



## EtO STERILIZATION

Designer and manufacturer of Industrial  
Ethylene Oxide and Steam Sterilizers

[www.mds-france.com](http://www.mds-france.com)



# COMPANY PROFILE

Thanks to its 15 years experience in engineering of medical device sterilizers, MDS company has been dedicated to offer sterilization solutions, process optimization and associated services.

We are working in partnership with our customers. By this way, we become a trusted and advising supplier. Through this relationship, our customers are able to see the way we work and demonstrates our ability to execute worldwide.

We design and manufacture Ethylene Oxide and Steam sterilizers, their related equipment and accessories for medical device manufacturers and sterilization service providers.

MDS offers a long experience in the field of industrial sterilization processes and proposes state-of-the-art, safe solutions either for single piece of equipment or turnkey plants.

Our manufacturing workshop and warehouse employs highly qualified staff working on the most efficient welding machines.

Our experience in medical and pharmaceutical industries allows us to offer to our customers turnkey solutions according to their requirements.

MDS is recognized for its availability and flexibility of its maintenance services.



Management  
System  
ISO 9001:2015  
[www.mds.com](http://www.mds.com)  
ID: 9108000891

## 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

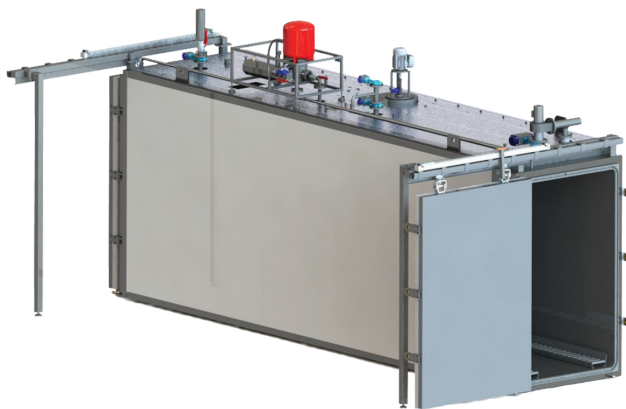
- European standards compliance
- Customer satisfaction
- Respect of our engagement

[www.mds-france.com](http://www.mds-france.com)

## TURNKEY EtO STERILIZATION SOLUTIONS

Worldwide preferred technology for sterilization of single use medical devices at low temperature is Ethylene Oxide (EO or EtO) with about 60% of the global sterilization. This sterilization process is optimized by MDS to offer fully turnkey solutions for manufacturers and sterilization services providers, and for a **safe** and **efficient sterilization** of medical devices.

Our sterilization cycle is based on a vacuum cycle using preferably a mixture containing 100 % EtO or 90% EtO+ 10% CO<sub>2</sub>.



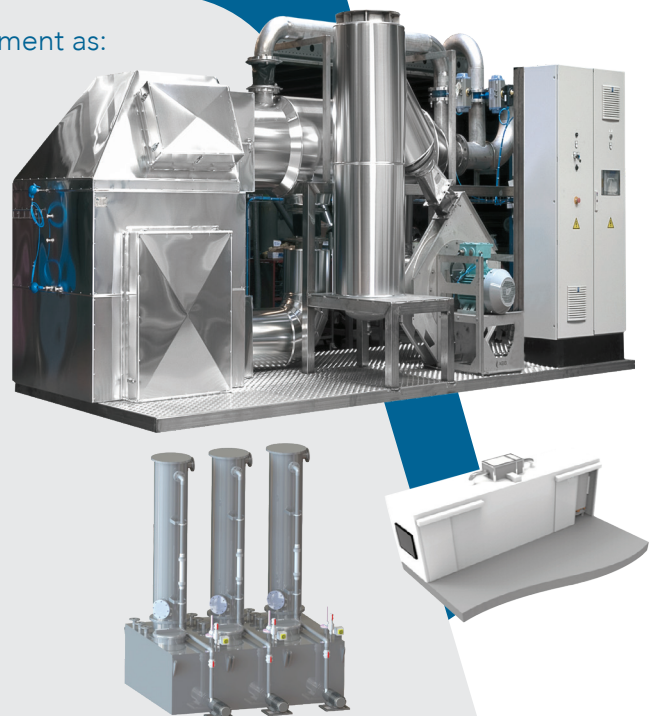
The process is controlled through four parameters:

- The Gas concentration
- The Temperature
- The Relative Humidity
- The Exposure time

Logic Controller (PLC) connected to a "human machine interface" HMI, or Supervision computer. Our programs and supervision interfaces are fully documented and answer the 21 CFR Part 11 and GAMP requirements

They could be associated to ancillaries equipment as:

- Pre-Conditioning cell: to warm and reach good humidity set point inside the product before sterilization cycle to save production time
- Desorption cell : to optimize the desorption of residual EtO from the sterilized products
- Gas treatment systems : to catch and neutralize the rejected gas pollutants from the sterilization cycle
- Automatic conveyors system: to simplify and ensure homogenous cycles
- Tracking system: to perform in production quality system Supervision



Performing a high level of qualifications and associated with a efficient preventive maintenance program, these equipment are efficient, repeatable and reliable.

