic-based products
- Drug–device combination products