



SteriDelta

*Autoclaves with Cycles
in Counterpressure*

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).

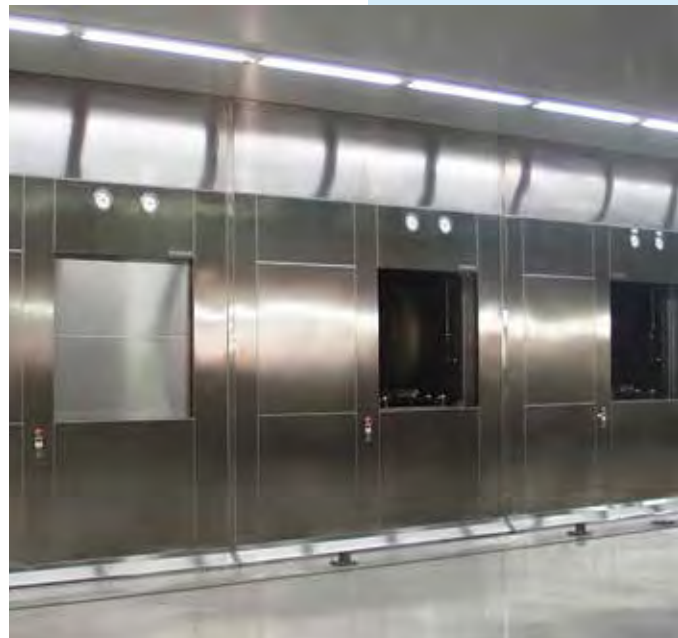


Terminal sterilization of liquids

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 ($\square T$) so deformation and damage of the plastic containers is prevented.



General construction features

Durable Construction

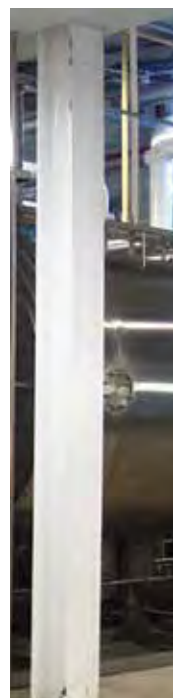
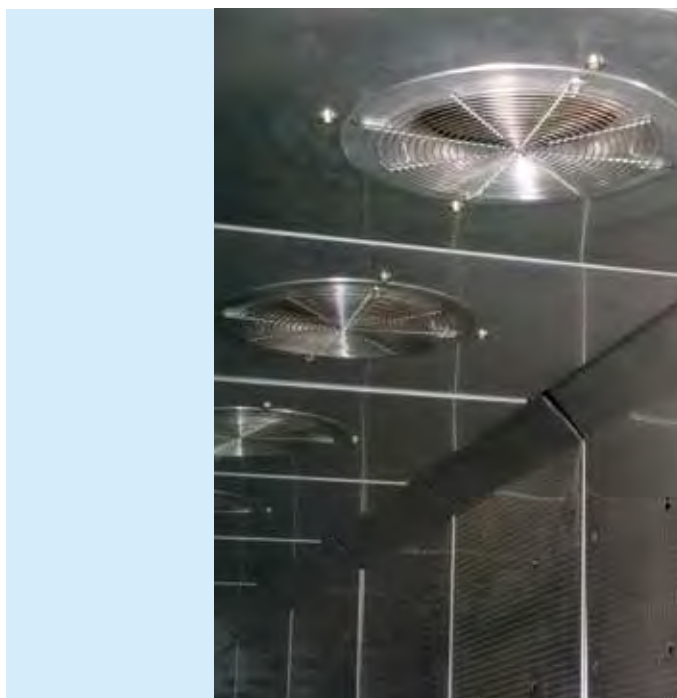
A cylindrical single-wall chamber with rectangular door/s both made entirely from AISI 316 L stainless steel providing highest corrosion resistances.

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 $Ra \leq 0.64 \mu m$ 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 μm 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.

