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Three different types of studies are carried out on each project: History of Risks, Risks Analysis (Hazard and Operative Risk Analysis, 4MEA), which enables Telstar to obtain the official ATEX certification (INERIS0001X) 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.

Telstar also provides 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. This is advantageous in that it eliminates the routine costs associated with biological indicators and laboratory testing.

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Since 1992, Telstar has delivered industrial scale EO (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, EO 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 EO 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.

**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 Glycolic acid.
- Catalytic system, which is more efficient and totally autonomous since it converts the EO into CO2.

Since the national and international regulations are becoming more stringent for emissions of ethylene oxide and residuals to the atmosphere, Telstar recommends the complete DSN32 catalytic abatement system. This system uses the proven technology of catalytic oxidation to achieve 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 times. Telstar provides customers the opportunity to install such a configuration, with a technology which uses high air circulation and renewal, resulting in shorter process times.

**EtO Gas dispensing system**

Installed in the Gas Room, classified as ATEX zone 1. The system provides automatic buffer 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 optimization of the load tests and has its own safety systems to prevent dangerous overheating (undercooling risk) or under-heating (dispersing liquid EO to the chamber).

**Vacuum Skid**

Installed in the chamber DLC (Damage Limited Construction), classified as ATEX zone 1 or perhaps in the ATEX zone 5 area. Vacuum systems use liquid ring pumps or centrifugal series vacuum pumps specifically selected to optimize vacuum phases.

**Pre-conditioning and degassing/ aeration chambers**

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.

**Pallet automatic loading/ unloading systems**

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**EO abatement or air purification system**

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

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

Since the national and international regulations are becoming ever more stringent for emissions of ethylene oxide and residues to the atmosphere, Telstar recommends the complete CDS® catalytic abatement system. The 280°C process temperature of the catalytic reaction tower is controlled by a safety and controlled purification with high obstruction efficiency from various gases vented during the sterilization process.

**EO Sterilization chamber**

- Installed in the chamber room which may be classified as ATEX zone 2 or at lower.
- Designed in stainless steel according to EN and/or ASME codes, using high quality stainless steel.
- Telstar’s design includes an external high volume centrifugal fan, which provides excellent uniform conditions. Chambers are installed at customer facilities demonstrating a minimal temperature difference of 0.6°C across the 60 probes installed in a 72m³ chamber.

**Pre-conditioning and degassing/ aeration chambers**

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

**Vacuum Skid**

- Installed in the chamber room, classified as ATEX zone 1/2. The system ensures the correct operation of the EO system and has its own safety systems to prevent dangerous overheating (overcompensation) or under-heating (dispatch-liquid EO to the chamber).

**Vaporizing Skid**

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- Catalytic system, which is more efficient and totally autonomous since converts the EO 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 EPA® catalytic abatement system for EO abatement due to its high destruction efficiency and its practicality for various gases vented during the sterilization process.

Pre-conditioning and degassing/avation chambers
The use of degassing and preconditioning cells can significantly reduce the EO cycle times. Telstar provides customers the opportunity to install such a configuration, with technology which uses high air circulation and removal, resulting in short cycle times.

Vacuum Skid
Installed in the Chamber Room or gas room, classified as ATEX zone 1. The system ensures the correct vapourization of the liquid EO in the chamber during the sterilization process.

Vaporizing Skid
Installed in the Chamber Room or gas room, classified as ATEX zone 1. The system provides an additional security, designed in accordance with the EO gas consumption per cycle.

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 EO gas consumption per cycle.

Turnkey EO plant delivery: the route to total solutions to the highest standards of safety and quality

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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 recognizes the potential risk are controlled through an integrated PLC module, SIL certified, incorruptible and with restricted access.

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Parametrical Release
Telstar can also provide a unique ATEX certified Di3-IR detector, which is connected to the recirculation pipe and indicates the value of the chamber EtO concentration in 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.