

Industrial Air Purification

# PRECONDITIONING & DEGASSING



Ethylene Oxide Sterilization for Medical Devices

# Ethylene Oxide (EtO) Sterilization Process

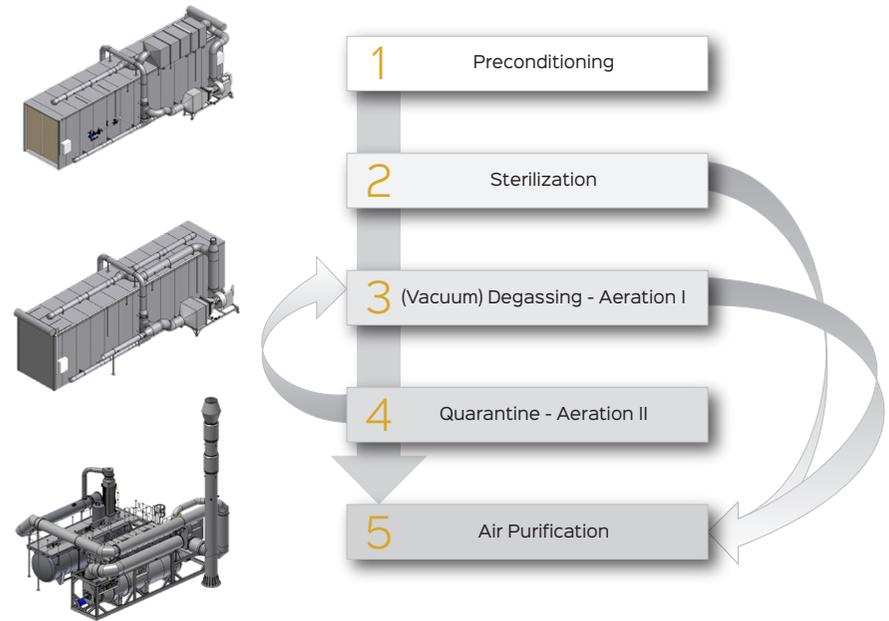
EtO gas infiltrates product as well as packages to kill microorganisms that are left during production or packaging processes.

Consequently, safety of personnel and the environment is an important issue due to the harmful effect of EtO on humans, and measures to efficiently extract and purify all evacuated gas from the sterilizer as well as fugitive air from aeration after post sterilization.

Processing occurs at temperatures around 45 – 55 °C, a lower temperature results in a less efficient process which leads to a longer exposure time. At least there are three stages in a typical EtO sterilization cycle, where cycle time is usually more than 14 hours, these are:

- Preconditioning
- Sterilization
- Aeration (Degassing)

When using this process, sufficient preconditioning, and multiple vacuum evacuation as well as degassing post sterilization is required; sometimes subsequent additional aeration of these medical devices are essential to reduce residual EtO levels to within acceptable limits complying with current European and international legislation. The design and operation of such degassing chamber should speed the rate of evaporation of the absorbed gas again from the sterilized items.

