



**Autoclaves with Cycles in Counterpressure**

**SteriDelta**



**Technology. Science. Life.**

## A choice of quality

Telstar represents nowadays one of the most advanced and quality alternatives worldwide in the field of sterilisation equipment under CGMP guidelines.

Engineering and manufacturing practices follow ISO 9001 procedures, ASME BPE criteria, GAMP guidelines, etc. Design and construction meets the most stringent Regulations and Codes from Europe, USA and others concerning Safety and Pressure Vessels.

To ensure the equipment meets your requirements, we work in partnership with you and a dedicated team follows your order as a unique project. We develop specific Quality Plans (DQ, IQ and OQ) and undertake factory acceptance testing (FAT).



## Terminal sterilization of liquids

When selecting an autoclave for terminal sterilization of liquids, these two questions have to be taken into account:

- 1) Selecting the chamber dimensions according to the critical batch quantity. The load has to be placed into the chamber properly so that homogeneous temperature distribution / penetration throughout the whole load has to be attained in a way that it can be reproduced (i.e. the process can be validated).
- 2) Investigating the process method and cycle recipe so the physical condition of the container at the end of the cycle remains unaffected. The wrong choice may lead to deformation of plastic containers, breaking or cracking of flasks and movement of stoppers in the case of vials and pre-filled syringes.

Our SteriDelta autoclaves are specially designed for terminal sterilization of liquids in closed containers as they are prepared to provide automatic differential pressure compensation based on product probes temperature measurements (T) so deformation and damage of the plastic containers is prevented.



# General construction features

## Durable Construction

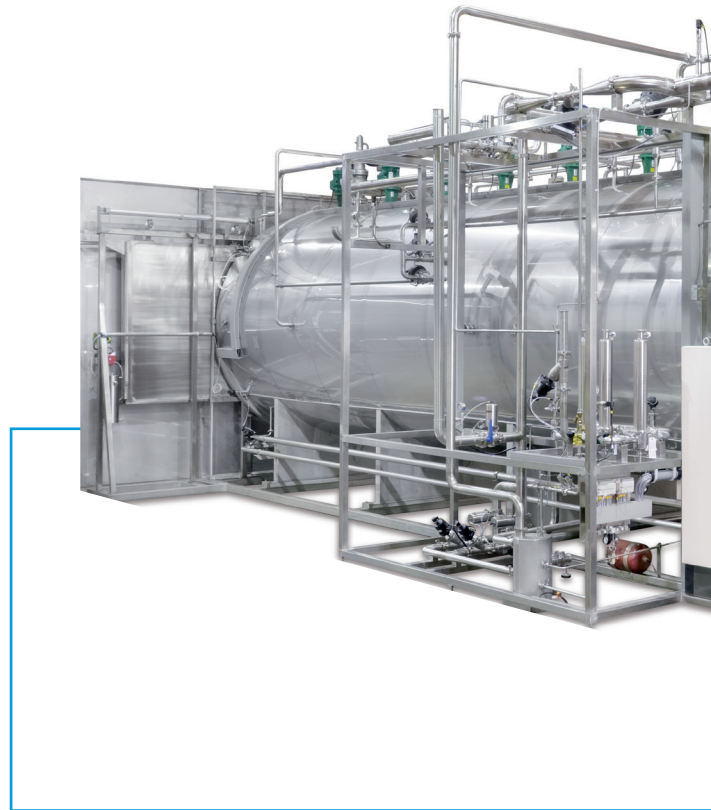
A cylindrical single-wall chamber with rectangular door/s both made entirely from AISI 316 L stainless steel providing highest corrosion resistances.

The doors are automated, typically of horizontal sliding motion, powered by pneumatic cylinders. Chamber is sealed by means of an O-ring silicone gasket, lodged inside a machined groove in the frame, which does not require lubrication.

## Hygienic Design

Chamber and door inner surfaces are mechanically polished to  $Ra \geq 0.64 \text{ }\mu\text{m}$  giving mirror appearance.

All components and pipe work parts such as valves, heat exchangers, pumps, filters, fittings, gaskets, etc. are supplied with quality certificates, according to current standards in sanitary installations and they are designed and installed for proper maintenance and long life cycles. I.e. pneumatic-operated valves, Tri-Clamp type connections and process tubing made of stainless steel AISI 316 L.





## Safety and Ergonomic Design for Users

The double door chambers incorporate the necessary interlocks and each door has precaution mechanisms to ensure maximum operator safety.

