



EtO STERILIZATION

Designer and manufacturer of Industrial
Ethylene Oxide and Steam Sterilizers



COMPANY PROFILE

With nearly two decades of expertise in the design and engineering of medical device sterilizers, **MDS is fully dedicated to delivering advanced sterilization solutions, process optimization and comprehensive services.**

We work in close partnership with our customers, positioning ourselves as a trusted advisor as well as a reliable supplier. This relationship-based approach demonstrates not only the way we work but also our proven ability to successfully execute projects worldwide.

MDS proudly designs and manufactures Ethylene Oxide and Steam sterilizers in France, with care and precision, along with all related equipment and accessories for medical device manufacturers and sterilization service providers. Our long-standing experience in industrial sterilization enables us to provide safe, state-of-the-art solutions, from single equipment to fully turnkey plants.

A key strength of MDS lies in its **in-house manufacturing workshop**, where highly qualified staff operate with advanced welding and production technologies. By mastering the entire fabrication process internally, we guarantee quality, reliability and compliance while maintaining the flexibility required to adapt to evolving customer needs throughout the project. This integrated approach allows us to combine industrial rigor with agility, ensuring tailor-made solutions from design to final validation.

In addition, **MDS develops and programs its own PLC and HMI software in-house**, enabling our team to customize automation sequences and supervision interfaces down to the smallest customer specification. This dual expertise—mechanical and automation—ensures seamless integration, maximum process control and full traceability for every project.

Beyond technology, **MDS is recognized for the availability and flexibility of its maintenance services**, ensuring long-term support and performance for our customers worldwide.



Management System
ISO 9001:2015
www.tuv.com
ID: 910865981

OUR ASSETS

Reactive & Flexible

- Human size company
- Team Spirit
- Communication

Design and manufacture control

- Integrated Designer
- Integrated manufacturing workshop
- Expertise in control system

Adapted solution to customer needs

- Safe, reliable and easy to use equipment
- Human safety
- Environment respect

Qualification and after sales services

- International standards compliance
- Customer satisfaction
- Respect of our engagement

www.mds-france.com

RELIABLE EQUIPMENT AND CUSTOMIZED SERVICES FOR PHARMACEUTICAL AND MEDICAL DEVICE COMPANIES

ANALYSIS

- ✓ URS analysis
- ✓ Quotation
- ✓ Planning
- ✓ Conceptual design
- ✓ Traceability matrix

DEVELOPMENT

- ✓ PID's layouts
- ✓ FMEA&HAZOP studies
- ✓ M&E engineering
- ✓ Design Qualification-DQ
- ✓ Control system development (PLC&SCADA)
- ✓ Software validations (SDS)

MANUFACTURING

- ✓ Pressure equipment and piping welding
- ✓ Mechanical Assembly
- ✓ Electrical installation
- ✓ Factory Acceptance Tests-FAT

INSTALLATION & COMMISSIONING

- ✓ On site installation
- ✓ Site Acceptance Tests-SAT
- ✓ Installation Qualification-IQ
- ✓ Operational Qualification -OQ
- ✓ Calibration services
- ✓ User and maintenance training
- ✓ Performance Qualification-PQ



Operator safety is at the heart of our design philosophy. To prevent any exposure to residual EtO during manual transfers, MDS systems incorporate several protective measures. Automatic aeration and degassing phases ensure that residual gas is removed from both the chamber and the load before operators access the products. In addition, efficient ventilation and continuous monitoring systems guarantee that EtO levels remain well below occupational exposure limits. These measures provide maximum protection for operators while maintaining smooth and efficient production flows.

EFFICIENT AND SAFETY PROCESS

- Powerful Gas recirculation system
- Back venting for operators safety
- No Explosion risk (Atex compliance)
- Non-flammable atmosphere in the chamber
- Safety layout organization (Atex zoning)
- Customized cycles through parameters recipe
- Supervision and cycle report (21 CFR Part 11)
- User friendly HMI

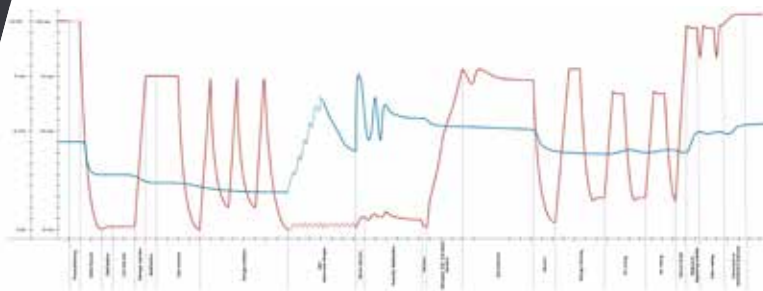
HIGH QUALITY MATERIALS

Proudly designed and manufactured in France:

- Solid stainless steel 304L chamber vessel
- Carbon steel U beams water jacket
- Single or double door sliding system
- Heat Insulation aluminium cladding
- Vaporizer and steam generator fully built in 316L stainless steel
- Impliance with: EN1422, ISO 11135, 2014/34/EC ATEX directive



CYCLES



TURNKEY EtO STERILIZATION SOLUTIONS

Worldwide, **Ethylene Oxide (EtO) sterilization** is the preferred low-temperature sterilization process for single-use medical devices, representing nearly 60% of all sterilization methods. **Building on nearly two decades of expertise, MDS delivers fully turnkey solutions for both manufacturers and contract sterilization service providers.** Our know-how ensures safe, efficient and reproducible sterilization for every type of medical device.

MDS solutions range from all-in-one sterilizers to complete, customized systems including preconditioning, desorption, conveyors and gas treatment units.

Each sterilization cycle is vacuum-based and typically uses either 100% EtO or a standard 90% EtO / 10% CO₂ mixture. Nitrogen is also used during the process to inert the chamber atmosphere, eliminating any risk of flammability and ensuring the highest level of safety for both operators and equipment.



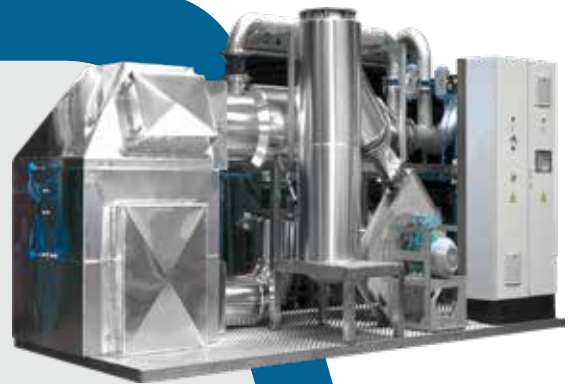
The process is controlled through four critical parameters:

- Gas concentration
- Temperature
- Relative Humidity
- Exposure time

Every function of our sterilizers is managed by a programmable logic controller connected to an intuitive HMI or a supervision computer. All programs and interfaces are fully documented and compliant with **21 CFR Part 11 and GAMP** requirements, ensuring complete traceability and regulatory conformity.

To enhance efficiency and safety, sterilizers can be integrated with additional systems such as:

- Preconditioning room: to optimize temperature and humidity before the cycle
- Degassing room: to remove residual EtO after sterilization
- Gas treatments: neutralize emissions
- Conveyors: to ensure homogeneous and simplified load transfers
- Supervision and tracking tools for real-time monitoring and full quality system integration



Combined with high-level qualifications and a robust preventive maintenance program, **MDS EtO sterilization systems guarantee efficiency, repeatability and long-term reliability** for the most demanding industrial applications.



Contact Us

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