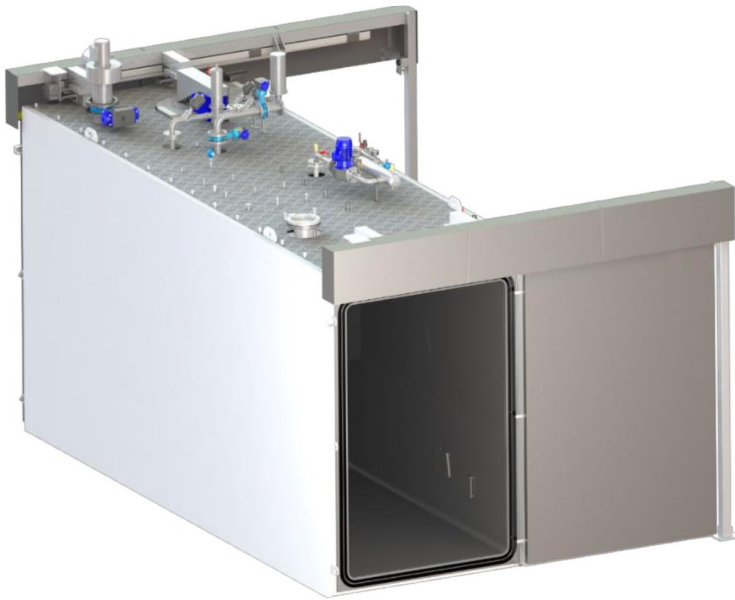


## TURNKEY ETO STERILIZATION SOLUTION

Worldwide preferred technology for sterilization of single use medical devices at low temperature is Ethylene Oxide (EtO). This sterilization process is optimized by MDS to offer turnkey solutions for medical devices manufacturers or sterilization services providers.



Our sterilization cycle is based on a vacuum cycle using preferably a non flammable mixture.

The process is controlled through 3 parameters:

- The Gas Concentration
- The Temperature
- The Relative Humidity

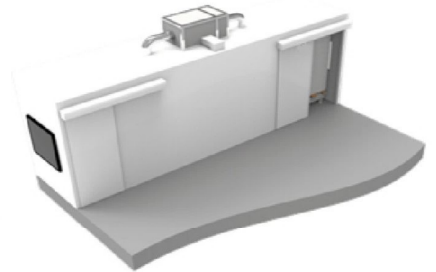
All the components and functions of the sterilizer are controlled by a Programmable Logic Controller (PLC) connected to a "Human Machine Interface" HMI, or supervision

computer. Our programs and supervision interfaces are fully documented and respect the 21CFR part11 and GAMP requirements.

They could be associated to other equipment as:

- **Pre-Conditioning room** : to warm and reach good humidity set point inside the product before sterilization cycle to save production time
- **Degassing room** : to remove residual EtO from the sterilized products
- **Gas treatment** : to catch and neutralize the rejected gas pollutant
- **Conveyors** : to simplify and ensure homogeneous cycles
- **Tracking system** : to perform in production quality system
- **Supervision** : to report and manage online all kind of actions

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



### HIGH QUALITY MATERIALS

Designed and manufactured in France:

- Rectangular stainless steel 304L chamber vessel
- Carbon steel U beams water jacket
- Single or double door sliding or hinged system
- Heat Insulation and stainless steel or aluminium cladding
- Compliance with EN1422, ISO 11135, ATEX
- Vaporizer and steam generator fully built in 316L stainless steel



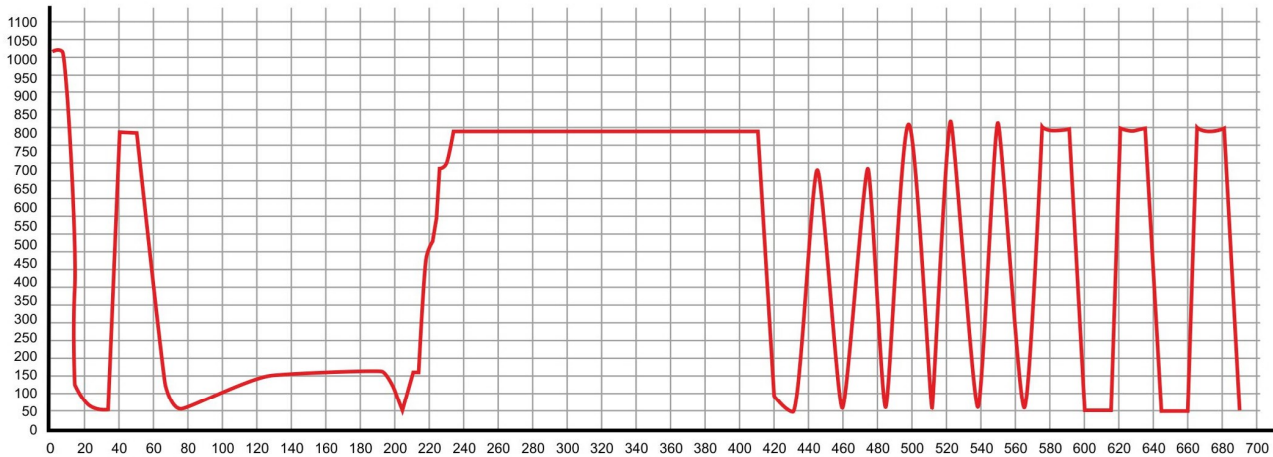
### EFFICIENT AND SAFETY PROCESS

- 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



### CYCLES

P (mbar)



t (min)

### PROVIDED WITH

- Manufacturer documentation
- Instructions & Maintenance manuals
- Technical documentation (P&ID, Electrical drawing, part list, etc.)
- First emergency spare parts list

### SERVICES

- Installation and commissioning
- Qualification regarding ISO 11135
  - IQ
  - OQ
  - PPQ
  - SQ
- Maintenance with preventive or curative intervention

