

# Superheated Water Sterilizers

## DLOS series



 **DE LAMA**

more than sixty years of experience in sterilization and drying


DE LAMA's Quality Management System is certified:




UNI EN ISO 9001 - Cert. n° 0351  
UNI EN ISO 13485 - Cert. n° 1275

# Superheated water sterilizers

 **DE LAMA DLOS series**

 **DE LAMA DLOS** autoclaves are **cGMP** designed to perform terminal sterilization of large volume infusion/parenteral solutions in non-deformable containers (e.g. glass bottles) as well as in containers deformable by differential pressure under heat exposure (e.g. plastic bottles, plastic bags) proven to withstand sterilization conditions by hot water spray.

The working principle of  **DE LAMA DLOS** autoclaves is based on the automatic counterpressure, by injection of compressed air into the chamber during the entire cycle, to minimize the differential pressure across the containers generated by the exposure to heat.

Sterilizers feature a high degree of operational flexibility that enables them to be used even for other applications - e.g. in the food industries - to perform sterilization and pasteurization treatment of foodstuffs. Suitable equipment configuration will be used for such application.

Sterilizers high flexibility in design, lay-out configuration, chamber sizing along with relevant load handling systems, conform with any User Requirement Specification.

Components are of the highest quality and reliability, world-wide available for easy replacement and assure the equipment longest lifetime.



Autoclave  **DE LAMA DLOS 43-50 2S type**  
capacity 12080 lts.

## APPLICABLE STANDARDS & GUIDELINES

Sterilizers are designed, manufactured and tested in compliance with **PED** European Directive for construction of pressure vessels, according to **UNI EN ISO 9001** and **UNI EN ISO 13485** Quality Management Systems procedures, following **cGMP** and **cGAMP** requirements and **FDA** Guidelines for **LVP/SVP**.

On request,  **DE LAMA** can supply even autoclaves according to pressure vessels codes of outside EC Countries.

