



EtO Sterilization Systems



Since 1992, Telstar has delivered industrial scale EtO (ethylene oxide) sterilization plants ATEX certified, fully documented with appropriate Factory Acceptance Tests, Installation/Operation Qualifications and so on. Telstar can offer a broad range of solutions and services; from cycle development to automatic loading/unloading systems, parametrical release, EtO monitoring system, and complete installation and commissioning of chambers, ancillary equipment and even utility services.

Telstar's expertise and experience has been challenged globally in multiple projects developed on a turnkey basis with highly demanding customers. The engineering and manufacturing practices for EtO installations follow ISO 9001 procedures as well as EN 1422, EN 550, ISO 11135:2007, FDA 21 CFR and GAMP guidelines. Design and construction in relation to Safety and Pressure Vessels meet the most stringent regulations and codes from Europe, USA and other regions.

Whether the business is device manufacture or contract sterilization (CMO), the Telstar certified design can be readily adjusted to requirements by virtue of its modular design and construction and is always in accordance with the ATEX classification.



Turnkey EtO plant delivery: the route to total solution

EtO abatement or air purification system

The treatment of EtO after its use in the sterilization chambers is typically carried out with two types of technologies:

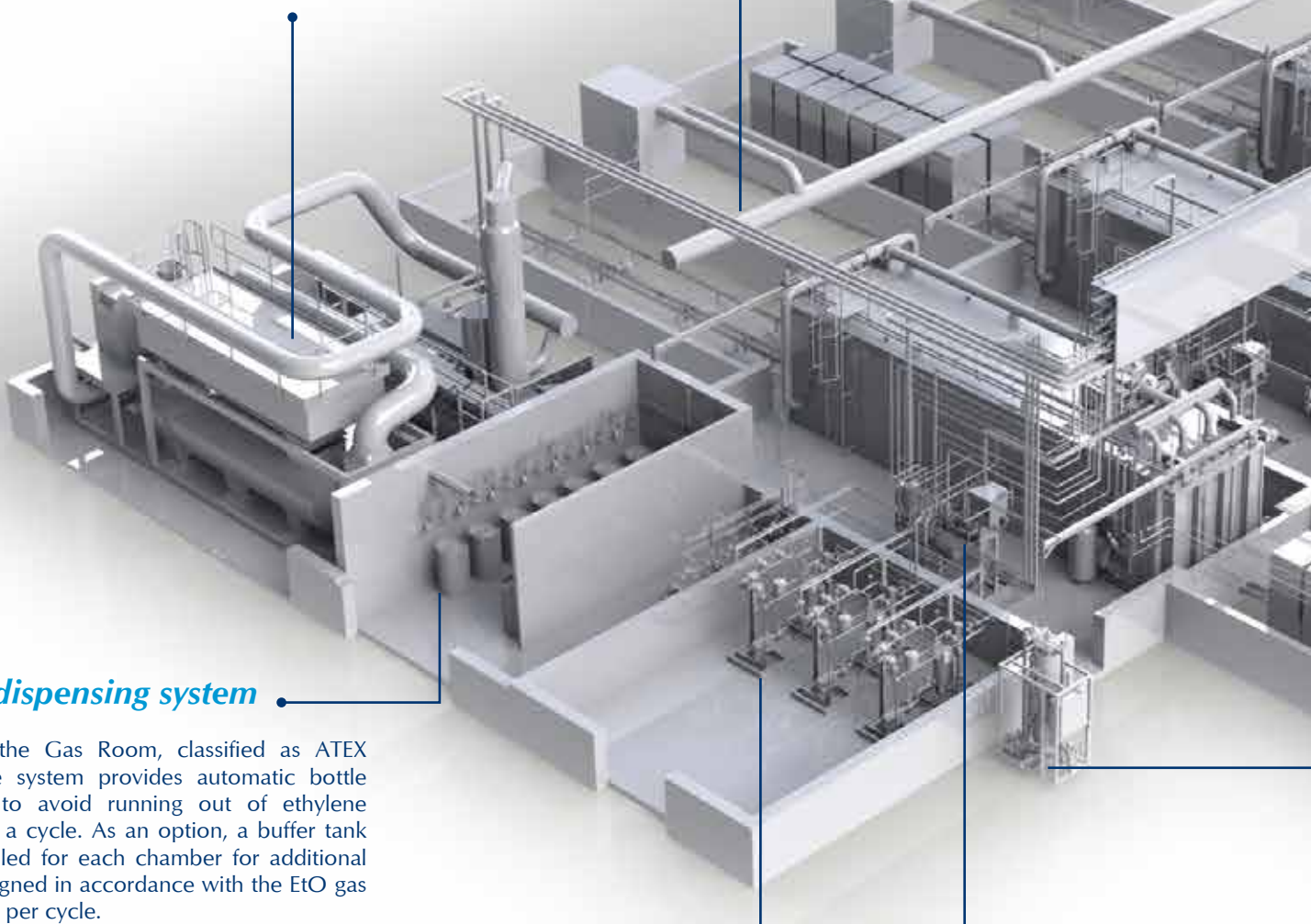
- Scrubber system, using water + sulphuric acid to transform EtO into Ethylene glycol.
- Catalytic system, which is more efficient and totally autonomous since it converts the EtO into CO₂.