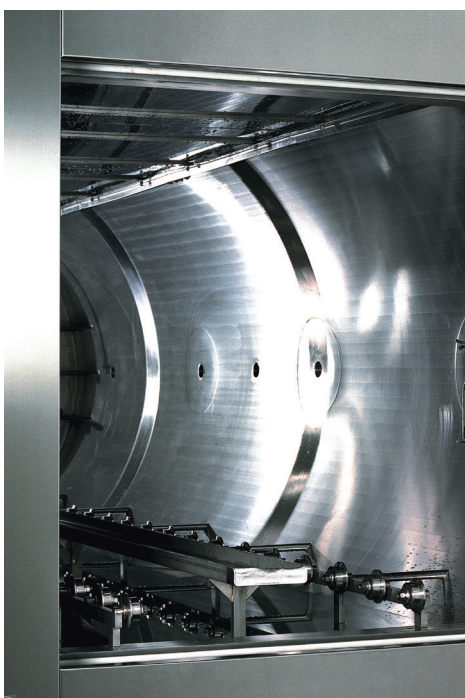
The technical area is designed for ergonomic maintenance, with enough access to components and ease replacement of spares without almost using tools. Potential hot piping is insulated with chloride free mineral wool within an external stainless steel AISI 304 sheet.

The loading and unloading handling operations can be done either manually or, when large and heavy loads have to be handled, by using automatic mechanisms. The automatic loading/unloading system consists of a bench located in front of the door, where the pallets are placed. The pallets are then introduced by a mechanical system below the bench. Another alternative for big and heavy loads is to install the unit in a pit, thus loading height is at floor level.

## Monitoring and Productivity

Venting is through a high efficiency filter, 0.22  $\mu$ m prepared for 'in situ' sterilization (SIP) and provided with the necessary connections to carry out the integrity test. This provides rapid start-up for production.

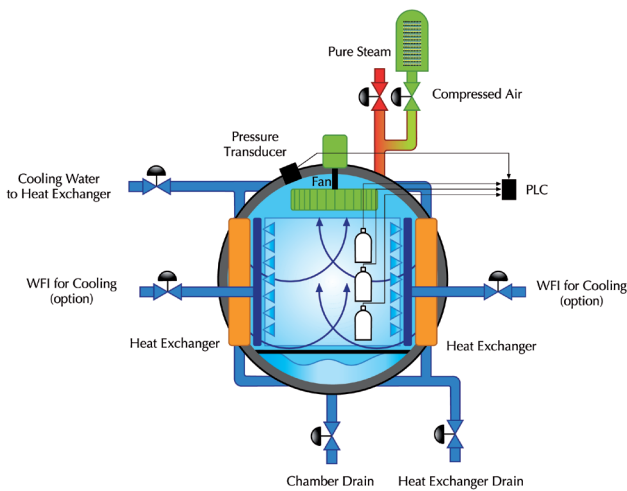
There are multiple temperature probes Pt-100, 1/3 DIN type, which are strategically placed in the chamber, mobiles or fixed.



# Types of autoclaves

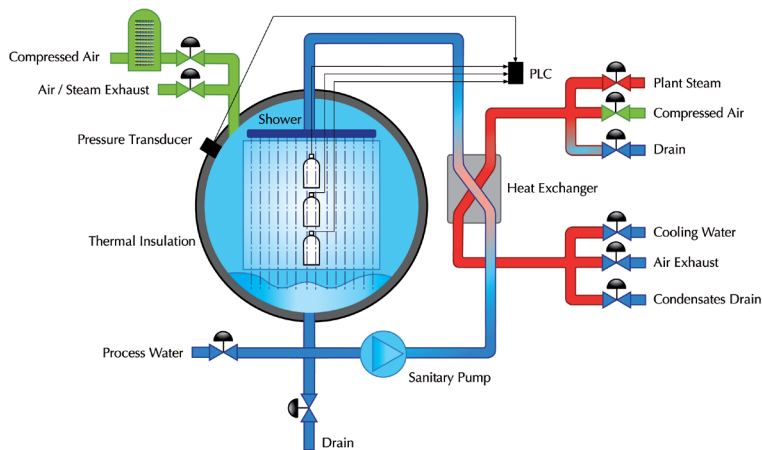
## SteriDelta A Air+Steam Mixture Autoclaves

These units are fitted with a ventilator system for mixing clean steam with air, which becomes the sterilization media. This process method should be recommended for complex plastic or glass containers such as pre-filled syringes or vials in which condensates may stagnant and be source of problems in the finish product. These autoclaves provide better drying finish thanks to the ventilator system and thus, products are downloaded ready for packing and labelling.



