

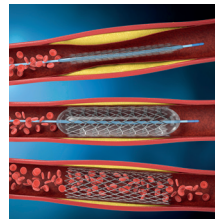
# ETHYLENE OXIDE STERILIZATION SOLUTIONS FOR MEDICAL DEVICES IN PHARMA 4.0 ENVIRONMENT

## YOUR MEDICAL DEVICES STERILIZATION PARTNER

Ethylene Oxide (EtO) is a low temperature gaseous process used to sterilize many healthcare products sensitive to temperature.

Polymeric components used in medical devices that cannot be exposed to excessive heat, moisture, or radiation may be sterilized with EtO.

Residuals of EtO may remain in the product after the sterilization process requiring an aeration cycle to reduce them to compliant levels.



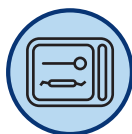
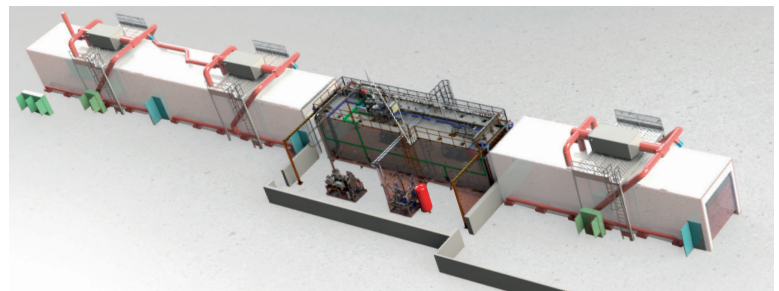
- Medical devices commonly processed:
- Empty syringes
  - Stents
  - Catheters
  - Complex ready-to-use sets



### EtO STERILIZATION TECHNOLOGY

Sterilization lines include:

- Preconditioning
- Sterilization chamber (for 100% EtO or mixtures)
- EtO neutralization
- EtO residue removal from product (by forced ventilation or vacuum)
- Automatic loading-unloading systems



### PROCESS FLOW



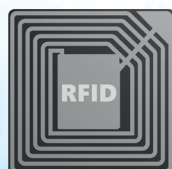
Autonomous Mobile Robots (AMR) to transfer pallets from warehouse to sterilization lines



Full batch loading system for pallet transferring on the different process steps



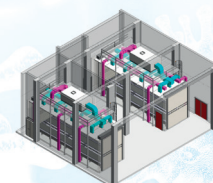
STERILIZATION PROCESS



Track and trace solutions by means of Radio Frequency Identification (RFID)

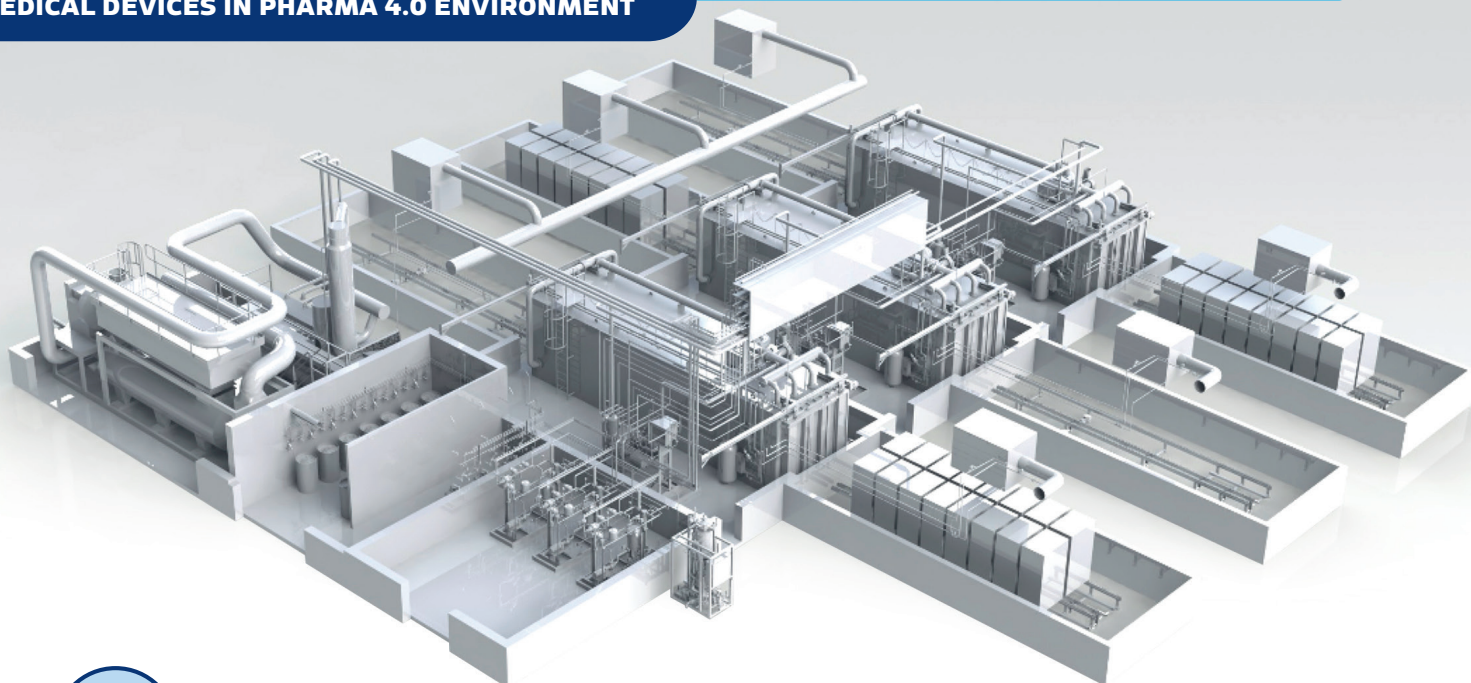


From traditional Biological Indicators (BI) to Parametric Release



Efficient aeration systems to reduce residual EtO in product





**STERILIZATION PROCESS SOLUTIONS**



IP6 WMS (Warehouse Management System) integrated with plant MES



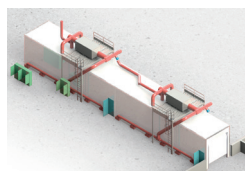
AMR integration for pallet transfer from warehouse to sterilization line



Preconditioning cell



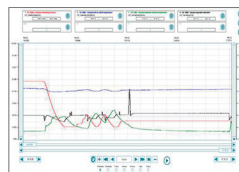
Sterilization chamber



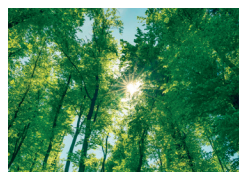
Primary and secondary aeration / vacuum degassing cells



Automatic Loading & Unloading systems for sterilization line



Parametric release



Air purification system integration



Intrinsically safe (ATEX/NEC) certified executions



Explosimetric and toxicometric detection system across the plant

**+ ADDITIONAL TELSTAR PRODUCTS / SERVICES**

- Process equipment
- Complete line solutions
- Lyophilization and sterilization process optimization/development services
- Calibration services
- Customer service (including equipment upgrade, retrofit & refurbishment)



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