Since the national and international regulations are becoming ever-more stringent for emissions of ethylene oxide and residuals to the atmosphere, Telstar recommends the complete LESNI™ catalytic abatement solution. The catalytic Abator system uses the proven technology of catalytic oxidation to offer a safe and controlled purification, with high destruction efficiency from various gases vented during the sterilization process.



Pre-conditioning and degassing/aeration chambers

The use of degassing and preconditioning cells can significantly reduce the EtO cycle time. Telstar provides customers the opportunity to install such a configuration, with a technology which uses high air circulation and removal, resulting in shorter process times.



EO Gas dispensing system

Installed in the Gas Room, classified as ATEX zone 1. The system provides automatic bottle changeover to avoid running out of ethylene oxide during a cycle. As an option, a buffer tank can be installed for each chamber for additional security, designed in accordance with the EtO gas consumption per cycle.



Vaporizing Skid

Installed in the Chamber Room or gas room, classified as ATEX zone 1/2. The system ensures the correct vaporization, of the liquid EtO, and has its own safety systems to prevent dangerous overheating (polymerization risks) or under-heating (dispatch liquid EtO to the chamber).

ons to the highest standards of safety and quality

• ***EtO Sterilization chamber***



Installed in the chamber room which may be classified as ATEX zone 2 as a minimum. A wide range of standard or customised chambers is available. Chambers are manufactured following EN and/or ASME codes, using high quality stainless steel.

Telstar's design includes an external high volume centrifugal fan, which provides excellent thermal uniformity; tests carried out at customer facilities demonstrated a maximum temperature difference of 0.2°C across the 60 probes installed in a 72m³ chamber.

The chamber sectioned jacket provides mechanical resistance and 50% of the jacket rings are used for heated water recirculation. Doors are also jacketed in a similar manner to the chamber. This design is the most cost effective and provides a very efficient and accurate heating system.

• ***Pallet automatic loading/unloading systems***

The advantages of acquiring such option are operation time (which can decrease by up to 30min, depending on the chamber size) and operator ergonomics and safety.



• ***Steam Generator for humidification***

Telstar manufactures steam generators and can offer customers either pharmaceutical grade equipment (PSG) or simple electrical boilers.



• ***Vacuum Skid***

Installed in the chamber DLC (Damage Limited Construction), classified as ATEX zone 2 or perhaps in the ATEX zone 1 area. Vacuum system uses liquid ring pumps or oil-sealed rotary vane pumps specifically selected to optimize vacuum phases.



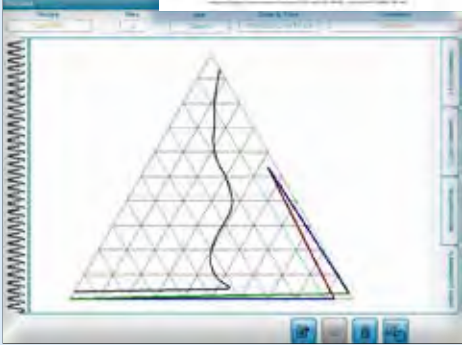
Safety is first and priority

Telstar pays highest attention to safety issues and this is assured by fulfilling ATEX regulations. The ATEX regulation applies to any installation under a potentially explosive atmosphere and it is in force in Europe. In the USA the counterpart regulation is called NEC 500.

Three different types of studies are carried out on each project: Hierarchy of Risks, Risks Analysis (HAZOP) and Failure Mode and Effect Analysis (FMEA), which enables Telstar to obtain the official ATEX certification (09ATEX0001X) from the notified body INERIS (France).