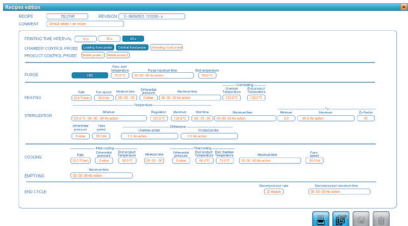
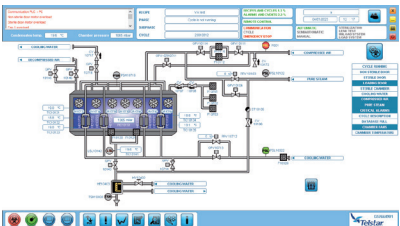
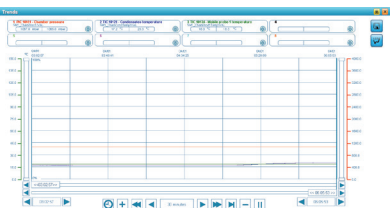
## SteriDelta W Superheated Water Rain Autoclaves

These units are fitted with a high flow recirculation system by a sanitary pump and heat exchanger that allows using (WFI) water as heat transfer media for heating up, sterilizing and cooling down the load. This process method provides faster cycles but containers come out damp. Anyhow, it is the preferred method in most cases due to its simplicity, economy and ease of validation.



# Control systems

The autoclave has a central control panel, which houses the PLC, signal conditioning units, safety circuits and general switchgear. The autoclave is fully managed through our SCADA system PharmaSter<sup>®</sup>. This control system includes an industrial PC with touch-sensitive colour display. The software allows not only for supervision and control of the process, but also compiling, storing and processing the whole information in a batch oriented mode. The system is fulfilling 21 CFR Part 11 guidelines.



# Technical data

Model		Systems available	Inner chamber dimension			Chamber diameter mm	Chamber capacity			Rack dimensions mm (WxHxL)	Approx. load capacity (bottles DIN 500 ml - Ø67 x H 200 mm) Units	Approx. load capacity bags 1.000 ml - 330 x 105 x 70 mm (Length x Width x Thickness) Units	Door sliding motion
			Width mm	Height mm	Depth mm		Total volume L	Useful volume L	No. of racks Units				
SD 101010	Single line	W/A	1000	1000	1000	1614	2046	1000	1	900*800*900	429	112	Horizontal
SD 101019	Single line	W/A	1000	1000	1900	1614	3887	1900	2	900*800*900	858	224	Horizontal
SD 101028	Single line	W/A	1000	1000	2800	1614	5729	2800	3	900*800*900	1287	336	Horizontal
SD 101037	Single line	W/A	1000	1000	3700	1614	7570	3700	4	900*800*900	1716	448	Horizontal
SD 121224	Single line	W/A	1250	1250	2400	1968	7300	3750	2	1150*1050*1150	1920	600	Horizontal
SD 121233	Single line	W/A	1250	1250	3550	1968	10799	5547	3	1150*1050*1150	2880	900	Horizontal
SD 121247	Single line	W/A	1250	1250	4700	1968	14297	7344	4	1150*1050*1150	3840	1200	Horizontal
SD 121258	Single line	W/A	1250	1250	5850	1968	17795	9141	5	1150*1050*1150	4800	1500	Horizontal
SD 121270	Single line	W/A	1250	1250	7000	1968	21293	10938	6	1150*1050*1150	5760	1800	Horizontal
SD 151541	Single line	W/A	1500	1500	4100	2322	17362	9225	4	1400*1300*1000	5200	1536	Horizontal
SD 151561	Single line	W/A	1500	1500	6100	2322	25831	13725	6	1400*1300*1000	7800	2304	Horizontal
SD 151581	Single line	W/A	1500	1500	8100	2322	34300	18225	8	1400*1300*1000	10400	3072	Horizontal
SD 1515101	Single line	W/A	1500	1500	10100	2322	42770	22725	10	1400*1300*1000	13000	3840	Horizontal
SD 1515121	Single line	W/A	1500	1500	12100	2322	51239	27225	12	1400*1300*1000	15600	4608	Horizontal
SD 1515141	Single line	W/A	1500	1500	14100	2322	59708	31725	14	1400*1300*1000	18200	5376	Horizontal
SD 191797	Double line	W	1950	1700	9700	2786	59132	32156	16	900*1500*1200	18720	5376	Horizontal
SD 1917121	Double line	W	1950	1700	12100	2786	73763	40112	20	900*1500*1200	23400	6720	Horizontal
SD 1917145	Double line	W	1950	1700	14500	2786	88393	48068	24	900*1500*1200	28080	8064	Horizontal

## Options and accessories

- Customised chambers according to existing loading accessories.
- Automatic loading/unloading system.
- Additional temperature probes.
- Additional channels in standard Chart recorder.
- Loading accessories: racks, pallets, trolleys, etc.



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Check for the nearest Telstar office at [www.telstar.com/international](http://www.telstar.com/international)

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