

## Medical Devices Sterilisation

EtO Sterilisation Chambers

Gas Treatment Systems

Steam Sterilisation Chambers

Maintenance



Sterimed today has worldwide references among the biggest companies on the market with its extensive knowhow in cycle development and validation. We have sterilisation solutions validated with various products such as: sutures, syringes, hemodialysis sets, and IV sets; procedure packs, and general nonwoven; we have also developed cycles for active and passive devices.

Based in Switzerland, Sterimed is one of the few companies able to deliver a fully comprehensive turnkey sterilisation project. From project engineering and customer advice, design, manufactured delivery and up to final validation and customer training. Sterimed provides a wide range of sterilizer sizes, door configurations, central heating, independent electrical heating, automatic pallet handling systems, with pre and post conditioning systems, and various gas treatment solutions depending on country regulations or customer requirements.

What makes Sterimed unique is its incomparable understanding of customer needs and our propensity to offer tailor-made solutions for every project.

Sterimed is certified ISO 9001 by Swiss TS in order to assure our customers receive the most advanced technical product responding to the highest quality standard prevailing in the world.



## Sterimed equipment

Sterimed has been designing and manufacturing its chambers with all necessary care required for such applications and each part has been carefully selected to give optimal results in terms of reliability and safety. Sterimed provides the highest level of safety by delivering ATEX solutions based on components with an intrinsic barrier in any hazardous area. Our equipment is controlled exclusively with Pneumatic actuators, and is recommended to be used with a safe vacuum cycle, to give to the complete system a target of absolute safety.

Sterimed provides innovative technical solutions for the sterilisation of medical devices, with probably the most innovative technically engineered designs. Our engineering capabilities cover environmental impact, energy consumption, but also the people safety and equipment, as well as process safety (repeatability) and high quality documentation, with comprehensive user and maintenance guides and very direct approach DQ, FAT, IQ, OQ, PQ and SQ documentation, based on our wide range of customer requirements and propositions.

Sterimed's preferred sterilisation cycle is based on using a vacuum cycle by choosing a mixture containing 100% EtO or 90% EtO + 10% CO<sub>2</sub> (CO<sub>2</sub> is mainly used as a pressure cushion in the bottle). In order to guarantee maximum safety, this proven process is simple, cost effective and reliable. But we can also recommend system engineered solutions as per customer requirement with the same positive approach and cost effective solution.

## EtO Sterilisation Chambers

Sterilisation "effect" is an alkylation reaction with the DNA structure by a chemical agent (here: Ethylene Oxide). The alkylating agent is damaging the DNA structure of the living cells and in our case is targeting bacteria (including in spore forms), viruses and fungi, making them partially killed but very impossible to reproduce.

Ethylene oxide is widely used today in medical device industries for sterilisation process, taking advantage of its universal capabilities. Harmful with living cells it is proven absolutely transparent of products. The growth of medical industry has been fuelling sterilisation exponential development. In addition the conversion of more and more health systems to procedure pack and other customized kits, oblige medical industries to sterilised same product twice, leveraging the sterilisation volume dramatically in the last decade.







## Hydrolyze (scrubber method)

The Hydrolyse is the transformation of Ethylene oxide gas into liquid ethylene glycol. The scrubber has to first wash air stream from EtO by solubilisation (washing tower) and then to achieve the chemical reaction in the reactor.

It is usually considered that a single stage scrubber well designed can have an efficiency of 98%. We can then have, 3 or more stages to increase the efficiency up to 99,995%.

For higher requirement with limits expressed in PPM, we can last staged a Dry Catalyst Filter in order to bring efficiency to almost 100% and treat the flow from eventual degassing room (hydrolyse systems are not efficient on large stream low concentration).

# Gas Treatment Systems

## Catalytic oxidation

EtO thermal decomposition point is at 570°C. The energy necessary to heat up the vacuum flow and the degassing flow to this temperature can be very costly. Therefore, after mid 70's it has been proposed to the medical industries to use a catalytic bed to bring the temperature down to 150°C by using a catalyzer to trigger the thermal oxidation.

Mid 80's a peak shaver system has been introduced to reduce the catalytic burner size. Therefore, today this well-known technology, has more than 4 decades of engineering behind it, a proven safe and cost effective solution to EtO disposal all over the world.

Peak shavers are working as a buffer tank, using water capabilities to adsorb EtO, to store it.

The vacuum pump exhaust (circa total chamber EtO volume to be evacuated in 20 minutes, 2 or 3 time a day) is stored and then controlled redeem over a much longer period of time. In other words, the peak shaver is here to transform a 20 minute large quantity of EtO into a 6 to 8 hours interrupted flow of much lower concentration.

