

Steam Sterilizers

DLOV & DLDM series



more than sixty years of experience in sterilization


DE LAMA's Quality Management System is certified:



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

Steam sterilizers

DE LAMA DLOV series

 **DE LAMA DLOV** are the most versatile steam autoclaves designed to meet the widest requirements of the Pharmaceutical Industry. Sterilizers incorporate a high degree of operational flexibility that enables them to be used even for a wide range of industrial and laboratory applications (at biotechnology centers, research centers, universities and animal facilities).

Typical applications:

- Empty and filled glassware (e.g. vials, ampoules, bottles)
- Stoppers and rubber materials
- Inox equipment, instruments, machine parts
- Filters and respective accessories
- Textiles
- Cages, beddings, feedstuffs and other products used at animal facilities




Autoclave  **DE LAMA DLOV 35-15 2S type**
nominal volume 1500 lts.

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.

APPLICABLE STANDARDS & GUIDELINES

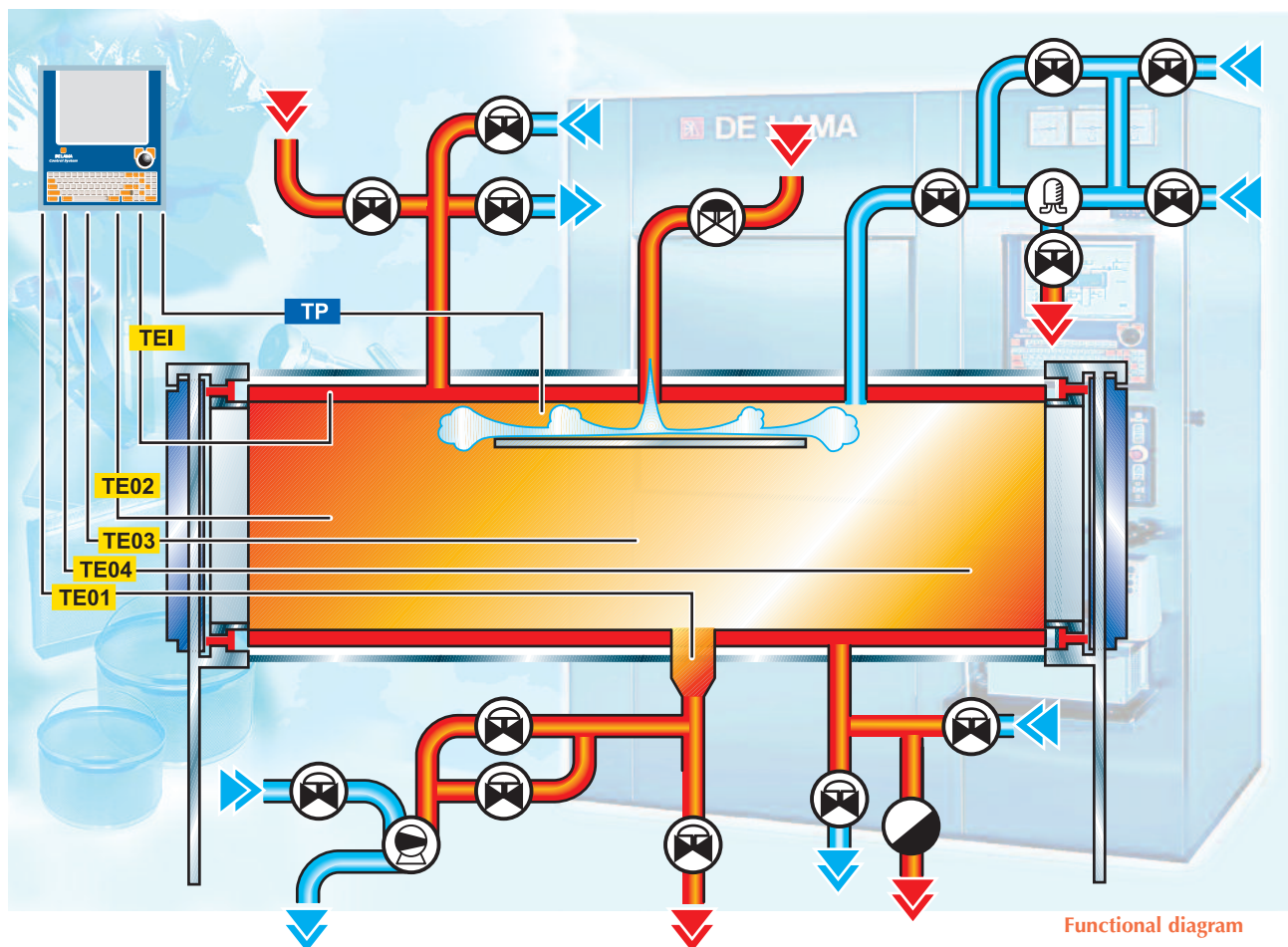
Sterilizers are designed, manufactured and tested in compliance with **PED** European Directive for construction of pressure vessels, according to **UNI EN ISO 9001** and **UNI EN ISO 13485** Quality Management Systems procedures, following **cGMP** and **cGAMP** requirements, **FDA** Guidelines, European Standard **EN 285** and **HTM 2010**.

