



## **STERILIZATION**

cGMP Process Equipment for Pharmaceutical Production and Biotechnology



### Pharma division

**LAST Technology's** Pharma Division provides highest quality washing, disinfection, sterilization, depyrogenation, decontamination and containment equipment for the pharmaceutical industry.

The products are developed to ensure the prevention of infections and safe processing during the development and production of pharmaceuticals. Higher performances with lower consumptions, reduced footprint dimensions and full tailor-made machines to meet exactly our customers' needs. Innovative design and process reliability, together with customer orientation for user friendly solutions is what makes the difference in LAST Technology's products.



## **STERILIZATION**

cGMP Process Equipment for Pharmaceutical Production and Biotechnology

## Comply to

- Quality Management (ISO 9001:2015)
- Current Good Manufacturing Practice (cGMP)
- International Society for Pharmaceutical Engineering (ISPE Baseline Guides)
- US Food and drug Administration (FDA)
- Medicine and Healthcare Products Regulatory Agency (MHRA)
- Good Automated Manufacturing Practice (GAMP 5)
- Code of Federal Regulation Title 21 (FDA 21 CFR part 211 and 212)
- Code of Federal Regulation Title 21 (FDA 21 CFR part 11)
- Sterilization, Steam Sterilizers, Large Capacities (EN 285:2006+A2:2009)
- Pressure vessels standards
   (97/23/EC or ASME code Sec. VIII Div. 1 or Chinese GB 150)
- American Society of Mechanical Engineers: Bioprocessing Equipment (ASME-BPE)
- Safety Requirements for Electrical Equipment (IEC 61010-1:2010)
- Safety Requirements for Electrical Equipment (IEC 61010-2-040:2015)
- EMC Directive (IEC 61326-1:2013)
- Governing directives for affixing the CE mark machinery directive (2006/42/EC)
- Underwriters Laboratories (UL)
- Canadian Standards Association (CSA)
- Occupational Safety and Health Administration (OSHA)

## Range of Products















VHPIT VHP Isolation Technologies ...... pag. 26



## The perfect steam sterilization process





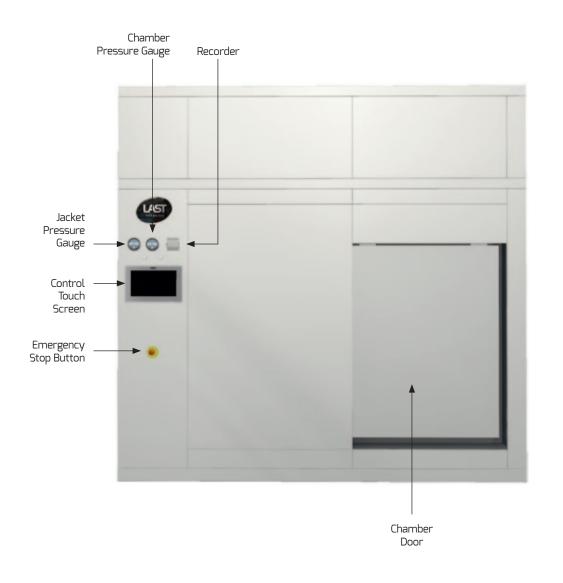


The Autoclaves type **RSA** are designed for sterilization by clean saturated steam of heat-resistant and moisture-stable materials such as metal parts, plastic and rubber components, liquids in sealed or vented containers, clothes, etc.

#### Process features

Pre-selected and custom made programs for any need. The machine process is developed by our Automation Department following the current codes/standards and type of product to be processed. Vacuum or Pressure leak test, Bowie & Dick test, Helix test, Filter sterilization and integrity test, Program for dry goods and porous loads, Program for liquids in vented containers, Program for liquids in sealed containers, Program for liquids in syringes, Program for high sensitive products (filters), Program for rubber stoppers, Decontamination cycle following BSL3 and BSL4, etc. The steam is injected into the chamber through a PID controlled valve and the condensate is continuously evacuated through the drain for guaranteeing an excellent distribution of the heat during all sterilization phase (temperature deviation below  $\pm\,0.4\,^{\circ}\text{C}$ ).

- Round or square or rectangular cross section chambers of double-wall type made of 316L or 316Ti stainless steel
- Jacket of dimple welded type made of 304 or 316L/316Ti stainless steel
- Piping completely made in 316L stainless steel with sanitary fittings (tri-clamp ferrules and hygienic flanges)
- Product contact surfaces mechanically polished to a degree of roughness below 0.35 micron (15 micro inches)
- Chamber doors of automatic vertical or side sliding type
- Chamber-door sealing by pneumatically pressurized gasket (by process air)
- Components and instruments made of 316L/316Ti stainless steel and FDA approved elastomer (21 CFR part 177)
- Chamber, doors, piping, components and instruments are properly insulated by an advanced type material
- Areas separation by means of bio-seal frame made of 304 or 316L/316Ti stainless steel
- Bio-seal flange for ducting to a VHP isolator
- Ergonomic product loading of manual or automatic type
- Floor or above the floor loading solution