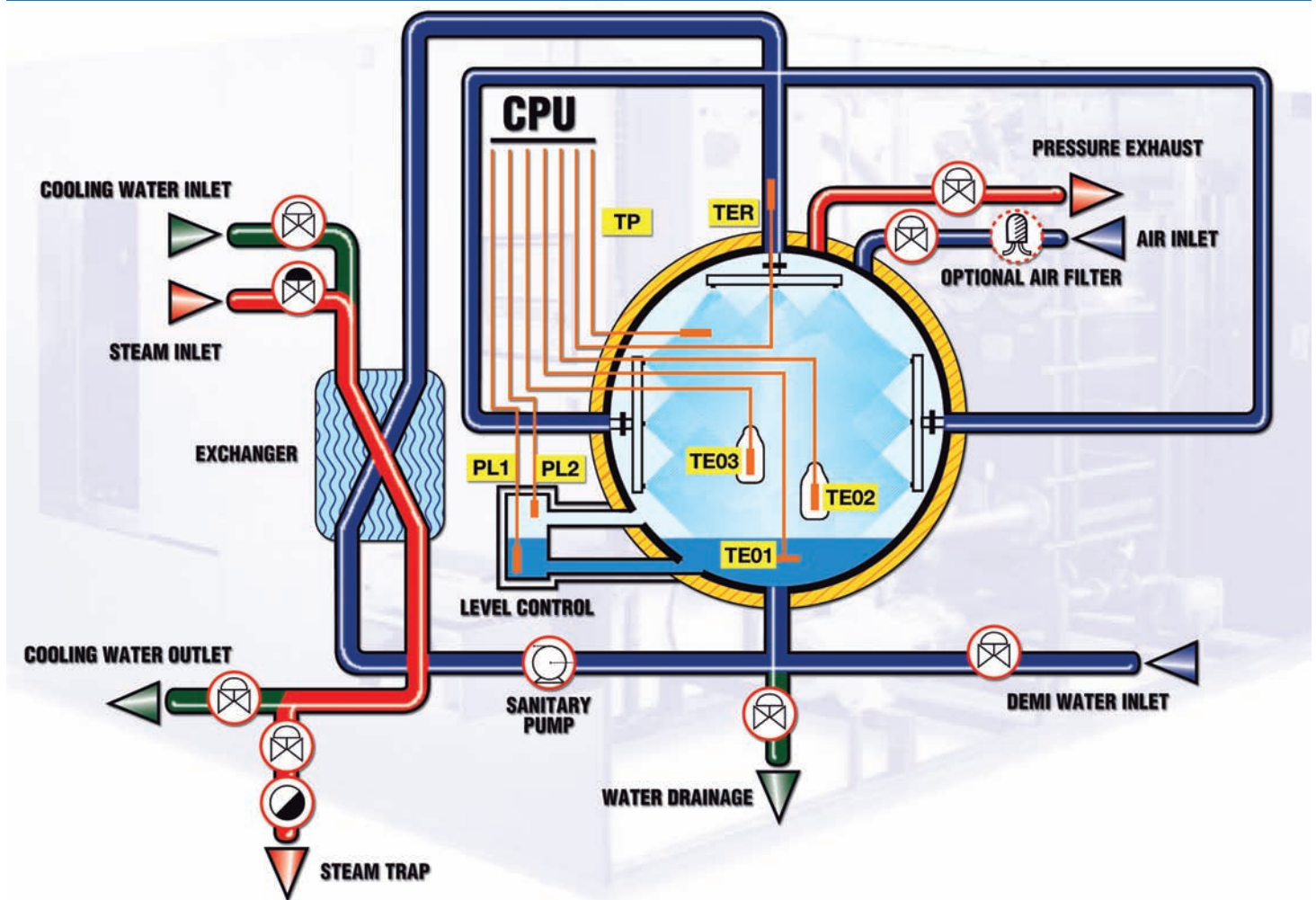
## STANDARD OPERATING PARAMETERS

- Pressure max. 4 bar abs.
- Temperature max. 139°C

## DESIGN, CONSTRUCTION & FUNCTIONAL FEATURES

- design for installation on the floor (for loading with in-chamber & transfer trolleys) or pit-mounted (for loading at floor level with in/out trolleys or automatic loading/unloading units)
- cylindrical single-wall chamber in highly satin finish AISI 316L stainless steel
- single or double door, semi-automatic hinged type or automatically sliding
- chamber pipings and fittings in AISI 316L stainless steel, tri-clamp connections. On request, sanitary execution
- water spray distribution headers fitted with nozzles suitably located to assure water uniform distribution on the product with consequent excellent temperature uniformity throughout the entire load
- high efficiency plate-type heat exchanger, in AISI 316L stainless steel, for recirculation of heating/cooling water
- high delivery pump, in AISI 316L stainless steel, for recirculation of heating/cooling water in a closed loop
- water circulation in a closed loop assuring quick heating/cooling and minimizing risks of contamination
- optional absolute filter with 0,22 micron cartridge for air inlet, assembled to allow integrity test (e.g. WIT)
- clamp connections for validation activities
- high grade thermal insulation
- built-in or separate electrical cabinet
- optional external panel/s in AISI 304 stainless steel
- pressure monitoring inside the chamber by pressure transmitter
- water level monitoring inside the chamber by sight level assembly and capacitive level sensors
- temperature monitoring/regulation inside the chamber by thermoresistances Pt 100 Ohm class A EN 60751/IEC 751
- wide range of alarms and safety devices to assure Operator protection and proper equipment operation

## Functional diagram





## PROGRAMS

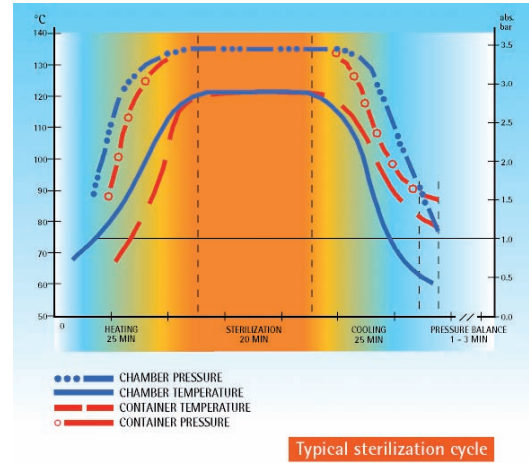
Customer can choose the more suitable operating parameters (time, temperature, pressure, etc.) to fit the widest variety of load and relevant packaging (e.g. glass, PVC, etc.).

Autoclave job parameters can be changed by the Operator according to the need. Different jobs can be stored and retrieved at any time for an easy and quick autoclave set up.

Reproducibility of cycles and process parameters enables Customers to perform easy and full validation.