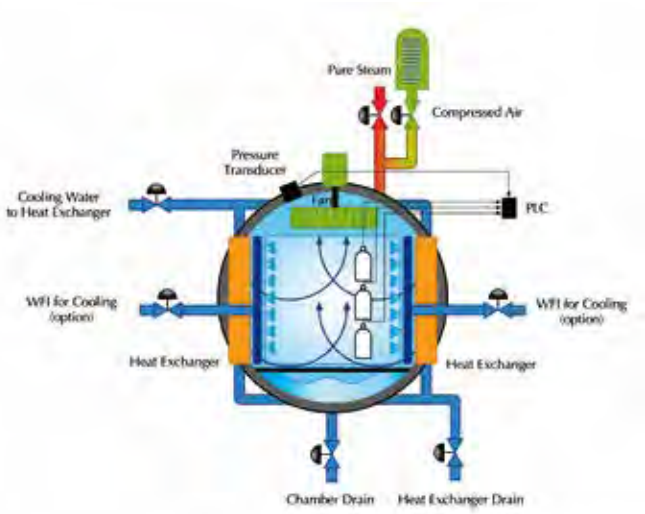
There are multiple temperature probes Pt-100, 1/3 DIN type, which are strategically placed in the chamber, mobiles or fixed.



Types of autoclaves

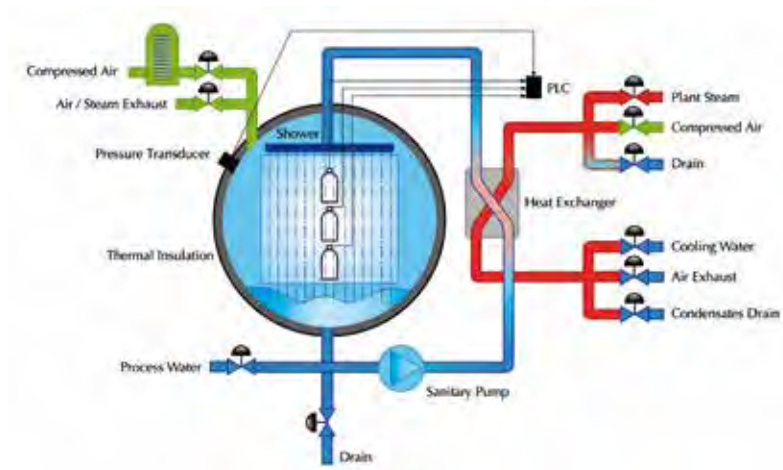
SteriDelta A Air+Steam Mixture Autoclaves

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®. 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	Inner chamber dimmensions			Chamber Diameter	Chamber capacity			Approx. load capacity (bottles DIN 500 ml - Ø88 x H 153 mm)	Door sliding motion
	Width	Height	Depth		Total Volume	Useful Volume	No. of rack units		
	mm	mm	mm		litres	litres			
SD 101010	1.000	1.000	1.000	1.614	2.067	1.000	1	396	horizontal
SD 101019	1.000	1.000	1.900	1.614	3.909	1.900	2	792	horizontal
SD 101028	1.000	1.000	2.800	1.614	5.771	2.800	3	1.188	horizontal
SD 101219	1.000	1.250	1.900	1.801	4.865	2.375	2	1.188	horizontal
SD 101228	1.000	1.250	2.800	1.801	7.182	3.500	3	1.782	horizontal
SD 101237	1.000	1.250	3700	1.801	9.500	4.625	4	2.376	horizontal
SD 121224	1.250	1.250	2.400	1.968	7.329	3.750	2	2.100	horizontal
SD 121235	1.250	1.250	3.550	1.968	10.857	5.547	3	3.150	horizontal
SD 121247	1.250	1.250	4.700	1.968	14.385	7.344	4	4.200	horizontal
SD 121258	1.250	1.250	5.850	1.968	17.912	9.141	5	5.250	horizontal
SD 121270	1.250	1.250	7.000	1.968	21.440	10.938	6	6.300	horizontal
SD 121535	1.250	1.500	3.550	2.139	16.993	6.656	3	3.675	horizontal
SD 121547	1.250	1.500	4.700	2.139	16.993	8.813	4	4.900	horizontal
SD 121558	1.250	1.500	5.850	2.139	21.161	10.969	5	6.125	horizontal
SD 121570	1.250	1.500	7.000	2.139	25.328	13.125	6	7.350	horizontal
SD 121581	1.250	1.500	8.150	2.139	29.496	15.281	7	8.575	horizontal

Note: Other chamber sizes are available. Please contact telstar@telstar.com for further information.

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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