



ETO STERILIZATION SOLUTIONS



*Your partner for comprehensive
ETO Sterilization solutions.*



WHY WORK WITH RSD:

- ✓ Expert in ETO sterilization process, from design to validation.
- ✓ Flexible design, based on several modules.
- ✓ High-efficiency equipment, optimizing energy consumption and cycle time.
- ✓ Excellent ETO concentration and temperature uniformity ($\pm 1^{\circ}\text{C}$).
- ✓ Use of Safety PLC, with safe modules (SIL 2 certified).
- ✓ Use of advanced 3D technology.
- ✓ 100% of the chamber insulated.
- ✓ High level of safety, ATEX-certified.
- ✓ Use of state-of-the-art components and materials to guarantee long-term equipment viability.
- ✓ Use of well proven technology for the SCADA control system.
- ✓ Compliant with 21 CFR Part 11, ATEX 2014/34/UE, ISO11135, and others.
- ✓ RSD staff Ism-ATEX certified by a notified body.
- ✓ Accurate instrumentation.
- ✓ 15-year warranty on the chamber.

RSD is a Spanish company specializing in ethylene oxide (EO/ETO) sterilization process, used to sterilize a wide variety of medical devices products such as syringes, latex gloves, catheters, etc.

Our promise: To design, manufacture, qualify and install high-quality ETO sterilizers, based on advanced technology and innovation. We commit to providing turnkey solutions that are totally adapted to our customers' needs, yielding a high level of safety, reliability and productivity. We fulfil the cGMPs guidelines set up by the EMEA and FDA, the safety of pressure vessels (2014/68/UE) and explosion risks (ATEX); and meet the most stringent regulations and standards from Europe, USA and others countries.

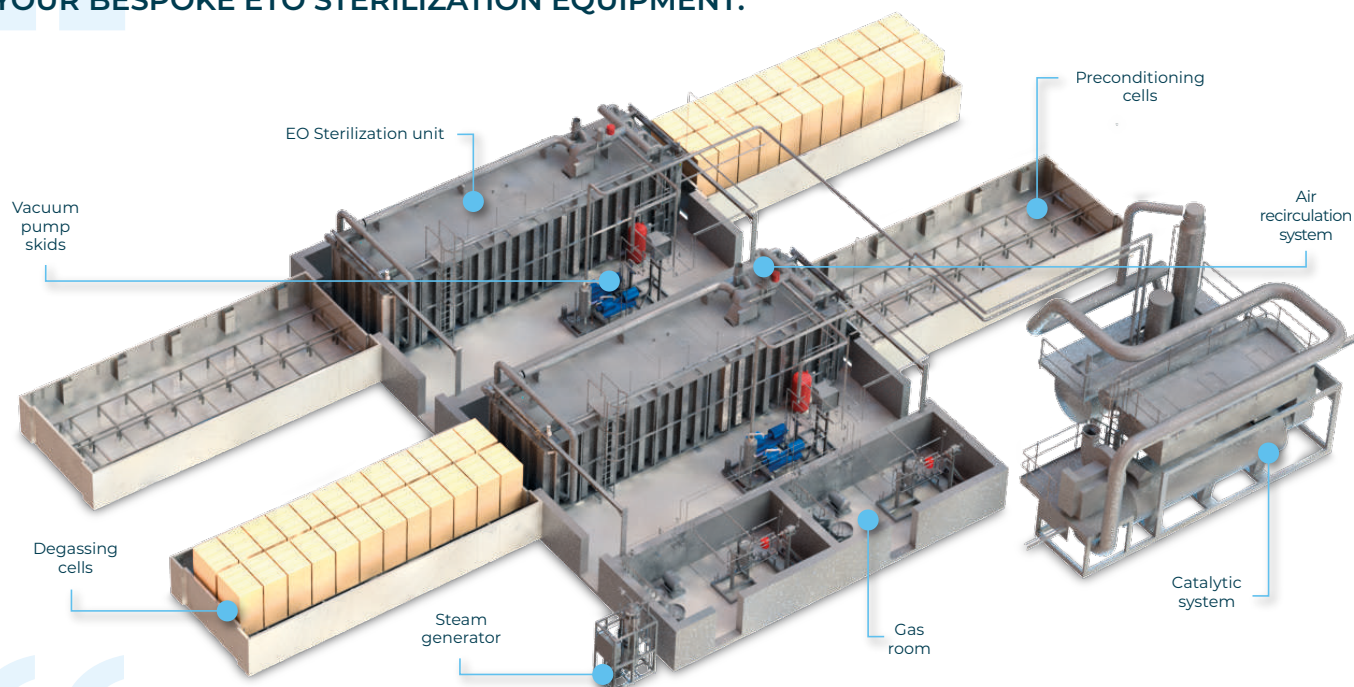
Our turnkey ETO sterilization facilities, a complete solution.

We deliver full sterilization units with their ancillary modules. The RSD design is focused on safety; therefore, we propose a modular design in order to divide the potential explosion risks and to suit the plant layout of our customers. Our design, manufacturing and qualification are in accordance with GMP standards, ATEX zone classification and all applicable regulations.

These projects are customizable as we offer a very flexible design that is based on the customer's requirements. Our chambers are suitable for working either with an all-in-one cycle or with preconditioning and degassing cells.