On request,  **DE LAMA** can supply even autoclaves according to pressure vessels codes other than **PED**.

STANDARD OPERATING PARAMETERS

- Pressure: max. 3,5 bar abs.
- Temperature: max. 139°C

Note: Operating parameters can be modified according to Customer requirements.



DESIGN, CONSTRUCTION & FUNCTIONAL FEATURES

- parallelepiped chamber in highly satin finish AISI316L stainless steel. Drainable execution. On request, cylindrical chamber
- jacket, in AISI 304 stainless steel, for heating, load drying and final cooling by recirculating water
- single or double door (pass-through execution for no-cross contamination), semi-automatic hinged type or automatically sliding
- chamber piping and fittings in AISI 316L stainless steel, tri-clamp connections. On request, sanitary execution
- vacuum pump group for vacuum phases, removal of air pockets and load drying
- device to cool drain
- absolute filter with 0,22 micron cartridge for air inlet, steam sterilizable, assembled to allow integrity test (e.g. W.I.T.)
- clamp connections for validation activities
- high grade thermal insulation
- built-in or separate electrical cabinet
- external panels in AISI 304 stainless steel
- chamber pressure control/regulation by pressure transmitter
- temperature monitoring inside the chamber, the drain and the jacket 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
- operation either through steam by factory utility line or through a dedicated steam generator (steam or electrically heated, built-in or externally located)



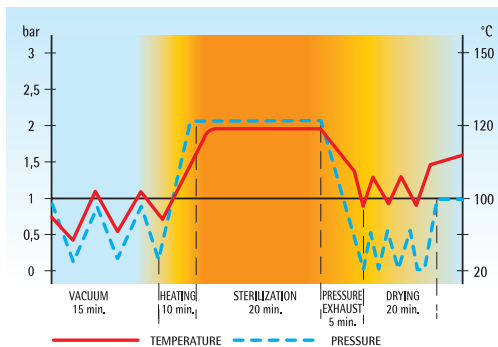
Autoclave **DE LAMA** DLOV 35-10 2H type
nominal volume 1000 lts.

PROGRAMS

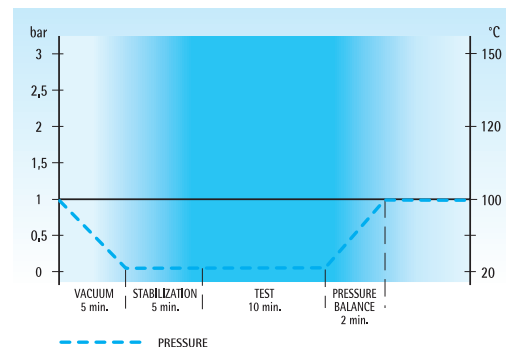
The system stores a variety of operating and control/utility programs out of which Customers can select the best ones to fit their own applications or kind of load:

- sterilization of solids
- sterilization of porous materials
- sterilization of stoppers with final vacuum drying. Possibility of additional devices to optimize final drying process and assure very low percentages of residual humidity
- sterilization of membrane filters and accessories
- sterilization of ampoules with "seal test" performed either by rapid vacuum or by water flooding
- sterilization of liquid solutions in sealed/unsealed glass containers (ampoules, vials, bottles). Counterpressure inside the chamber and final cooling by demineralized water spray on load or water circulation inside the jacket
- tyndallization of products sensitive to high temperatures
- pasteurization for treatment of packed food products
- chamber vacuum/pressure leakage tests
- Bowie & Dick test, Helix test
- washdown treatments for removal of powder residuals, particulates and contaminants (**combined sterilizers DE LAMA DLOV-W series**)

Some of listed programs require suitable equipment options.



Example of sterilization cycle for solids and porous materials



Vacuum leakage test conforming to EN 285

Customer can choose the more suitable operating parameters (time, temperature, pressure, etc.) to fit each program to requirements of type of load and relevant packaging.