Type RSA Regular Steam Autoclaves - doors of vertical or side sliding type

. 1 P	1105					_		
	Chamber	Dimensions (mn	ı - inches)	Capacity	Overall Dimensions (mm - inches)			
Туре	Width (a)	Height (b)	Lenght (c)	(litres / cu. ft.)	Width (d)	Height (e)	Lenght (f)	
RSA 150	350 / 14	700 / 27.5	680 / 27	150 / 5	1040 / 41	1900 / 75	1000 / 39	
RSA 250	350 / 14	700 / 27.5	980 / 38.5	250 / 9	1040 / 41	1900 / 75	1300 / 51	
RSA 300	650 / 25.5	700 / 27.5	680 / 27	300 / 10.5	1340 / 53	1900 / 75	1000 / 39	
RSA 450	650 / 25.5	700 / 27.5	980 / 38.5	450 / 16	1340 / 53	1900 / 75	1300 / 51	
RSA 550	650 / 25.5	700 / 27.5	1280 / 50.5	550 / 19	1100 / 43	1900 / 75	1600 / 63	
RSA 650	950 / 37.5	700 / 27.5	980 / 38.5	650 / 23	1640 / 64.5	1900 / 75	1300 / 51	
RSA 850	950 / 37.5	700 / 27.5	1280 / 50.5	850 / 33.5	1400 / 55	1900 / 75	1600 / 63	
RSA 1000	950 / 37.5	700 / 27.5	1580 / 62	1000 / 39.5	1400 / 55	1900 / 75	1900 / 75	
RSA 1250	950 / 37.5	700 / 27.5	1880 / 74	1250 / 49	1400 / 55	1900 / 75	2200 / 86.5	
RSA 1500	975 / 38	1400 / 55	1280 / 50.5	1500 / 52.5	2800 / 110	2200 / 86.5	1760 / 69.5	
RSA 2000	975 / 38	1400 / 55	1580 / 62	2000 / 70	2800 / 110	2200 / 86.5	2060 / 81	
RSA 2500	975 / 38	1400 / 55	2180 / 86	2500 / 87.5	2800 / 110	2200 / 86.5	2660 / 105	
RSA 2850	975 / 38	1900 / 75	1580 / 62	2850 / 100	2800 / 110	2800 / 110	2060 / 81	
RSA 3400	975 / 38	1900 / 75	1880 / 74	3400 / 119	2800 / 110	2800 / 110	2360 / 93	
RSA 4000	975 / 38	1900 / 75	2180 / 86	4000 / 140	2800 / 110	2800 / 110	2660 / 105	
RSA 5000	1250 / 49	2200 / 86.5	1880 / 74	5000 / 175	3450 / 136	3000 / 118	2360 / 93	
RSA 6000	1250 / 49	2200 / 86.5	2180 / 86	6000 / 210	3450 / 136	3000 / 118	2660 / 105	
RSA 6800	1250 / 49	2200 / 86.5	2480 / 98	6800 / 238	3450 / 136	3000 / 118	2960 / 116.5	







# The perfect terminal sterilization process



The Sterilizers type **TS-AS** & **TS-OW** are specifically designed for the Terminal Sterilization of liquids contained in sealed containers (plastic bags, glass bottles, BFS bottles, syringes, ampoules, etc.) as they are prepared to provide an automatic differential pressure compensation based on product probes (RTD) temperature measurement ( $\Delta$ T). This kind of control prevent the deformation, damaging and bad coloring of the plastic containers.

#### Process features

Pre-selected and custom made programs for any need.

The machine process is developed by our Automation Department following the current codes/standards and type of product to be processed. Two are the methods/ typology currently used:

#### Terminal Sterilization using Air + Steam Mixture, machine type TS-AS

These Sterilizers are fitted with an integrated 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. The system guarantees an excellent distribution of the heat during all sterilization phase (temperature deviation below  $\pm\,1^{\circ}\text{C}$ ). These autoclaves also provide better drying finish thanks to the ventilator system and thus, products are downloaded ready for packing and labeling.

#### Terminal Sterilization using Overheated Water, machine type TS-OW

These Sterilizers are fitted with a high flow recirculation system by a sanitary pump and heat exchanger of multi-tubes double-heads type that allows using (WFI or Demi) water as heat transfer media for heating up, sterilizing and cooling down the load. The system guarantees an excellent distribution of the heat during all sterilization phase (temperature deviation below  $\pm\,1\,^\circ\text{C}$ ). 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.

- Round cross section chambers of double-wall type made of 316L or 316Ti stainless steel (double wall available on machines type TS-AS only)
- Jacket of round/flat type made of 304 or 316L/316Ti stainless steel (available on machines type TS-AS only)
- Round or square or rectangular hatches/doors made of 316L or 316Ti stainless steel
- Piping completely made in 316L stainless steel with sanitary fittings (tri-clamp ferrules and hygienic flanges)
- Product contact surfaces mechanically polished to a degree of roughness below 0.35 micron (15 micro inches)
- Chamber doors of automatic vertical or side sliding type
- Chamber-door sealing by pneumatically pressurized gasket (by process air)
- Components and instruments made of 316L/316Ti stainless steel and FDA approved elastomer (21 CFR part 177)
- Chamber, doors, piping, components and instruments are properly insulated by an advanced type material
- Areas separation by means of bio-seal frame made of 304 or 316L/316Ti stainless steel
- Bio-seal flange for ducting to a VHP isolator
- Ergonomic product loading of manual or automatic type
- Floor or above the floor loading solution





Type TS Terminal sterilizers (air + steam mixture) - doors of vertical or side sliding type