Autoclaves come, as a standard, with a service cycle for water drainage to be used according to Customer experience/internal procedures to renovate the water on a periodical basis.

Since the lower sector of the cylindrical chamber is filled with process water, **DE LAMA DLOS** autoclaves do not require any external tank for process water storage upon cycle completion.

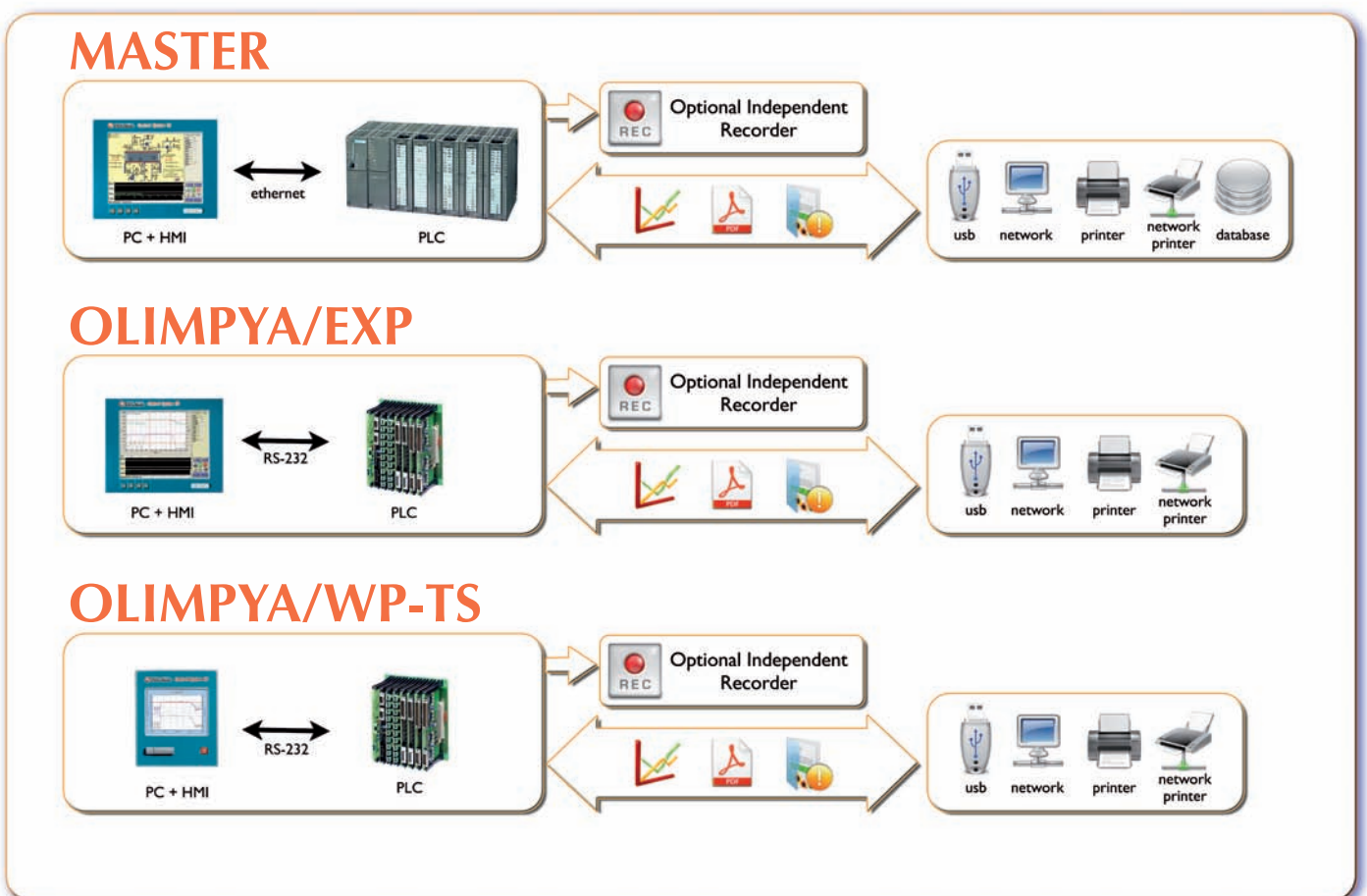


## PROCESS CONTROLLERS

**DE LAMA** offers a complete range of control systems, described in a separate leaflet, able to meet the most demanding Customer requirements and fit the widest variety of application. **DE LAMA** controllers are fully compliant with FDA CFR 21-PART 11 and cGAMP:

- **MASTER** based on industrial PC + PLC Siemens S7
- **OLIMPYA/EXP** based on industrial PC + PLC
- **OLIMPYA/WP-TS** based on embedded PC + PLC

Customized design and configurations are available on request.