Possibility to program vacuum pulses, steam injections and trend of heating/cooling phases.

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

Combined sterilizers DE LAMA DLOV-AV series

Sterilizers **DLOV-AV** series are designed to enable Customer to use the same equipment to run two different types of process cycles. The conventional steam sterilization is combined with the air/steam mixture sterilization.

Autoclaves **DLOV-AV** allow performance of all available programs for **DLOV** sterilizers plus the specific treatment of pressure/temperature sensitive products such as plastic containers, products in blister packs, pre-filled syringes, etc. by air/steam mixture.

This line of autoclaves features:

- maximum operating pressure of 4,5 bar abs.
- ventilator group which provides for air/steam mixture forced recirculation and homogenization throughout the chamber, heat transfer during the heating phase, internal temperature uniform distribution during the cycle phases
- load cooling in counterpressure and drying

Sterilizers **DLOV-AV** type are usually in cylindrical chamber execution in order to house the ventilator group into the upper circular sector without affecting the available internal useful area.



Autoclave DE LAMA DLOV/C-AV 45-25 2S type
nominal volume 3625 lts.

Steam sterilizers

DE LAMA DLOM series

Saturated steam sterilizers  **DE LAMA DLOM** are specifically conceived for applications at microbiology/virology laboratories and research institutes.

Typical applications:

- containers
- culture media
- animal cages
- wastes which are not highly infected

Sterilizers **DLOM** have the general technical features of the sterilizers **DLOV** type and come with a cycles package suitable for the treatment of above-mentioned materials.

 **DE LAMA DLOM** series normally range between 80 and 1500 lts.



Autoclave  **DE LAMA DLOM 20-10 2S** type
nominal volume 640 lts.

Combined sterilizers

DE LAMA DLOM-HP series

The materials **at high pathogenic risk** have to be specifically treated before being re-used, disposed or recycled in order to avoid any risk of pollution/contamination for the Operator, the working area and the environment.

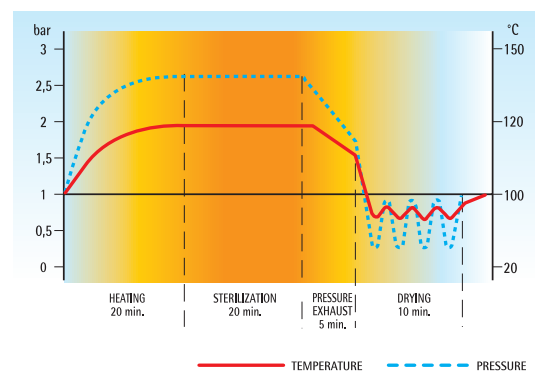
Sterilizers **DLOM-HP** series are designed to perform, in addition to sterilization programs of **DLOM** autoclaves, even the specific treatment of high pathogenic solids and liquids so that, after treatment, load is safe and ready to be re-used or disposed. Such line of autoclaves combines the conventional sterilization by saturated steam with the air/steam mixture sterilization.

Typical applications:

- materials coming from the pharmaceutical field (e.g. from laboratories for production of vaccines, serums, etc.)
- products coming from research and/or microbiology laboratories (e.g. diagnostic or biotechnological products or manufacturing wastes)
- products coming from the hospitals (e.g. materials outcoming from infectious diseases areas)
- highly resistant pathogenic organisms (e.g. from Creutzfeldt-Jakob disease - bovine spongiform encephalopathy well-known as "mad cow disease" - and from correlated syndromes)

Main features:

- sterilization in overpressure (5 bar abs.)
- no evacuation of fluids before being sterilized
- no venting of contaminated air till the end of the sterilization process
- homogenization of the air/steam mixture throughout the chamber by the application of a ventilator group which assures the internal temperature uniform distribution during the cycle phases
- cylindrical chamber to house the ventilator group into the upper circular sector without affecting the available internal useful area
- application of pressure gauges with diaphragm seal and pressure transmitters with diaphragm separator.