								-		
Туре	Cha	mber Dimensi	ons (mm - inc	hes)	Useful	Overall Di	Overall Dimensions (mm - inches)			
	Diameter	Width (a)	Height (b)	Lenght (c)	Capacity (litres / cu. ft.)	Width (d)	Height (e)	Lenght (f)		
TS-AS 250	900 / 35.5	600 / 23.5	600 / 23.5	700 / 27.5	250 / 9	1100 / 43.5	1900 / 75	1050 / 41.5		
TS-AS 500	900 / 35.5	600 / 23.5	600 / 23.5	1400 / 55	500 / 17.5	1100 / 43.5	1900 / 75	1750 / 69		
TS-AS 1000	1200 / 47	800 / 31.5	800 / 31.5	1600 / 63	1000 / 35.5	2200 / 86.5	2300 / 90.5	1950 / 77		
TS-AS 2000	1200 / 47	800 / 31.5	800 / 31.5	3100 / 122	2000 / 70.5	2200 / 86.5	2300 / 90.5	3450 / 136		
TS-AS 3000	1600 / 63	1000 / 39	1000 / 39	3000 / 118	3000 / 106	2400 / 94.5	2500 / 98.5	3350 / 132		
TS-AS 4000	1600 / 63	1000 / 39	1000 / 39	4000 / 157.5	4000 / 141	2400 / 94.5	2500 / 98.5	4350 / 171		
TS-AS 5000	1600 / 63	1000 / 39	1000 / 39	5000 / 197	5000 / 176.5	2400 / 94.5	2500 / 98.5	5350 / 210.5		
TS-AS 6000	2000 / 79	1250 / 49	1600 / 63	3000 / 118	6000 / 212	3000 / 118	3000 / 118	3350 / 132		
TS-AS 7000	2000 / 79	1250 / 49	1600 / 63	3500 / 138	7000 / 247	3000 / 118	3000 / 118	3850 / 151.5		
TS-AS 8000	2000 / 79	1250 / 49	1600 / 63	4000 / 157.5	8000 / 282.5	3000 / 118	3000 / 118	4350 / 171		
TS-AS 9000	2000 / 79	1250 / 49	1600 / 63	4500 / 177	9000 / 318	3000 / 118	3000 / 118	4850 / 191		
TS-AS 10000	2000 / 79	1250 / 49	1600 / 63	5000 / 197	10000 / 353	3000 / 118	3000 / 118	5350 / 210.5		
TS-AS 11000	2000 / 79	1250 / 49	1600 / 63	5500 / 216.5	11000 / 388.5	3000 / 118	3000 / 118	5850 / 230		
TS-AS 12000	2000 / 79	1250 / 49	1600 / 63	6000 / 236	12000 / 424	3000 / 118	3000 / 118	6350 / 250		
TS-AS 12000	2000 / 79	1250 / 49	1600 / 63	6000 / 236	12000 / 424	3000 / 118	3000 / 118	6350 / 250		

Type TS Terminal sterilizers (over heated water) - doors of vertical or side sliding type

Туре	Cha	mber Dimensi	ons (mm - inc	hes)	Useful	Overall Dimensions (mm - inche			
	Diameter	Width (a)	Height (b)	Lenght (c)	Capacity (litres / cu. ft.)	Width (d)	Height (e)	Lenght (f)	
TS-0W 250	900 / 35.5	600 / 23.5	600 / 23.5	700 / 27.5	250 / 9	1100 / 43.5	1900 / 75	1050 / 41.5	
TS-OW 500	900 / 35.5	600 / 23.5	600 / 23.5	1400 / 55	500 / 17.5	1100 / 43.5	1900 / 75	1750 / 69	
TS-OW 1000	1200 / 47	800 / 31.5	800 / 31.5	1600 / 63	1000 / 35.5	2200 / 86.5	2300 / 90.5	1950 / 77	
TS-OW 2000	1200 / 47	800 / 31.5	800 / 31.5	3100 / 122	2000 / 70.5	2200 / 86.5	2300 / 90.5	3450 / 136	
TS-OW 3000	1600 / 63	1000 / 39	1000 / 39	3000 / 118	3000 / 106	2400 / 94.5	2500 / 98.5	3350 / 132	
TS-OW 4000	1600 / 63	1000 / 39	1000 / 39	4000 / 157.5	4000 / 141	2400 / 94.5	2500 / 98.5	4350 / 171	
TS-OW 5000	1600 / 63	1000 / 39	1000 / 39	5000 / 197	5000 / 176.5	2400 / 94.5	2500 / 98.5	5350 / 210.5	
TS-OW 6000	2000 / 79	1250 / 49	1600 / 63	3000 / 118	6000 / 212	3000 / 118	3000 / 118	3350 / 132	
TS-OW 7000	2000 / 79	1250 / 49	1600 / 63	3500 / 138	7000 / 247	3000 / 118	3000 / 118	3850 / 151.5	
TS-OW 8000	2000 / 79	1250 / 49	1600 / 63	4000 / 157.5	8000 / 282.5	3000 / 118	3000 / 118	4350 / 171	
TS-OW 9000	2000 / 79	1250 / 49	1600 / 63	4500 / 177	9000 / 318	3000 / 118	3000 / 118	4850 / 191	
TS-OW 10000	2000 / 79	1250 / 49	1600 / 63	5000 / 197	10000 / 353	3000 / 118	3000 / 118	5350 / 210.5	
TS-0W 11000	2000 / 79	1250 / 49	1600 / 63	5500 / 216.5	11000 / 388.5	3000 / 118	3000 / 118	5850 / 230	
TS-0W 12000	2000 / 79	1250 / 49	1600 / 63	6000 / 236	12000 / 424	3000 / 118	3000 / 118	6350 / 250	





# The perfect low temperature sterilization

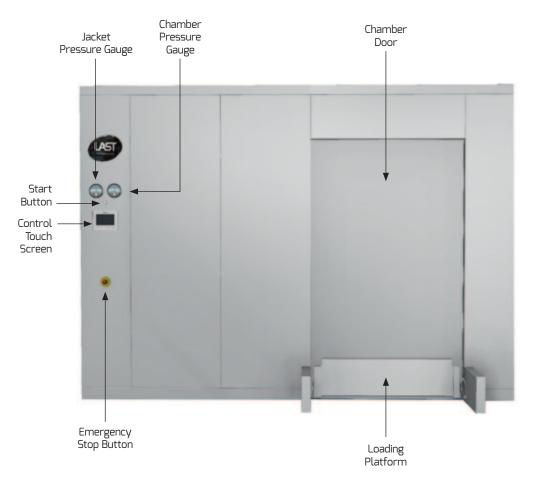


The Sterilizers type **ETO** are designed for the sterilization by Ethylene Oxide of heat sensitive products such as plastic syringes, perfusion sets, dialysis cartridges, heat sensitive rubber products and special surgical instruments.