## QUALITY CONTROL & VALIDATION

Equipment and process controllers are designed and manufactured to be easily validated in compliance with FDA quality standards for pharmaceutical processes. Careful tests, specific controls and high technical skill in pre-validation activities assure that plants are fully compliant with the strictest standards.

## TECHNICAL DOCUMENTATION & ACTIVITIES

Sterilizers are delivered with a full dossier of documentation:

- User and Control System User Manual
- P&ID general diagram
- Equipment data sheet and lay-out
- Equipment materials list
- Sub-vendor technical documentation
- Calibration Manual
- Conformity certificate
- FAT protocol

 **DE LAMA** supplies, on request:

- SAT protocol
- cGAMP and IQ/OQ/PQ validation support documentation customizable by the end-Users
- Additional specific documentation
- Training to Customer personnel



Autoclave  **DE LAMA DLOS 20-12 2S type**  
capacity 1405 lts.

## ACCESSORIES

- Wide range of load handling accessories, made of stainless steel, conforming to ergonomic criteria and high quality standards:
    - in-chamber shelf racks & trolleys
    - trays, baskets, cassettes to house load
    - transfer trolleys
  - Semi-automatic/fully automatic loading/unloading systems for load handling
- Further information in a separate leaflet



Autoclave  **DE LAMA DLOS 55-122 2S type**  
capacity 35555 lts.

# TECHNICAL DATA

MODEL	CHAMBER VOLUME	CHAMBER INTERNAL DIMENSIONS				APPROX. LOADING CAPACITY ISO infusion glass bottles 500 ml.
		DIAMETER	HEIGHT	WIDTH	DEPTH	
	lts.	mm	mm	mm	mm	pcs.
DLOS 20-10	1158	1120	800	800	1000	340
DLOS 20-12	1405	1120	800	800	1250	430
DLOS 20-20	2195	1120	800	800	2000	700
DLOS 20-25	2685	1120	800	800	2500	850
DLOS 20-30	3180	1120	800	800	3000	1050
DLOS 20-37	3870	1120	800	800	3700	1250
DLOS 35-10	1880	1400	1000	1000	1000	600
DLOS 35-12	2265	1400	1000	1000	1250	750
DLOS 35-15	2650	1400	1000	1000	1500	860
DLOS 35-20	3420	1400	1000	1000	2000	1200
DLOS 35-25	4265	1400	1000	1000	2500	1500
DLOS 35-30	5035	1400	1000	1000	3000	1800
DLOS 35-37	6115	1400	1000	1000	3700	2250
DLOS 35-40	6575	1400	1000	1000	4000	2400
DLOS 35-50	8115	1400	1000	1000	5000	3000
DLOS 43-30	7540	1700	1200	1200	3000	2800
DLOS 43-37	9130	1700	1200	1200	3700	3400
DLOS 43-40	9810	1700	1200	1200	4000	3700
DLOS 43-50	12080	1700	1200	1200	5000	4700
DLOS 43-61	14575	1700	1200	1200	6100	5700
DLOS 43-75	17750	1700	1200	1200	7500	7000
DLOS 43-85	20016	1700	1200	1200	8500	8050
DLOS 43-99	23195	1700	1200	1200	9900	9400
DLOS 55-40	12315	1900	1450	1200	4000	4500
DLOS 55-61	18265	1900	1450	1200	6100	6850
DLOS 55-92	27050	1900	1450	1200	9200	10300
DLOS 55-122	35555	1900	1450	1200	12200	15250



DLOS IN. 05-09

Models indicated in the table are only some of standard sizing for **DE LAMA DLOS**.

Besides the standard configurations indicated in the table, sterilizers can be proposed even with other dimensions, on request, according to Customer production needs.



**Autoclave**  
**DE LAMA DLOS 35-40 2H type**  
**capacity 6575 lts.**

The technical contents of present brochure are not binding and can be varied by **DE LAMA** without any prior notice.

