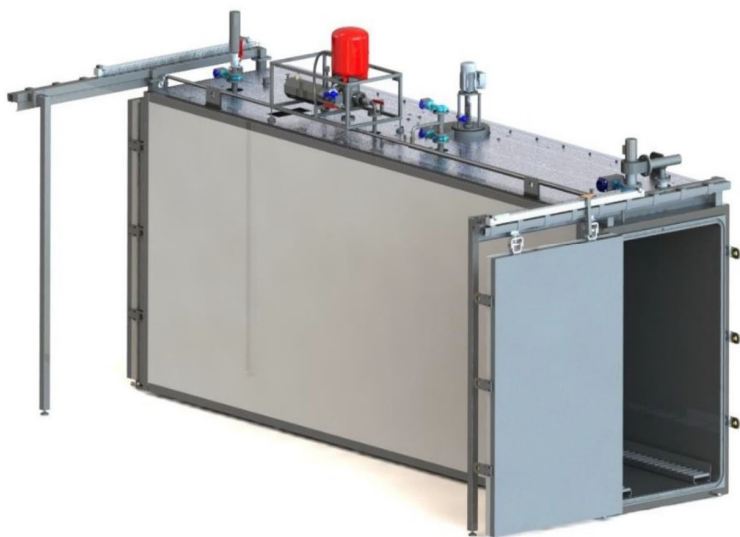


## TURNKEY ETO STERILIZATION SOLUTION

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 fully turnkey solutions for medical devices manufacturers and sterilization services providers.



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:

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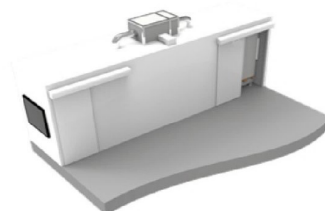
- The Gas concentration
- The Temperature
- The Relative Humidity
- The Exposure time

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 answer the 21 CFR Part 11 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 treatments:** to catch and neutralize the rejected gas pollutants
- **Conveyors:** to simplify and ensure homogenous 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, these equipments 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 system
- Heat Insulation and stainless steel or aluminium cladding
- Vaporizer and steam generator fully built in 316L stainless steel
- Compliance with EN1422, ISO 11135, ATEX



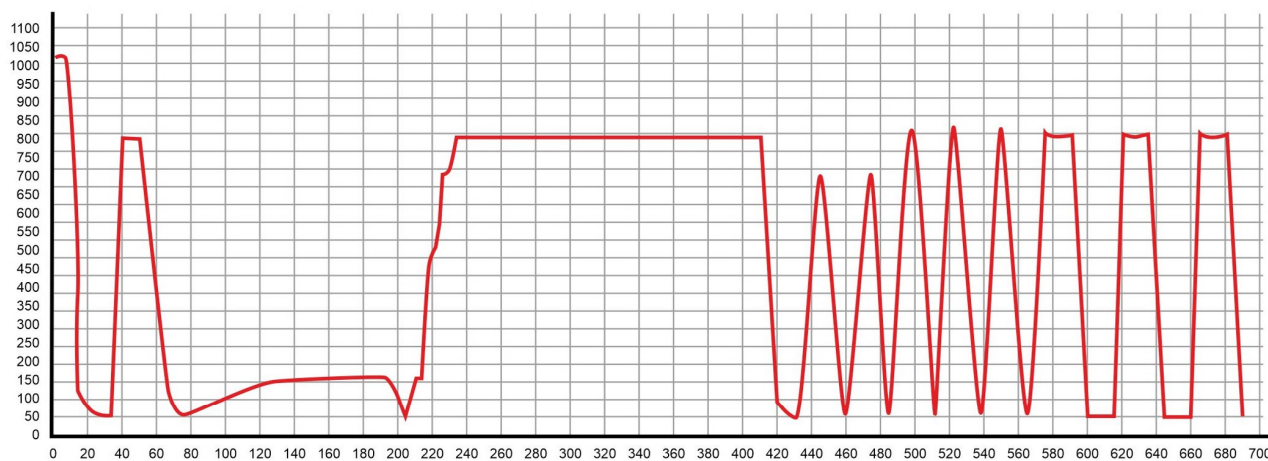
### EFFICIENT AND SAFETY PROCESS

- 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...)
- First emergency spare parts list

### SERVICES

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