**Example of sterilization cycle
for solids at high pathogenic risk**



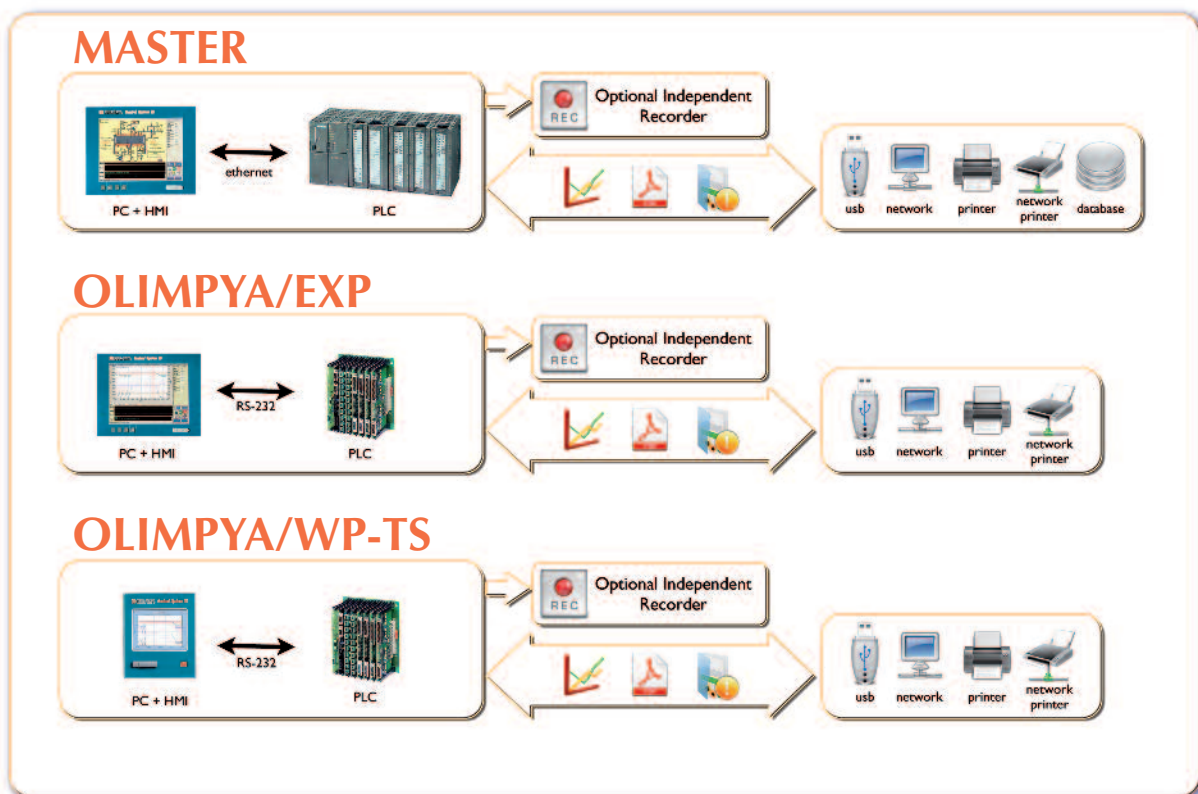
Autoclave  **DE LAMA DLOM 15-12 1S** type
nominal volume 545 lts.

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 applications. 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.