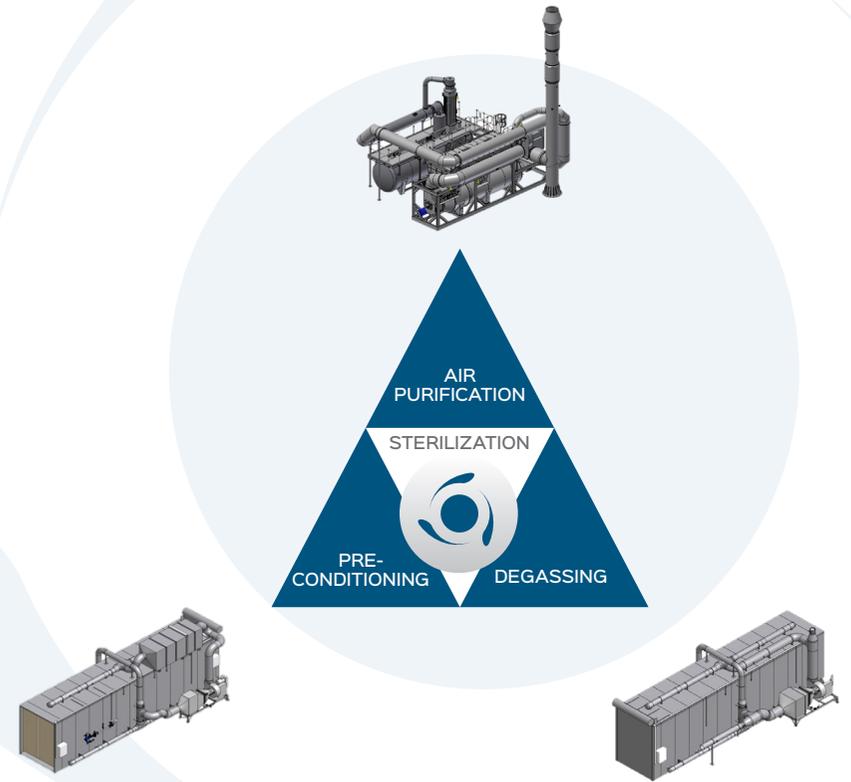


# Sterilization Equipment

The use of LESNI accelerated Degassing Cell and / or Vacuum Degassing Cell after sterilization can significantly reduce the post sterilization cycle time, and thus the need for large quarantine aeration rooms, while ensuring optimized treatment and purification of all fugitive emissions in the final Catalytic Abatement Plant.

LESNI works to provide customers the opportunity to support the sterilization process and thus integrate where possible the installation of dedicated Preconditioning and Degassing Cells in a configuration that improves cycle time, reliability, and operation. The cells are designed and delivered to ensure high air circulation and exchange in a close environment where all relevant parameters and conditions are controlled in such a manner resulting in shorter process times.

The Preconditioning and Degassing Cells are engineered to meet client's cycle requirements ensuring maximized cell and utility usage performance. Our 2D and 3D conception and detail design facilities allow the client to visualize complete layout well before detail design and construction, to avoid delays.



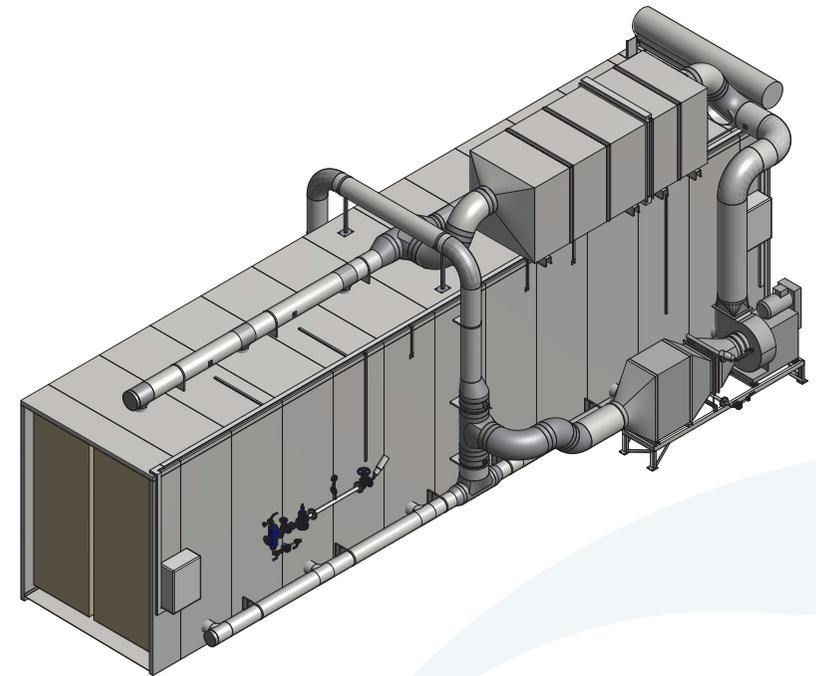
## Preconditioning Cell

Preconditioning is a necessary step in the sterilization process, which prepares products / devices ahead of sterilization and save precious time inside the sterilizer, it enhances ethylene oxide penetration into the product and packaging.