This association allows to have the right burner size to be as close as possible to the autothermic mode. The peak shaver is an easy CAPEX investment based on the OPEX saving, without highlighting the reduce carbon foot print of the installation and the saving of fossil energy.

A catalytic burner is the beneficent association of three functions:

Heat exchanger

To allow autothermic mode, and limit energy consumption down to zero in theory.

Heater or burner

It is in charge to level up the stream temperature up to 200°C if required; and to start the system.

Catalytic bed

To finally oxidize ethylene oxide into CO<sub>2</sub> and H<sub>2</sub>O, prior to atmosphere release.

Ethylene Oxide (EtO) is used worldwide to sterilize medical disposable devices. The medical device industries use large volume autoclaves and very performing degassing cells.

Today regulation imposes in most countries to have a gas treatment system to address both high concentration of low volume and low concentration of high volume flows.

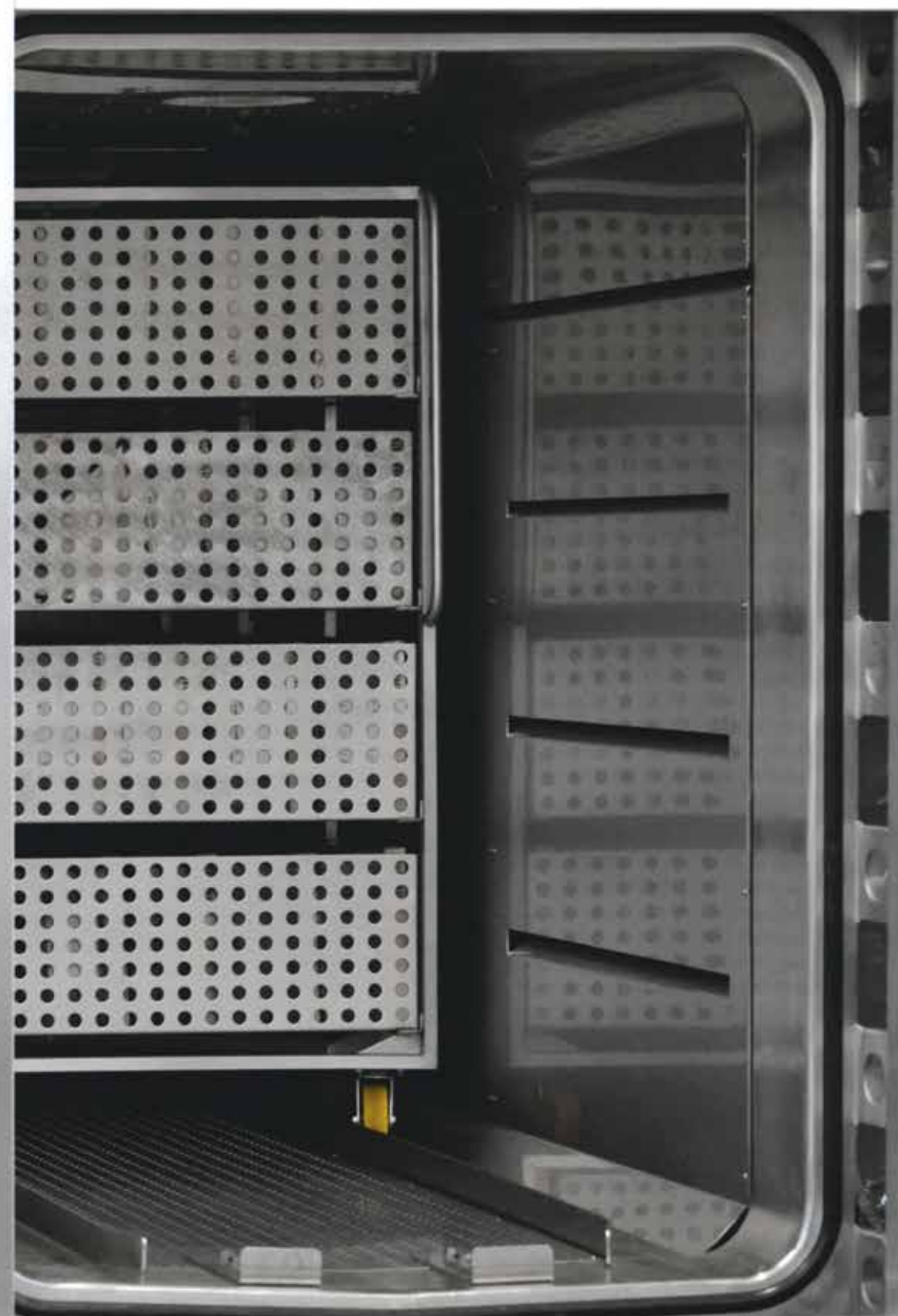
For installation where local regulation does not impose gas concentration control, we do recommend a simple cost effective solution to treat the largest proportion of gas.