## EFFICIENT AND SAFETY PROCESS

- Gas recirculation system
- Back venting for operators safety
- No Explosion risk (Atex compliance)
- Non-flammable atmosphere in the chamber
- Safety layout organization (Atex zoning)
- Adjustable cycles through parameters
- Supervision for cycle report (21 CFR Part 11)
- Easy to use HMI

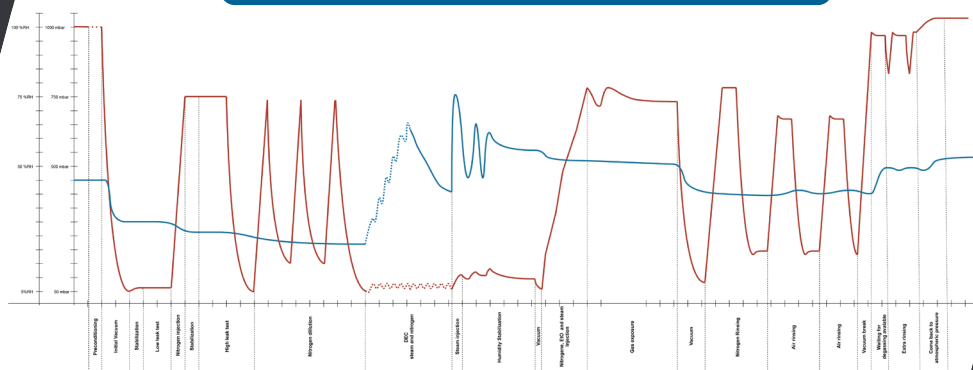
## HIGH QUALITY MATERIALS

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 and aluminium cladding
- Vaporizer and steam generator fully built in 316L stainless steel
- Compliance with: EN1422,  
ISO 11135, 2014/34/EC ATEX directive



## CYCLES





## RELIABLE EQUIPMENT AND CUSTOMIZED SERVICES FOR PHARMACEUTICAL AND MEDICAL DEVICE COMPANIES

### ANALYSIS

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

### DEVELOPMENT

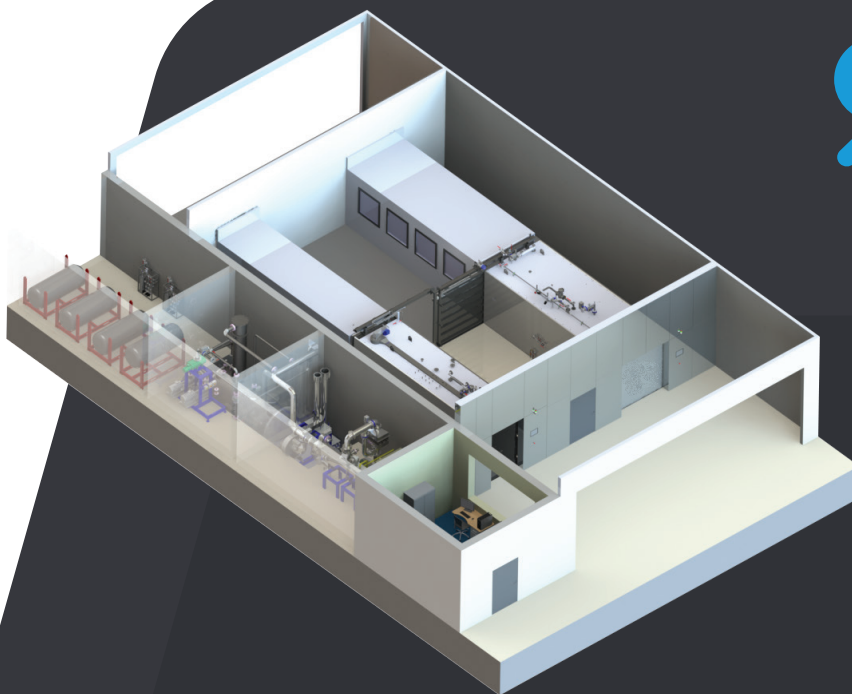
- ✓ PID's layouts
- ✓ FMEA&HAZOP studies
- ✓ M&E engineering
- ✓ Design Qualification-DQ
- ✓ Control system development (PLC&SCADA)
- ✓ Software validations (SDS)

### MANUFACTURING

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

### INSTALLATION & COMMISSIONING

- ✓ In-situ M&E installation
- ✓ Site Acceptance Tests-SAT
- ✓ Installation Qualification-IQ
- ✓ Operational Qualification -OQ
- ✓ Calibration services
- ✓ Personnel training
- ✓ Performance Qualification-PQ





## Contact Us

ZA de Treigny  
Rue Sainte Anne  
60173 Ivry le Temple  
France  
[contact@mds-france.com](mailto:contact@mds-france.com)  
+33 (0) 364 19 84 75