In LESNI Preconditioning Cell the products are in a temperature and humidity controlled area.

A typical range for this preconditioning step is a temperature at 40 – 60 °C and relative humidity of 50 – 65 %.

Product on pallets placed in closed, insulated chamber where air flow, temperature and relative humidity evenly distributed and maintained at pre-set values.



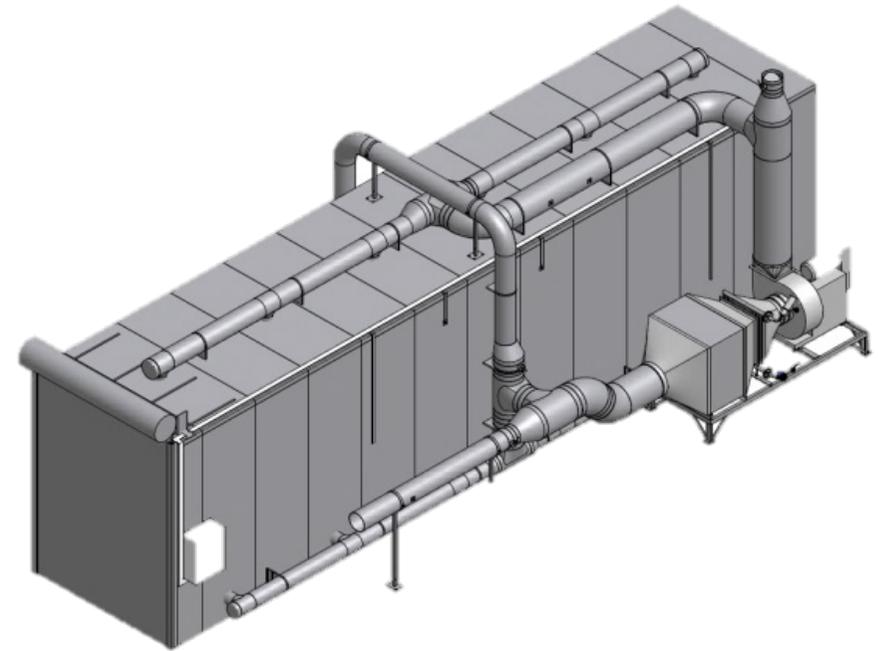
## Degassing Cell

Degassing is the next step after sterilization to get residual ethylene oxide out of the packaging and products by aerating the cell with heated air.

In LESNI Degassing Cell the products are in a temperature controlled environment, designed to ensure turbulent but accelerated air speed around the product to improve gas evaporation and reduce the degassing time.

A typical operating range for this degassing step is a temperature at 40 –55 °C and several air changes.

Aeration time may vary and is related to product type and different materials used, for this reason it is very important to have an efficient degassing and aeration stage to remove remaining EtO gas.