Important to note it proved that, depending on circumstances, Ethylene Oxide can have harmful effects on people and the environment, especially in case of long-term exposure.

The transformation of Ethylene Oxide can be achieved by various methods, we have developed and enhanced two technologies: the thermal oxidation and the chemical hydrolyse.







## Steam Sterilisation Chambers



### Cycles

Air steam cycles  
(Ventilated autoclaves)

Temperature rise: during this phase, steam is injected inside the chamber and the temperature increases consequently, the pressure also increases in a controlled manner.

Sterilisation dwell-time: the temperature and pressure are regulated separately by steam and/or air injection, in order to protect the batch against explosion or accidental opening (bags, pre-filled syringes, ...)

The air + steam mixture is permanently mixed by internal fans in order to maintain an accurate and homogeneous mixture.

Cooling: an accelerated cooling phase brings the batch temperature to an acceptable level before discharging the sterilisation chamber. During the whole cooling phase, a filtered air counter-pressure is maintained, in order to protect the batch.

Thanks to extensive experience in the medical industries, in accordance with major companies in this field, Sterimed is also a leader in tailored steam solutions.

Liquid cycles	Solid cycles
Preheating : this phase is intended to pre-heat the batch during a variable time, using the air displacement (fluent steam) principle.	Preheating : in some application, this phase allows to preheat the batch during an adjustable time.
Temperature raise : steam is injected into the chamber in order to reach the sterilisation set temperature.	Pre-vacuum : in order to evacuate the air from the chamber and load in the case of porous materials.
Sterilisation dwell time : the pressure and temperature inside the sterilisation chamber are regulated accurately in order to meet the required process temperature.	Steam injection under vacuum : in order to complete the air evacuation by sub-atmospheric steam pulses.
Pressure release and cooling : various possibilities are offered, depending of the batch : natural or accelerated cooling with filtered air counter-pressure.	Steam injection over pressure : in order to preheat the batch and eliminate condensates, the number and pressure pulse levels are adjustable, depending on the application.
	Sterilisation dwell time : the pressure and temperature inside the sterilisation chamber are regulated accurately in order to meet the required process temperature.
	Final vacuum drying phase : the purpose of this phase is to deliver a perfectly tight load, especially in case of porous loads, wrapped or packed in paper bags.

Control panel

All the components and functions of the sterilizer are controlled by a programmable logic controller PLC connected to a « human machine interface » HMI, or supervision computer. Our programs and supervision interfaces are fully documented and comply WIH the 21CFR PART11 and GAMP requirements.

Autoclave

Fully built in stainless steel DIN 1.4404-316L, with single or double sliding doors. Depending on the process, the chamber design may be rectangular with steam heating/ cooling jacket or cylindrical with internal heat exchanger and baffle plates (Air/Steam process).

Vacuum pumps

A high vacuum can be obtained by a heavy duty water-ring pump, connected to a water tank or cooled by loose water.

Steam generator

Our pure steam generators are built in stainless steel DIN1.4404-316L, their size as well as electric power are calculated in order to bring high quantity of steam necessary for a fast and efficient sterilisation. On option a GMP design fully meets the pharmaceutical regulation (material, polishing, and components) and can accept WFI water.

Water treatment

We can offer a complete solution for water treatment in order to feed our steam generator with highly purified water, complying with the highest pharmaceutical standards.

