Medistri

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

Residual EO Testing Post-Sterilization

EO Free Supply Chain Validation

Following sterilization and aeration, residual EO may continue interacting with packaging materials and logistics environments throughout the post-sterilization supply chain. Packaging systems may absorb and progressively release EO during storage, transport, handling, and distribution activities. While device residuals are governed by ISO 10993-7, EO behavior across post-sterilization logistics operations remains less extensively monitored and documented.

Time-Based Packaging Evaluation

GC-FID / GC-MS analysis of primary, secondary, and tertiary packaging layers at defined post-aeration intervals. EO-Free Supply Chain Validation evaluates EO release across packaging systems, logistics environments, and personnel interaction points, from the sterilization chamber to the hospital dock.

Device Residuals Governed Under ISO 10993-7

EO Free Supply Chain Validation Study

Sterilization → **Degassing & Aeration** → **Storage** EO desorbs in Warehouse → **Transport** EO desorbs in Vehicle → **Customer** EO desorbs in Warehouse

Who Is It For

Medical DeviceDevice Manufacturers
- Risk Management
- Customer Assurance

Logistics & 3PL
- Personnel safety
- Warehouse monitoring

Healthcare Procurement
- Controlled goods-in assurance

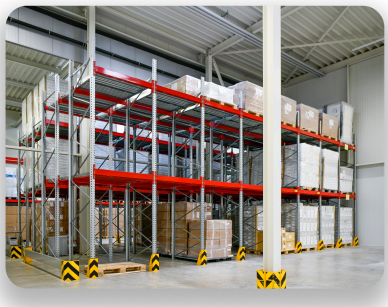
Regulatory Affairs
- PMS
- Chemical safety documentation

Summary
- **Where:** In-house laboratory testing performed in Switzerland
- **Lead Time:** ~10 week
- **Standards:** ISO 11135, ISO 10993-7, ISO 14971, EU MDR

The Challenge

EO does not necessarily stop at aeration. Understanding its behavior beyond sterilization supports safety, compliance, and risk management.

- EO persists beyond device aeration
- Packaging materials continue releasing EO
- Palletized loads can concentrate residual EO
- Logistics exposure remains poorly characterized
- Repeated handling may increase exposure
- Regulatory expectations are rising



What We're Testing

Pallet System

Evaluation of cumulative EO retention and release across full pallet configurations under operational conditions.

Packaging System

Assessment of EO retention and release across primary, secondary, and tertiary packaging materials over defined post-aeration intervals.

Environmental Monitoring

Air sampling across transport, warehousing, storage, and order-picking environments.

Personel Safety

Passive TWA dosimetry for warehouse, QC, logistics, and transport personnel compared against OSHA and EU exposure limits.

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The New Stack of Fully Integrated Services.

Laboratory Infrastructure

- Chemistry
- Biocompatibility
- Microbiology
- Sterility Assurance
- Extractable's & Leachable's

Manufacturing Infrastructure

- Product Assembly
- Custom Packaging Solutions
- Quality Control & CE Marking
- Labelling & Distribution
- Picking, Packing, Shipping

Sterilization Infrastructure

- Steam Sterilization
- EO Sterilization

Validation Infrastructure

- Sterilization Validation
- Cleaning & Disinfection Validation
- Laboratory Method Validation
- Reprocessing Validation

Packaging Validation

- Transport Simulation
- Sterile Barrier Integrity Testing

Medistri is continually innovating its **in-house** range of services. We're expanding our infrastructure to offer a completely integrated stack of services for healthcare companies. Organizations of every size — from startups to large enterprises use our suit of services to start, grow & optimize their business.

Within our site located at the heart of Switzerland, Medistri **combines all its technical infrastructure together** and places quality at the heart of its day-to-day operations. Allowing you to simplify your supply chain management, focus on growth & maintain excellence.

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