### Process features

Pre-selected and custom-made programs for any need. The machine process is developed by our Automation Department following the current codes/standards and type of product to be processed. Vacuum or Pressure leak test, Program for conditioning of products, Program for sterilization in pressure, Program for sterilization in vacuum, Program for degassing of product, Program for gas neutralization, etc. The ETO is injected into the chamber through a PID controlled valve at a temperature of approx.  $60^\circ$  C and the condensate is continuously evacuated through the drain for guaranteeing an excellent distribution of the heat during all sterilization phase (temperature deviation below  $\pm\,1^\circ$ C).

- Rectangular cross section chambers of double-wall type made of 316L or 316Ti stainless steel
- Jacket of dimple welded type made of 304 or 316L/316Ti stainless steel
- Piping completely made in 316L stainless steel with sanitary fittings (tri-clamp ferrules and hygienic flanges)
- Product contact surfaces mechanically polished to a degree of roughness below 0.35 micron (15 micro inches)
- Chamber doors of automatic side sliding type
- Chamber-door sealing by pneumatically pressurized gasket (by process air)
- Components and instruments made of 316L/316Ti stainless steel and FDA approved elastomer (21 CFR part 177)
- An advanced type material properly insulates chamber, doors, piping, components and instruments
- Built-in steam generator
- Built-in vacuum pump with closed water loop (water saving system)
- Built-in ETO gas evaporator system
- Built-in devices for product conditioning, sterilization and degassing
- Ergonomic product loading of manual or automatic type
- Gas neutralization system by Thermal Combustor or Scrubber
- Floor or above the floor loading solution