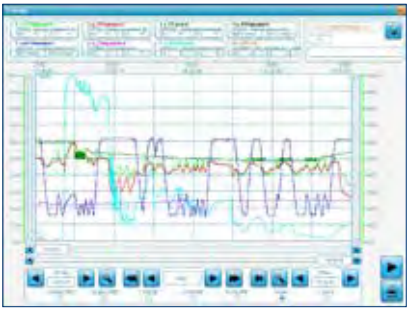
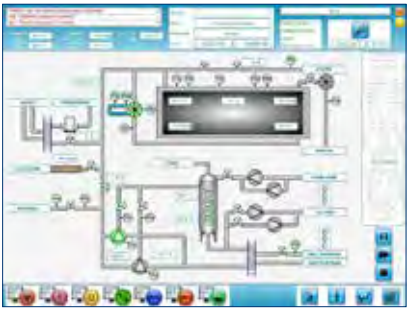
A safety PLC is integrated for orchestrating control of the entire installation in accordance to regulations required to comply with the SIL classification.

Moreover, Telstar's cycle software programming recognises the flammability diagram for EtO mixtures, and avoids performing a recipe which has parameters that could result in an explosive mixture.



SCADA Control System

SCADA Control System integrating the entire sterilization plant (comprised of all of the above modules or systems) located in a non-classified area. All authorized functions are accessible through the user interface. Actions posing a potential risk are controlled through an integrated PLC module, SIL certified, incorruptible and with restricted access.



Parametrical Release

Telstar can also provide a unique ATEX certified EtO IR detector, which is connected to the recirculation pipe and indicates the value of the chamber EtO concentration in a real time.

Parametric release enables product to be released to the market based only on process records instead of the traditional biological indicator sterility test. This is advantageous in that it eliminates the routine costs associated with biological indicators and laboratory testing.



Product Range

	Model	Nº of Euro Pallet	Chamber Width (mm)	Chamber Depth (mm)	Chamber Height (mm)	Chamber Volume (m³)
Single Line	EUP 1x4 1.8	4	1.440	3.800	1.800	9,8
	EUP 1x4 2.2				2.200	12,0
	EUP 1x4 2.6				2.600	14,2
	EUP 1x5 1.8	5		4.700	1.800	12,2
	EUP 1x5 2.2				2.200	14,9
	EUP 1x5 2.6				2.600	17,6
	EUP 1x6 1.8	6		5.600	1.800	14,5
	EUP 1x6 2.2				2.200	17,7
	EUP 1x6 2.6				2.600	21
	EUP 1x8 1.8	8		7.400	1.800	19,2
	EUP 1x8 2.2				2.200	23,4
	EUP 1x8 2.6				2.600	27,7
	EUP 1x10 1.8	10		9.200	1.800	23,8
	EUP 1x10 2.2				2.200	29,1
	EUP 1x10 2.6				2.600	34,4
	EUP 1x12 1.8	12		11.000	1.800	28,5
	EUP 1x12 2.2				2.200	34,8
	EUP 1x12 2.6				2.600	41,2
EUP 1x16 1.8	16	14.600	1.800	37,8		
EUP 1x16 2.2			2.200	46,3		
EUP 1x16 2.6			2.600	54,7		
Dual Line	EUP 2x4 1.8	8	2.760	3.800	1.800	18,9
	EUP 2x4 2.2				2.200	23,1
	EUP 2x4 2.6				2.600	27,3
	EUP 2x5 1.8	10		4.700	1.800	23,3
	EUP 2x5 2.2				2.200	28,5
	EUP 2x5 2.6				2.600	33,7
	EUP 2x6 1.8	12		5.600	1.800	27,8
	EUP 2x6 2.2				2.200	34,0
	EUP 2x6 2.6				2.600	40,2
	EUP 2x8 1.8	16		7.400	1.800	36,8
	EUP 2x8 2.2				2.200	44,9
	EUP 2x8 2.6				2.600	53,1
	EUP 2x10 1.8	20		9.200	1.800	45,7
	EUP 2x10 2.2				2.200	55,9
	EUP 2x10 2.6				2.600	66,0
	EUP 2x12 1.8	24		11.000	1.800	54,6
	EUP 2x12 2.2				2.200	66,8
	EUP 2x12 2.6				2.600	78,9
EUP 2x16 1.8	32	14.600	1.800	72,5		
EUP 2x16 2.2			2.200	88,7		
EUP 2x16 2.6			2.600	104,8		

* Customized chambers available upon request.



ISO 9001: Certified Company

BR-ETOSTERILIZATION-EN-1020

Telstar reserves the right to improvements and specifications changes without notice.

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