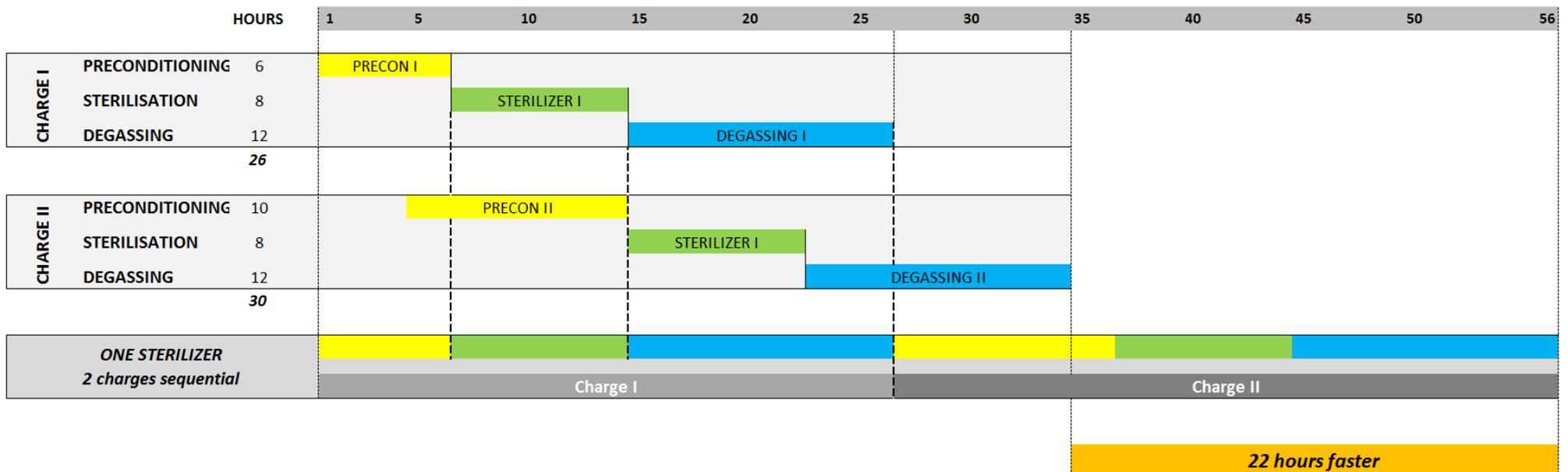


## Saving Time and Space

The use of LESNI accelerated Degassing Cell and Vacuum Degassing Cell after sterilization can significantly reduce the post sterilization cycle time, and thus the need for large quarantine aeration rooms, while ensuring optimized treatment and purification of all fugitive emissions in the final Catalytic Abatement Plant.

# Reduction of Lead Time

The benefit by using separate equipment for the sterilization process is a reduction of lead time during this process and is visualized in the following diagram, where parallel sterilization process of two different products / product mixes with variable preconditioning and degassing period, using two Preconditioning Cells, one sterilizer and two Degassing Cells, is compared with a sequential process operated by one sterilizer.

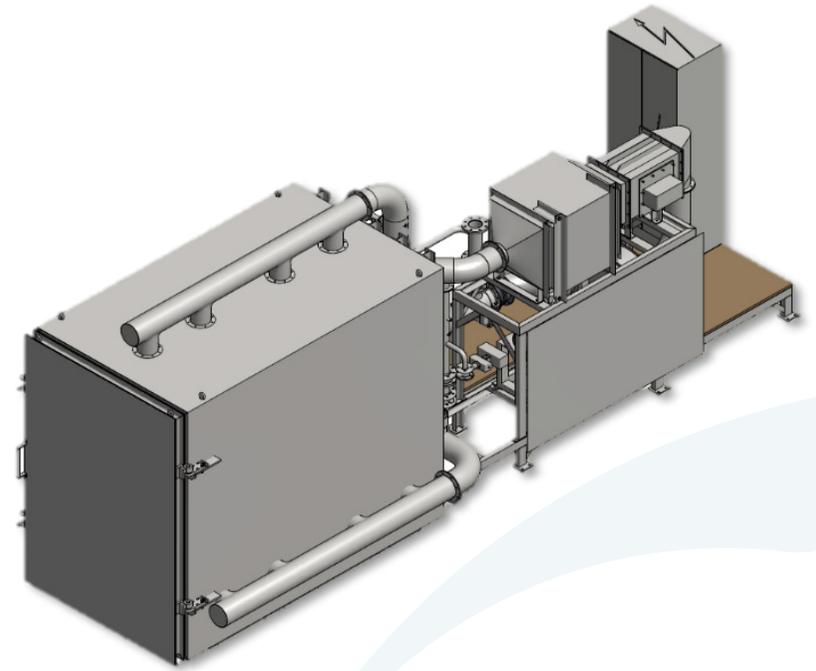


## Vacuum Degassing

Vacuum Degassing accelerate the evacuation of the residual ethylene oxide out of the packaging and products during aeration with heated air.

The rapid degassing of EtO under slight shallow vacuum expected to reduce time of degassing by 65 % or better depending on the vacuum break performed.

When loaded with sterilized product the cell door will be closed and sealed, with turbulent air circulated evenly around the product to give a homogenous atmosphere mix. This circulated atmosphere will then be heated to the cycle selected temperature point and maintained.