**Type ETO** Ethylene Oxide Sterilizers - doors of side sliding type

•				<i>J</i> /;			
Chamber Dimensions (mm - inches)			Canadity	Quantity of	Overall Dimensions (mm - inches)		
Width (a)	Height (b)	Lenght (c)	(litres / cu. ft.)	Euro pallet per load	Width (d)	Height (e)	Lenght (f)
975 / 38	1400 / 55	1580 / 62	2000 / 70	1	2800 / 110	2200 / 86.5	2060 / 81
975 / 38	1400 / 55	2480 / 98	3300 / 115.5	2	2800 / 110	2200 / 86.5	2960 / 116.5
975 / 38	1900 / 75	3680 / 145	6800 / 238	3	2800 / 110	2800 / 110	4160 / 164
975 / 38	1900 / 75	4880 / 192	9000 / 315	4	2800 / 110	2800 / 110	5360 / 211
1250 / 49	2200 / 86.5	4280 / 168.5	11000 / 385	5	3450 / 136	3000 / 118	4760 / 187.5
1250 / 49	2200 / 86.5	4880 / 192	13000 / 455	6	3450 / 136	3000 / 118	5360 / 211
1250 / 49	2200 / 86.5	5780 / 227.5	15000 / 525	7	3450 / 136	3000 / 118	6260 / 246.5
1250 / 49	2200 / 86.5	6680 / 263	18000 / 630	8	3450 / 136	3000 / 118	7160 / 282
1250 / 49	2200 / 86.5	7280 / 286.5	20000 / 700	9	3450 / 136	3000 / 118	7760 / 305.5
1250 / 49	2200 / 86.5	8180 / 322	22500 / 787.5	10	3450 / 136	3000 / 118	8660 / 341
1250 / 49	2200 / 86.5	9080 / 357.5	25000 / 875	11	3450 / 136	3000 / 118	9560 / 376.5
1250 / 49	2200 / 86.5	9680 / 381	26500 / 927.5	12	3450 / 136	3000 / 118	10160 / 400
	Width (a)  975 / 38  975 / 38  975 / 38  975 / 38  975 / 38  1250 / 49  1250 / 49  1250 / 49  1250 / 49  1250 / 49  1250 / 49	Width (a) Height (b) 975 / 38 1400 / 55 975 / 38 1400 / 55 975 / 38 1900 / 75 975 / 38 1900 / 75 1250 / 49 2200 / 86.5 1250 / 49 2200 / 86.5 1250 / 49 2200 / 86.5 1250 / 49 2200 / 86.5 1250 / 49 2200 / 86.5 1250 / 49 2200 / 86.5 1250 / 49 2200 / 86.5 1250 / 49 2200 / 86.5 1250 / 49 2200 / 86.5 1250 / 49 2200 / 86.5 1250 / 49 2200 / 86.5	Width (a)  Height (b)  975 / 38  1400 / 55  1580 / 62  975 / 38  1400 / 55  2480 / 98  975 / 38  1900 / 75  3680 / 145  975 / 38  1900 / 75  4880 / 192  1250 / 49  2200 / 86.5  4280 / 168.5  1250 / 49  2200 / 86.5  4880 / 192  1250 / 49  2200 / 86.5  5780 / 227.5  1250 / 49  2200 / 86.5  7280 / 286.5  1250 / 49  2200 / 86.5  8180 / 322  1250 / 49  2200 / 86.5  9080 / 357.5	Width (a)         Height (b)         Lenght (c)         Capacity (litres / cu. ft.)           975 / 38         1400 / 55         1580 / 62         2000 / 70           975 / 38         1400 / 55         2480 / 98         3300 / 115.5           975 / 38         1900 / 75         3680 / 145         6800 / 238           975 / 38         1900 / 75         4880 / 192         9000 / 315           1250 / 49         2200 / 86.5         4280 / 168.5         11000 / 385           1250 / 49         2200 / 86.5         4880 / 192         13000 / 455           1250 / 49         2200 / 86.5         5780 / 227.5         15000 / 525           1250 / 49         2200 / 86.5         6680 / 263         18000 / 630           1250 / 49         2200 / 86.5         7280 / 286.5         20000 / 700           1250 / 49         2200 / 86.5         8180 / 322         22500 / 787.5           1250 / 49         2200 / 86.5         9080 / 357.5         25000 / 875	Chamber Dimensions (mm - inches)         Capacity (litres / cu. ft.)         Quantity of Euro pallet per load           975 / 38         1400 / 55         1580 / 62         2000 / 70         1           975 / 38         1400 / 55         2480 / 98         3300 / 115.5         2           975 / 38         1900 / 75         3680 / 145         6800 / 238         3           975 / 38         1900 / 75         4880 / 192         9000 / 315         4           1250 / 49         2200 / 86.5         4280 / 168.5         11000 / 385         5           1250 / 49         2200 / 86.5         4880 / 192         13000 / 455         6           1250 / 49         2200 / 86.5         5780 / 227.5         15000 / 525         7           1250 / 49         2200 / 86.5         6680 / 263         18000 / 630         8           1250 / 49         2200 / 86.5         7280 / 286.5         20000 / 700         9           1250 / 49         2200 / 86.5         8180 / 322         22500 / 787.5         10           1250 / 49         2200 / 86.5         9080 / 357.5         25000 / 875         11	Width (a)         Height (b)         Lenght (c)         Capacity (litres / cu. ft.)         Quantity of Euro pallet per load         Width (d)           975 / 38         1400 / 55         1580 / 62         2000 / 70         1         2800 / 110           975 / 38         1400 / 55         2480 / 98         3300 / 115.5         2         2800 / 110           975 / 38         1900 / 75         3680 / 145         6800 / 238         3         2800 / 110           975 / 38         1900 / 75         4880 / 192         9000 / 315         4         2800 / 110           975 / 38         1900 / 75         4880 / 192         9000 / 315         4         2800 / 110           1250 / 49         2200 / 86.5         4280 / 168.5         11000 / 385         5         3450 / 136           1250 / 49         2200 / 86.5         4880 / 192         13000 / 455         6         3450 / 136           1250 / 49         2200 / 86.5         5780 / 227.5         15000 / 525         7         3450 / 136           1250 / 49         2200 / 86.5         7280 / 286.5         20000 / 700         9         3450 / 136           1250 / 49         2200 / 86.5         8180 / 322         22500 / 787.5         10         3450 / 136           1250 / 49	Chamber Dimensions (mm - inches)         Capacity (litres / cu. ft.)         Quantity of Euro pallet per load         Width (d)         Width (e)           975 / 38         1400 / 55         1580 / 62         2000 / 70         1         2800 / 110         2200 / 86.5           975 / 38         1400 / 55         2480 / 98         3300 / 115.5         2         2800 / 110         2200 / 86.5           975 / 38         1900 / 75         3680 / 145         6800 / 238         3         2800 / 110         2800 / 110           975 / 38         1900 / 75         4880 / 192         9000 / 315         4         2800 / 110         2800 / 110           1250 / 49         2200 / 86.5         4280 / 168.5         11000 / 385         5         3450 / 136         3000 / 118           1250 / 49         2200 / 86.5         4880 / 192         13000 / 455         6         3450 / 136         3000 / 118           1250 / 49         2200 / 86.5         5780 / 227.5         15000 / 525         7         3450 / 136         3000 / 118           1250 / 49         2200 / 86.5         6680 / 263         18000 / 630         8         3450 / 136         3000 / 118           1250 / 49         2200 / 86.5         7280 / 286.5         20000 / 700         9         3450 / 136 <t< td=""></t<>





# The perfect depyrogenation process





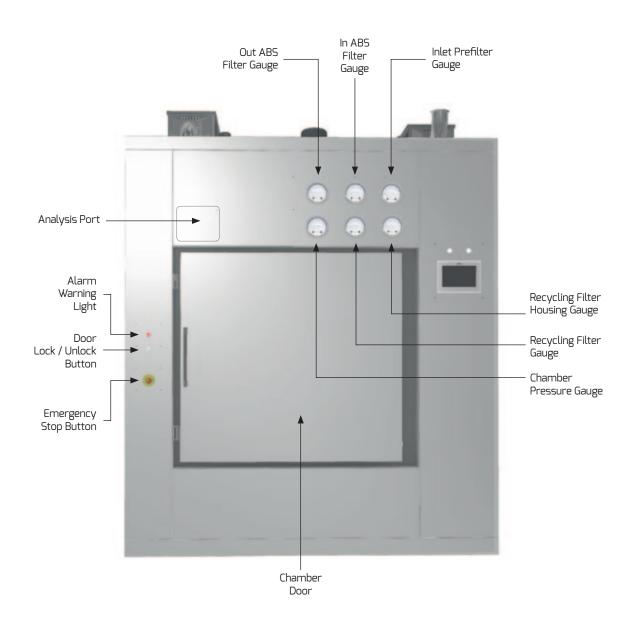


The Dry Heat Sterilizers type **DHS** are designed for sterilization and depyrogenation by hot air in Class 100 (ISO 5) of empty glass containers such as vials, ampoules, bottles and stainless steel parts. The inactivation and destroying of micro-organisms is by means of dry heat at 260  $^{\circ}$ C maintained for a controlled period of time.

