

### Europe's Largest Independent Contract Sterilization Company

# Mixed Load or Single Load Cycles

Cycle configuration plays a critical role in achieving sterility assurance while maintaining product integrity and regulatory compliance. Depending on product characteristics, development stage, and production strategy, sterilization can be performed using Single Load or Mixed Load cycles. Each approach follows the same regulatory principles but responds to different operational and validation needs.

## Mixed Load Cycles

## Single Load Cycles

### Maximum Load (Validation)

1 Euro Pallet

### Minimum Load (Validation)

1 Box

### Routine Batch Size

1 Box - 16 Euro Pallet

### Max. Pallet Height

205 cm (CH), 240 cm (HU)

### Max. Pallet Weight

250kg

### Routine Sterilization Costs

Per Pallet

### Lead Times

Standard - 7 to 14 Days  
Express - 5 to 7 Days  
Super-Express - Under 4 Days

### Cycle Parameters

Medistri Standard Cycle

### Shared Chamber

Yes

### Regulatory Compliance

ISO 11135

### Typically Chosen For

Low Volume, Small Routine Batches

### FDA Compatibility

Yes

### Degassing Cycle

Yes, Minimum 6 Hours

### Best for

Best for customers who need flexibility and speed across many products:

- Startups / scale-ups running early-stage programs (clinical, pilot, low-volume commercial)
- High product variety portfolios (many references, many formats, many packaging types)
- Low-to-medium volumes per Product (no dedicated batches available)
- Customers more frequent shipment cycles
- Products compatible with shared cycle conditions (validated to run under a common cycle family)
- Cost-sensitive sterilization needs, where cost can be optimized by load sharing
- Unpredictable demand (forecast variability, irregular production releases)

### Site Availability

Switzerland, Hungary

### 16 Euro Pallet

### 1 Box or 1 Euro Pallet

### 1 Box - 16 Euro Pallets

### 240 cm (CH & HU)

### -

### Per Chamber/ Per Cycle

Standard - 7 to 14 Days  
Express - 5 to 7 Days  
Super-Express - Under 4 Days

### Customized Cycle or Standard Cycle

### No

### ISO 11135

High Volume, Large Routine Batches  
Products Requiring Specific Sterilization Parameters  
Yes

### Product Dependent

### Best for customers who need customized cycles and high-volume predictability.

- High-volume commercial production (steady throughput, predictable demand)
- Products requiring strict segregation
- Dedicated medical device programs where cycle ownership matters
- Complex validated product families (tight parameter windows)
- Products with special requirements (EO absorption, aeration profile, packaging sensitivity)
- Large OEMs expecting batch traceability and minimal co-processing risk
- Pharmaceutical Products & Pharmaceutical Packaging

### Switzerland, Hungary

### An Overview

Validation is performed in accordance with the internationally recognized standard ISO 11135 for EO sterilization.

Mixed Load EO Sterilization is best suited for medical devices with low production volumes and limited material/product complexity, allowing customers to share chamber capacity and sterilisation costs with other validated products, all processed under the same cycle specification using a worst-case validation approach to ensure compliance and safety. Single Load EO sterilisation is best suited for pharmaceutical products & medical devices requiring dedicated processing, due to higher material/product complexity, higher production volumes, or specific cycle parameters.

## The New Stack of Fully Integrated Services.

### Laboratory Infrastructure

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

### Manufacturing Infrastructure

- Product Assembly
- Custom Packaging Solutions
- Quality Control & CE Marking
- Labelling & Distribution

### Sterilisation Infrastructure

- Steam Sterilization
- EO Sterilization

### Validation Infrastructure

- Sterilization Validation
- Cleaning Validation
- Process Validation
- Disinfection 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 suite 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.



**Swissmedic  
& FDA Registered**