YOUR BESPOKE ETO STERILIZATION EQUIPMENT:



OPTIONS:

- ✓ Preconditioning & degassing cells
- ✓ ETO Monitoring system (LEL/PPM)
- ✓ Modulating pneumatic valves
- ✓ Automatic conveyor system
- ✓ Catalytic system/Scrubber
- ✓ Vacuum degassing chamber
- ✓ Preventive maintenance
- ✓ Pure steam generator
- ✓ Cooling jacket system
- ✓ Parametric release
- ✓ Vertical sliding door
- ✓ Spare parts

MODULAR DESIGN:

Chamber:

A wide range of pressure chambers is available and can be customized. Automated doors are offered, and high quality stainless steel is used for the chamber, the door and the piping. The jacket system is highly efficient, allowing fast heating and cooling time. An all-in-one process can be chosen, and accurate and reliable instrumentation ensures safe cycles.



Air recirculation:

On the top of the chamber, an air recirculation system with a high rating ensures excellent ETO concentration and temperature distribution ($\pm 1^\circ\text{C}$) to make the validation easier. The stable process uses an efficient mechanical seal.



Vacuum pump skid:

The best technology is used for the vacuum system: Liquid ring pump technology. The pumps have a long lifetime and are sized to provide a fast vacuum in safe conditions.



Gas room:

ATEX zone-1 rated, the gas room should be separated from the chamber room. We have a special design to allow the automatic changeover of the ETO containers, which are placed on weight scales.



Steam generator:

In order to humidify the load in the chamber or preconditioning cell, a pure steam generator is required. Two designs can be chosen: Electrical or steam / steam heated. Our equipment adheres to GMP guidelines and provides high-quality saturated steam.



Vaporizer skid:

A high-efficiency SS316L vaporizer is installed, either close to the chamber or in the gas room, to inject ETO to the chamber. A flame arrestor and other instruments are placed on the process piping to ensure maximum safety.



Our strength:
The combination of our extensive experience and our specific ETO know-how lets us provide optimal solutions to the most demanding customers.

Pre-conditioning and degassing cells:

To reduce the cycle time, preconditioning and degassing cells can be installed, usually in-line with the chamber. For degassing cells, ETO residuals are removed and fresh air is brought. Our design gives excellent temperature uniformity.

Air purification system:

Two technologies can be delivered: Catalytic system or Scrubber; both are ATEX rated. To address concerns over atmospheric waste emissions, we have developed a special design for ETO treatment.

Safety is not an option, it is a priority.

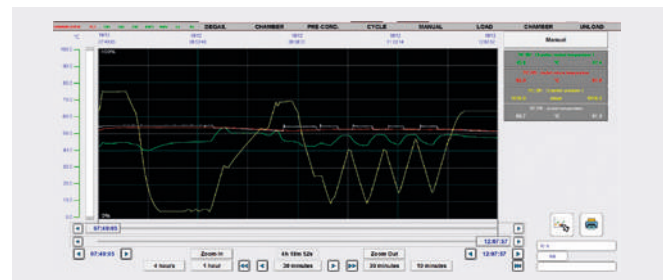
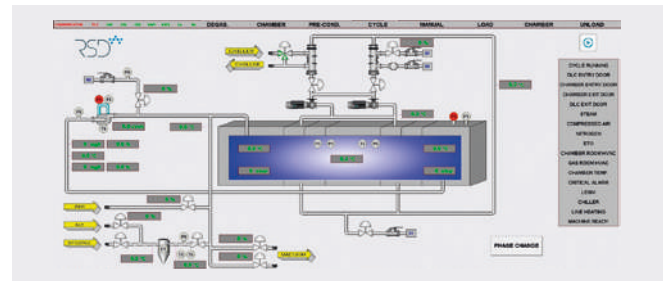


FOR RSD, SAFETY FOR PROCESS AND PERSONNEL IS A PRIORITY. FOR THIS REASON, RSD PROPOSES:

- ✓ One of the safest equipment on the market, always based on an ATEX design.
- ✓ Several safety instruments like flame arrestors and other instruments to prevent hazardous situations.
- ✓ A qualified team that is Ism-ATEX certified by the INERIS notified body.
- ✓ In-depth risk analysis based on several HAZOP and FMEA.
- ✓ Safety PLC (Siemens/Allen Bradley) with advanced components, SIL-certified as per IEC 61508.

CONTROL SYSTEM:

RSD has developed its own control system, based on SCADA technology, and programmed according to the HAZOP analysis and SIL definition for each project.



QUALITY ASPECTS:

Strict qualification protocols are essential in order to sterilize in optimum conditions. RSD standard offers a full package for quality protocols such as DQ, FDS, FAT, IQ, OQ and support for PQ.

The protocols are generated and executed during each phase of the project as per GMP guidelines. They prove that the equipment has been designed and manufactured according to the applicable regulation and customer requirements and complies with all current regulations in the country of destination.



YOUR ADVANTAGE: Working with a single, trusted partner that gives you full support, and controls every single step of the project, to provide reliable and safe sterilization equipment.



Your **ETO** sterilization projects in good hands.

RANGE OF PRODUCTS: EOS MODELS*

RSD MODELS	EOS 1X4	EOS 1X8	EOS 1X12	EOS 1X16	EOS 2X5	EOS 2X8	EOS 2X12	EOS 2X16
	Single line				Dual line			
No of Euro Pallets	4	8	12	16	10	16	24	32
Chamber volume (m ³)	12,7	24,8	36,9	49	30,6	48,3	71,8	95
Chamber Width (mm)	1.400				2.720			
Chamber Height (mm)	2.400				2.400			
Chamber depth (mm)	3.800	7.400	11.000	14.600	4.700	7.400	11.000	14.600

* Dimensions could be adjusted according to customer's requirements.

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