#### Process features

Pre-selected and custom made programs for any need. The machine process is developed by our Automation Department following the current codes/standards and type of product to be processed. The Dry Heat Sterilizers type DHS are designed to be ISO 14664-1 comply (formal Class 100 for US Federal Standard 209 E) up to a temperature of 260 °C. The Class 100 is guaranteed during the entire cycle (heating, sterilizing/depyrogenation and cooling phases).

- Square or rectangular cross section chambers of single-wall type made of 316L or 316Ti stainless steel
- Chamber bottom-jacketed with 316L or 316Ti stainless steel plate
- Piping and air duct's are completely made of 316L stainless steel with sanitary fittings (tri-clamp ferrules and hygienic flanges)
- Product contact surfaces mechanically polished to a degree of roughness below 0.35 micron (15 micro inches)
- Chamber doors of manual hinged or automatic side sliding type
- Chamber-door sealing by double lips silicone gasket
- Components and instruments made of 316L/316Ti stainless steel and FDA approved elastomer (21 CFR part 177)
- Chamber, doors, piping, components and instruments are properly insulated by an advanced type material
- HEPÁ 14 filtration on air intake, air recycling and air exhoust
- Areas separation by means of bio-seal frame made of 304 or 316L/316Ti stainless steel
- Bio-seal flange for ducting to a VHP isolator
- Ergonomic product loading of manual or automatic type
- Floor or above the floor loading solution





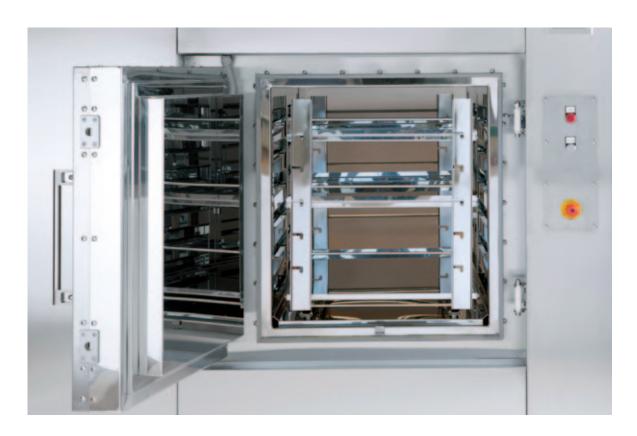


Type DHS Dry Heat Sterilizers - doors of hinged or side sliding type

Туре	Chamber Dimensions (mm - inches)			Capacity	Overall Dimensions (mm - inches)			
	Width (a)	Height (b)	Lenght (c)	(litres / cu. ft.)	Width (d)	Height (e)	Lenght (f)	
DHS 300	650 / 25.5	730 / 32.5	715 / 28	300 / 10.5	1625 / 64	2000 / 79	1135 / 44.5	
DHS 600	650 / 25.5	730 / 32.5	1345 / 53	600 / 21	1625 / 64	2000 / 79	1765 / 70	
DHS 1000	1050 / 41	730 / 32.5	1345 / 53	1000 / 35	2025 / 80	2000 / 79	1765 / 70	
DHS 1500	1050 / 41	1075 / 42	1345 / 53	1500 / 53	2145 / 84.5	2405 / 94.5	1765 / 70	
DHS 2000	1050 / 41	1375 / 54	1345 / 53	2000 / 70.5	2145 / 84.5	2705 / 106.5	1765 / 70	
DHS 2500	1050 / 41	1375 / 54	1675 / 66	2500 / 88	2225 / 88	2495 / 98	2095 / 82.5	
DHS 3000	1050 / 41	1375 / 54	1975 / 78	3000 / 106	2225 / 88	2495 / 98	2395 / 94	
DHS 3500	1050 / 41	1720 / 68	1975 / 78	3500 / 123.5	2225 / 88	2840 / 112	2395 / 94	
DHS 4000	1200 / 47	1720 / 68	1975 / 78	4000 / 141	2375 / 93.5	2840 / 112	2395 / 94	



The perfect tray drying process





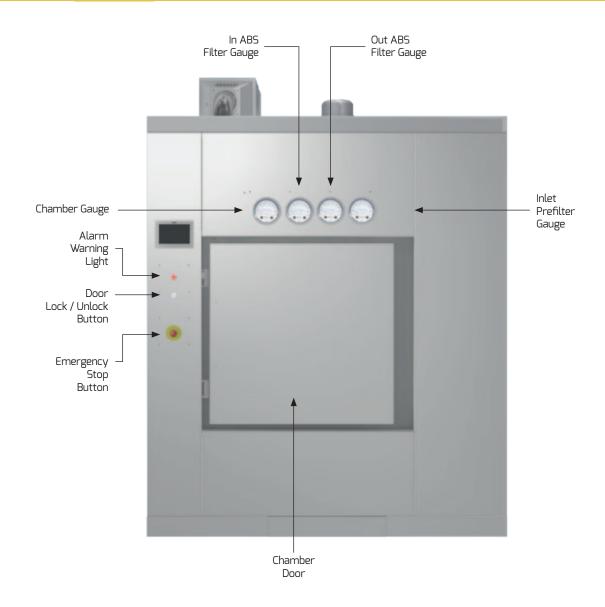


The Tray Dryers type  ${\bf TD}$  are designed for the hot air drying of hard goods, powders and granulates. The drying process is by means of dry heat at 50-150 °C maintained for a controlled period of time.

#### Process features

Pre-selected and custom-made programs for any need. The machine process is developed by our Automation Department following the current codes/standards and type of products to be processed. The Tray Dryers type TD are designed to dry any kind of solid products up to an exposure temperature of 150 °C. LAST is proving the high level performances reached by the Dryer during the FAT by keeping monitored the humidity contains of the product. The system also guarantees an excellent distribution of the heat during all drying phase (temperature deviation below ± 2 °C).