## Vacuum Degassing Cell Features

Similar to standard Degassing Cell, a minimum air circulation rate will be targeted to achieve necessary turbulence throughout the cell. Also the air flow will be distributed and balanced along the full length of the cell to give an even distribution of cell temperature and air flow conditions throughout the load. The inlet and outlet ducting will be designed to give the best atmosphere flow across the surface of all the product within the cell.

- Extraction of the internal cell atmosphere will be achieved by the vacuum pumping system and diverted to the final LESNI Catalytic Abatement Plant.
- The Degassing Cell walls and door will be insulated all around to maintain a temperature variation across the free space of the cell.
- A suitably sized vacuum pump will be fitted to extract Degassing Cell in a short time.
- An air break from vacuum to atmospheric pressure will be installed to vent Degassing Cell in a similar period of time.
- The Degassing Cell for this application will be constructed as a stand-alone cell / chamber to be placed on the floor adjacent to the sterilizer.

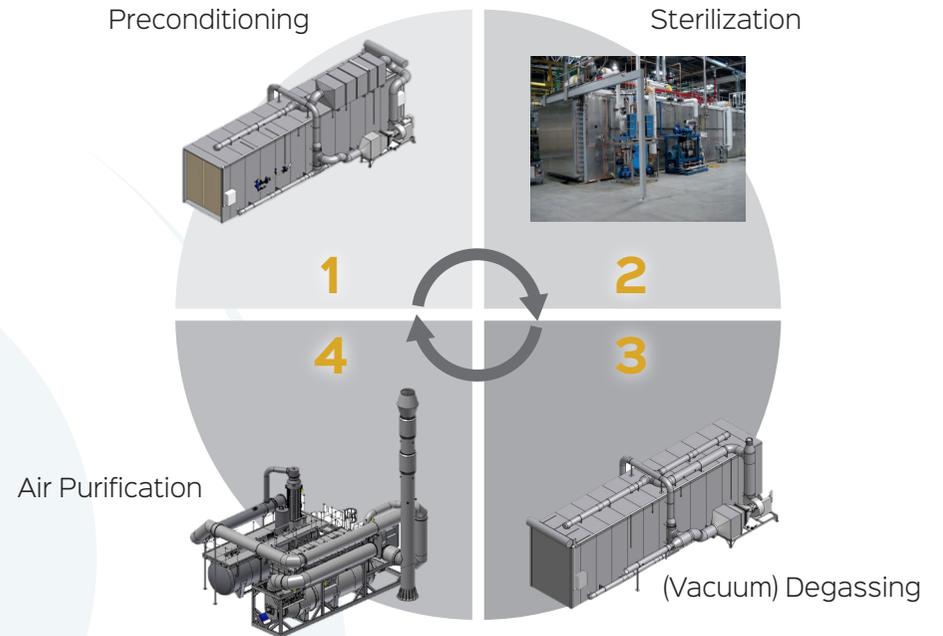


# All around Sterilization

The integration of the Preconditioning and Degassing Cells together with the well proven LESNI - EtO Catalytic Abatement System, ensures also complete EtO elimination and destruction from any environmental release to atmosphere.