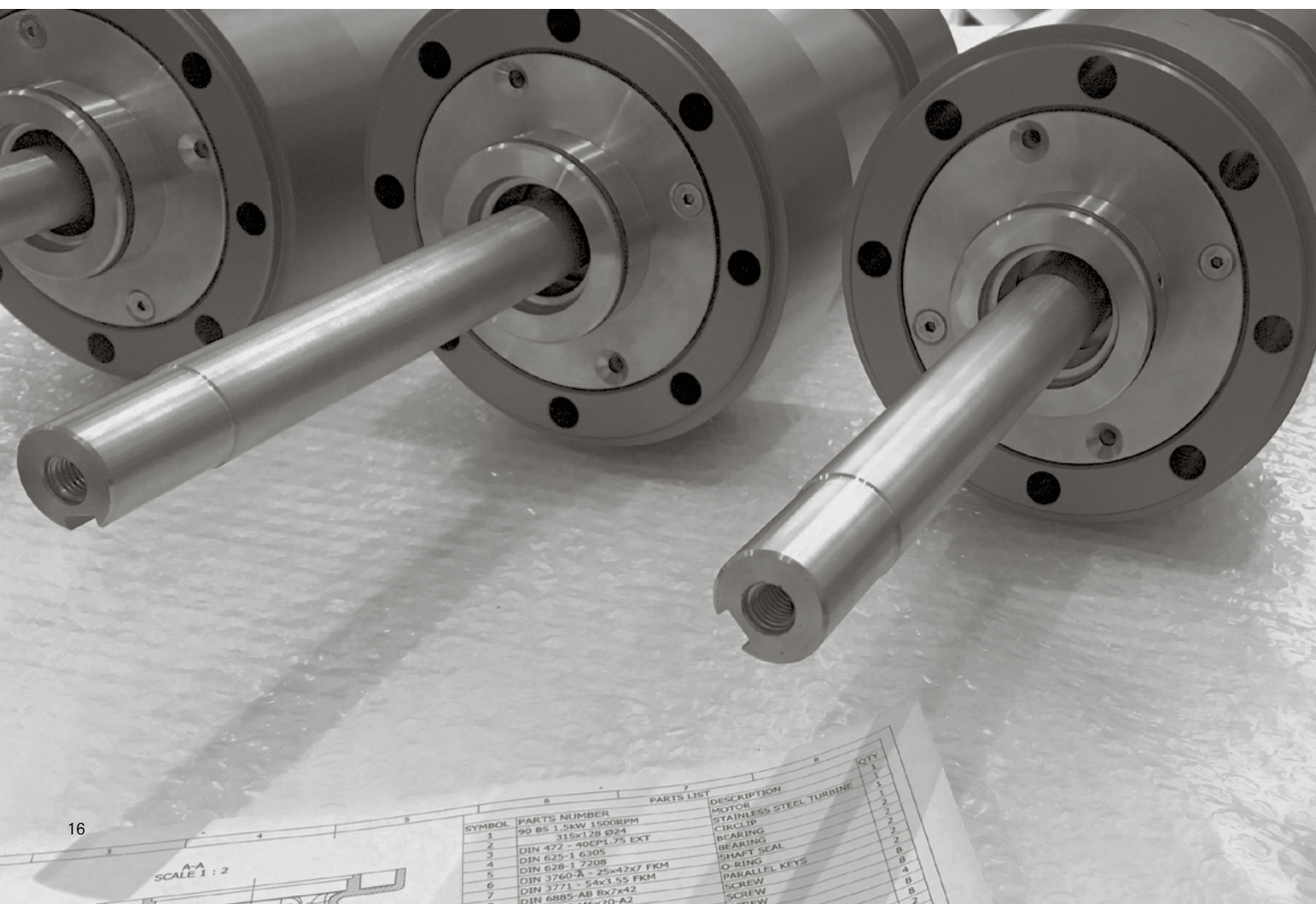
Chilled water loop

Energy saving solutions are available, in order to work completely in closed loop, in order to cool the condensates, vacuum pump, accelerated cooling circuits... while minimizing the water consumption, various sizes of chilling units and circuits can be offered as turn-key systems.



Maintenance

Sterimed specializes in maintenance, metrology, revalidation and revamping of sterilisation systems.  
An ounce of prevention is worth a pound of cure!



Maintenance Services

Preventive maintenance  
Better control of customer equipment and an efficient follow-up service.

Corrective maintenance  
Immediate response to customer calls relating to breakdowns.

Remote access  
Thanks to reliable tele maintenance switches, sterilisation system downtime is minimized.

On site training  
Sterimed provides all the know-how for user maintenance on a 1<sup>st</sup> level basis.

Spare Parts  
Dedicated service department for the speedy supply of original and high quality parts guaranteed.

Metrology

The accuracy of the measured and recorded data on your system is the guarantee of your sterilisation process and more importantly the sterility of your products!

That's why Sterimed also provides on request:

Calibration : Our swiss certified partner is LabCal. All of our metrology equipment is controlled annually and certified by Coffrac.

Re validation : As per our metrology service, the annual re validation of your chamber can be handled by our team to complete our partnership

Revamping : Status assessment of your existing equipment and consulting for partial or complete revamping.

Sterimed grants to all its customers high quality equipment, reliable support and follow-up in order to gain their confidence about the sterilisation process: we can assemble the right team with the right experience to help clients anywhere in the world, any time!





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