- Rectangular cross section chambers of single-wall type made of 316L or 316Ti stainless steel
- Chamber bottom-jacketed with 316L or 316Ti stainless steel plate
- Piping and air ducts are completely made of 316L stainless steel with sanitary fittings (tri-clamp ferrules and hygienic flanges)
- Product contact surfaces mechanically polished to a degree of roughness below 0.35 micron (15 micro inches)
- Chamber doors of manual hinged or automatic side sliding type
- Chamber-door sealing by double lips silicone gasket
- Components and instruments made of 316L/316Ti stainless steel and FDA approved elastomer (21 CFR part 177)
- An advanced type material properly insulates chamber, doors, piping, components and instruments
- HEPA H 14 filtration on air intake and air exhaust
- Areas separation by means of bio-seal frame made of 304 or 316L/316Ti stainless steel
- Temperature, Pressure and Humidity control over the entire cycle
- Ergonomic product loading of manual or automatic type
- Floor or above the floor loading solution







Type TD Tray Dryers - doors of hinged or side sliding type

Туре	Chamber	Dimensions (mm	ı - inches)	Canadity	Overall Dimensions (mm - inches)			
	Width (a)	Height (b)	Lenght (c)	Capacity (litres / cu. ft.)	Width (d)	Height (e)	Lenght (f)	
TD 300	650 / 25.5	730 / 32.5	715 / 28	300 / 10.5	1500 / 59	2000 / 79	1135 / 44.5	
TD 600	650 / 25.5	730 / 32.5	1345 / 53	600 / 21	1500 / 59	2000 / 79	1765 / 70	
TD 1000	1050 / 41	730 / 32.5	1345 / 53	1000 / 35	1900 / 75	2000 / 79	1765 / 70	
TD 1500	1050 / 41	1075 / 42	1345 / 53	1500 / 53	2020 / 80	2405 / 94.5	1765 / 70	
TD 2000	1050 / 41	1375 / 54	1345 / 53	2000 / 70.5	2020 / 80	2705 / 106.5	1765 / 70	
TD 2500	1050 / 41	1375 / 54	1675 / 66	2500 / 88	2100 / 83	2495 / 98	2095 / 82.5	
TD 3000	1050 / 41	1375 / 54	1975 / 78	3000 / 106	2100 / 83	2495 / 98	2395 / 94	
TD 3500	1050 / 41	1720 / 68	1975 / 78	3500 / 123.5	2100 / 83	2840 / 112	2395 / 94	
TD 4000	1200 / 47	1720 / 68	1975 / 78	4000 / 141	2250 / 86	2840 / 112	2395 / 94	





The perfect clean steam generation



Type CSG Clean Steam Generators - stand alone type electrical or steam to steam

Туре	Productivity	Droductivity	Overall Dimensions (mm				
	(kg/h / Lbs/h)	(Bar / PSI)	Width (a)	Height (b)	Lenght (c)		
CSG 50	50 / 110	3 / 43.5	500 / 19.5	1400 / 55	600 / 23.5		
CSG 100	100 / 220	3 / 43.5	500 / 19.5	1400 / 55	800 / 31.5		
CSG 150	150 / 330	3 / 43.5	800 / 31.5	1400 / 55	1000 / 39.5		
CSG 250	250 / 550	3 / 43.5	800 / 31.5	1400 / 55	1200 / 47		
CSG 350	350 / 770	3 / 43.5	800 / 31.5	1400 / 55	1400 / 55		

The Generators type  $\pmb{\mathsf{CSG}}$  are designed for the production of clean steam used in the process machines.

#### Process features

Process of steam generation by means of an heat exchange between clean water – heating element. The heating system can be of two types: electrical or steam to steam. On the electrical system the heating elements are directly immerged into the water (this system is also called "direct heating"). While for the steam to steam version the heating media is running inside the coils (this system is called "indirect heating"). Both system can be equipped with a cartridge 0.2  $\mu$ m filter and a water separation unit to guarantee the cleaning and saturation (free of condensate) of the generated clean steam.

- Round cross section chambers of single-wall type made of 316L or 316Ti stainless steel
- Double head flange made of 316L or 316Ti stainless steel (easy cleaning of internal surfaces)
- Heating elements made of Incoloy material (electrical version) or made of 316L or 316Ti stainless steel coil (steam to steam version)
- Piping completely made in 316L stainless steel with sanitary fittings (tri-clamp ferrules and hygienic flanges)
- Clean Steam contact surfaces mechanically polished to a degree of roughness below 0.35 micron (15 micro inches)
- Components and instruments made of 316L/316Ti stainless steel and FDA approved elastomer (21 CFR part 177)
- Chamber, heads, piping, components and instruments are properly insulated by an advanced type material
- Generator of built-in type (into the technical area of the process machine) or in standalone version with its own skid made of 304 or 316L/316Ti stainless steel.

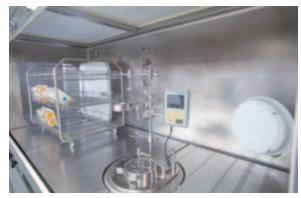


## The perfect containment & sterility test process









The Barrier Isolators type **VHPIT** are designed in order to grant the sterile handling and transfer of products throughout the Process Equipments.

#### Process features

Pre-selected and custom made programs for any need. The process of sterilization/ decontamination by Vaporized Hydrogen Peroxide (VHP) is developed by our Automation Department following the current codes/standards. Low temperature process for bio-decontamination of small and sealed enclosures such as isolators, biological safety cabinets, and small pass-through chambers used in research, biological safety, and production applications. The output of VHP is between 1 to 12 grams/min by a dedicated cartridge. The device is provided with a desiccant system which is regenerated separately from the unit.