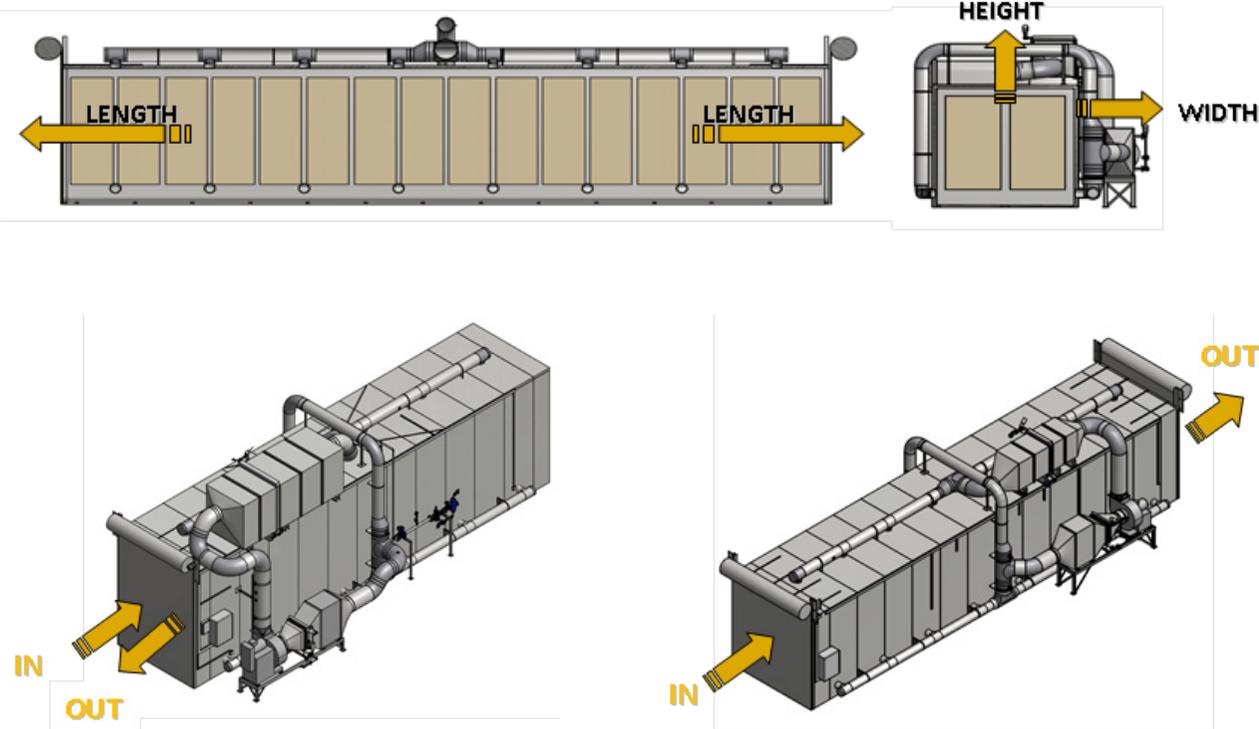
To meet continuous stringent requirements to reduce EtO residuals on the product, the LESNI Vacuum Pilot Degasser is available for testing and optimizing degassing cycle time. The unit is constructed to withstand shallow vacuum intervals of up to 700 mbar and is built for use with 3 EU pallets, with settings to control temperature, relative humidity and airflow circulation.

This complement LESNI long history and contribution to the sterilization of medical devices industry, while help to achieve our goal and commitment to product excellence for this process.



# Design Parameters

Following table and sketch will give you an idea about some possible parameters available to configure and design your cell to fit best to your existing sterilizer respectively sterilization process.



<b>AMOUNT OF PALLETS</b>			
X PCS.			
<b>SIZE OF PALLETS</b>			
WIDTH	LENGTH	HEIGHT (with products)	WEIGHT
<b>STERILIZATION CYCLE TIME</b>			
HOURS			
<b>LOADING / UNLOADING</b>			
1 DOOR	2 DOORS		
<b>MODE OF TRANSPORT</b>			
MANUELL	CONVEYER BELT		
<b>EXTERNAL ENVIROMENT CONDITION</b>			
<b>TEMPERATURE</b>		<b>RELATIVE HUMIDITY</b>	
° C		%	
<b>OPERATING TEMPERATURE</b>			
° C - Range & Tolerance			
<b>OPERATING RELATIVE HUMIDITY</b>			
% - Range & Tolerance			
<b>SUPPLY AIR CONDITION</b>			
WAREHOUSE	OUTSIDE		
<b>INSTALLATION AREA CONDITIONS</b>			
SAVE AREA	ATEX / EX ZONE		



Air purification by physical and chemical scrubbers



Activated carbon plants for VOC purification, odour removal and solvent recovery



Air purification systems for removing mist, dust and particulate matter



Safe and efficient catalytic and thermal oxidisers for VOC purification and solvent destruction



LESNI has developed a variety of innovative solutions for specific pollutants and processes in operation worldwide



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