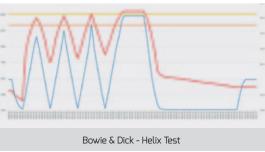
- Range from 50 to 2000 liters volume.
- Single chamber design providing defined barrier between the process and surrounding environment.
- Chamber completely made of 316L or 316Ti stainless steel.
- Piping and air ducts completely made in 316L stainless steel with sanitary fittings (tri-clamp ferrules and hygienic flanges).
- Respect of 3D dead legs on all piping, system and 3 degree piping slopping to the floor drain.
- Product contact surfaces mechanically polished to a degree of roughness below 0.35 micron (15 micro inches).
- Full access to components installed inside the isolator.
- Inclined front panel to aid operator access
- Large areas of glazing to provide maximum viewing of all process operations.
- Gloves arrangement to assure best operator access and operations within the working chamber.
- Positive pressure regime between enclosure and surrounding environment to ensure all potential contamination for sterile process is kept outside.
- ${\mbox{\small \bullet}}$  The isolator is designed to be sterilized with Vapour Hydrogen Peroxide (VHP  ${\mbox{\small +}}$  H2O2).
- The generator of VHP can be of integrated (built-in the skid of the ventilator system) or stand alone type.
- One cut out IS present on the bottom of the isolator shell for the installation of a Rapid Transfer Port (RTP).

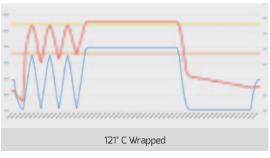


## **STERILIZATION**

cGMP Process Equipment for Pharmaceutical Production and Biotechnology







T-Chamber (°C)T-Jacket (°C)P-Chamber (bar)P-Jacket (bar)

# Supervision, Traceability and Control System Machines automated by a Programmable Logic Controllers (PLC) which

Machines automated by a Programmable Logic Controllers (PLC) which guarantee high level reliability. The Human Machine Interface (HMI) is guaranteed by a touch screen Operating Panel (OP). A PID based control manage all machine parameters, recipes, settings, sequence of operations, and their storage. The brand commonly used for hardware and software are Siemens, Allen Bradley and Asem.

#### Remote Control

All machines are equipped with a software for a remote control. The application can be installed in any iOS and Android devices. The system allows the remote control of the machines via wireless connection. Operators do not need any longer to be in the same room of the machine to control the progress of the cycle, they will get a notification for any problem with the machine. Multiple number of machines can be controlled through this simple APP from a single source (device).

## FDA 21 CFR Part 11 compliant

**LAST** provides the right answer to the issue of compliance to the 21 CFR Part 11 by the installation of a Supervisory Control and Data Acquisition (SCADA) system. The software is developed and engineered following the Good Automated Manufacturing Practices (GAMP 5). The hardware can be installed "integrated" in the fascia panel of the machine or in a standalone version (remote solution).



## **STERILIZATION**

cGMP Process Equipment for Pharmaceutical Production and Biotechnology





## Product Handling System

- Possibility to choose between manual or full automatic product loading systems, both developed in order to ensure the highest ergonomic standards considering the height and weight of the loads.
- The cart system is of multi-level type according to products that need to be processed.
- Transport trolleys for the movement of the carts can be of fixed or variable height.
- An automatic feed-in and feed-out system can be provided to make the movement of heavy loads/carts easier.
- External conveyor application for pallet insertion and extraction.
- Highly technological integrated solutions with possibility to move the loads automatically thanks to robot installations







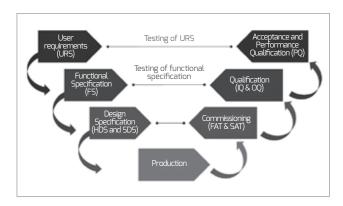
## Sustainability

Concentrating on environmental sustainability as a differentiation feature of the company is an informed decision of LAST, which is in fact convinced and conscious that the attention towards environmental issues can lead to substantial economic benefits in the medium-long term.

The company's decision to invest in human capital highly qualified in the technical-engineering field, and in research projects to develop new equipment and improve their performance in energy and water consumption terms, embodies LAST's idea of being green and considering the environment as an opportunity to grow.

## GAMP 5 / V-Model

Sequential approach for system validation.



### Activities, Services and Documentation

From the User Requirement Specification (URS) to the machine Qualification, LAST provides extensive documentation and services for supporting all steps of the project as per the internal operating procedures and flow diagram:

- Analysis of URS and reexamination of feasibility
- Project Plan (Gantt)
- Quality Plan (QP)
- Document Qualification (DQ) including P&ID, lay out drawing (GAD), Utility Interface Agreement (UIA), Software Interface Agreement (SIA), Electrical Diagram (ED), Pneumatic Diagram (PD), Bill of materials/ components (BOM), Functional Design Specification (FDS), Software Design Specification (SDS), Hardware Design Specification (HDS), Installation, User and Maintenance Manual (IUMM), Welding Validation Manual (WVM), Machine and software Validation Manual (MSVM).
- Factory Acceptance Test (FAT)
- Site Acceptance Test (SAT)
- Machine positioning, Installation and Start up
- Installation, operation and performance qualification (IQ, OQ & PQ)
- Training courses
- Program of preventive maintenance
- Spare parts and consumable products

LAST Technology reserves the rights to make product improvement and specification changes without prior notice



### LAST Technology S.r.l.

Via Sagree, 9 - I-33080 Prata di Pordenone (PN) – Italy

Phone: +39 0434 1660006 Fax: +39 0434 1660102

 $sales@last technology. it - {\color{blue}www.last technology.} it$