Autoclave DE LAMA DLOV 45-30 2S type
with automatic loading/unloading system

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

Standard 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

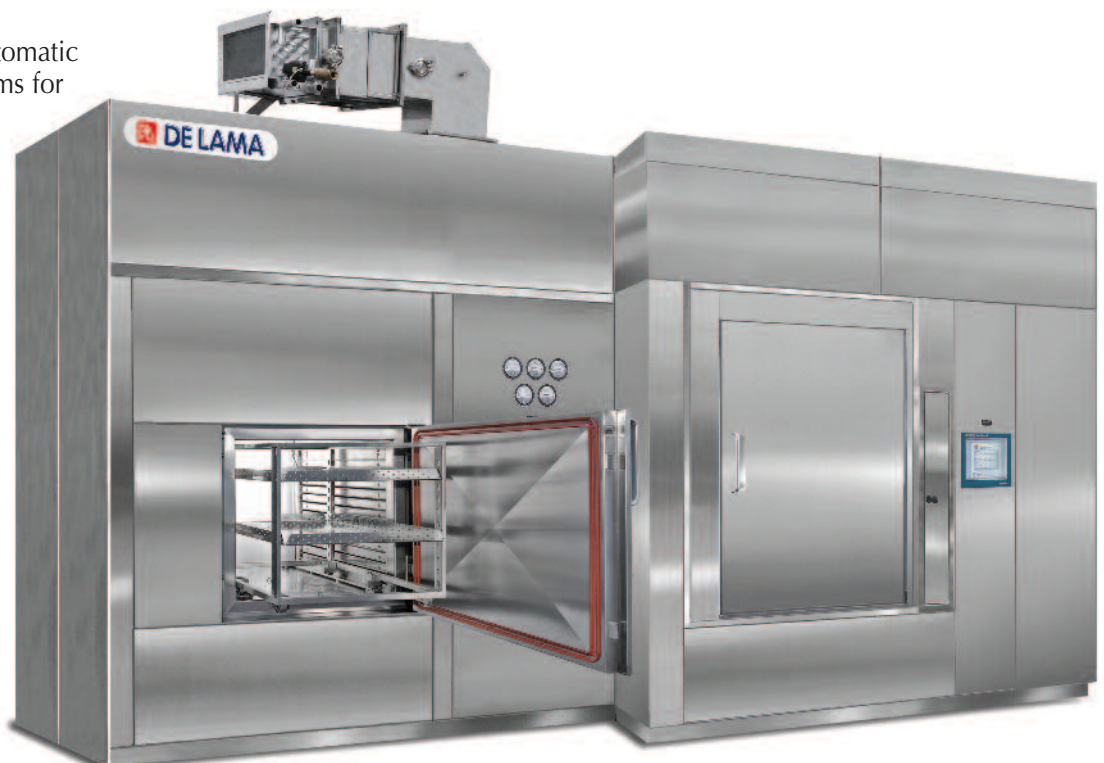



Autoclave  **DE LAMA DLOV-W 40-15 2S type**
nominal volume 1755 lts.

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 DLOV 20-10 2S type** + dry heat sterilizer  **DE LAMA DLST/L 10-10 2H type**

TECHNICAL DATA



SEMI-AUTOMATIC HINGED DOOR

MODEL	NOMINAL VOLUME	CHAMBER NOMINAL INTERNAL DIMENSIONS		
		HEIGHT	WIDTH	DEPTH
	lts.	mm	mm	mm
DLOV 25-07	439	950	660	700
DLOV 25-10	627	950	660	1000
DLOV 25-13	815	950	660	1300
DLOV 25-15	941	950	660	1500
DLOV 30-10	800	1000	800	1000
DLOV 30-12	1000	1000	800	1250
DLOV 35-10	1000	1000	1000	1000
DLOV 35-12	1250	1000	1000	1250
DLOV 35-15	1500	1000	1000	1500
DLOV 35-20	2000	1000	1000	2000
DLOV 35-25	2500	1000	1000	2500
DLOV 40-13	1521	1300	900	1300
DLOV 40-15	1755	1300	900	1500
DLOV 40-18	2106	1300	900	1800
DLOV 40-20	2340	1300	900	2000
DLOV 40-24	2808	1300	900	2400
DLOV 45-20	2900	1450	1000	2000
DLOV 45-25	3625	1450	1000	2500
DLOV 45-30	4350	1450	1000	3000
DLOV 70-25	6500	2000	1300	2500
DLOV 73-18	3780	2100	1000	1800
DLOV 73-	4620	2100	1000	2200



Autoclave **DE LAMA** DLOV/C 20-12 2S type
nominal volume 800 lts.



AUTOMATIC SLIDING DOOR

MODEL	NOMINAL VOLUME	CHAMBER NOMINAL INTERNAL DIMENSIONS		
		HEIGHT	WIDTH	DEPTH
	lts.	mm	mm	mm
DLOV 05-07	81	340	340	700
DLOV 05-10	116	340	340	1000
DLOV 05-13	150	340	340	1300
DLOV 10-07	142	450	450	700
DLOV 10-10	203	450	450	1000
DLOV 10-13	263	450	450	1300
DLOV 15-07	305	660	660	700
DLOV 15-10	436	660	660	1000
DLOV 15-13	566	660	660	1300
DLOV 20-10	640	800	800	1000
DLOV 20-12	800	800	800	1250
DLOV 20-15	960	800	800	1500
DLOV 25-07	439	950	660	700
DLOV 25-10	627	950	660	1000
DLOV 25-13	815	950	660	1300
DLOV 25-15	941	950	660	1500
DLOV 30-10	800	1000	800	1000
DLOV 30-12	1000	1000	800	1250
DLOV 35-10	1000	1000	1000	1000
DLOV 35-12	1250	1000	1000	1250
DLOV 35-15	1500	1000	1000	1500
DLOV 35-20	2000	1000	1000	2000
DLOV 35-25	2500	1000	1000	2500
DLOV 40-13	1521	1300	900	1300
DLOV 40-15	1755	1300	900	1500
DLOV 40-18	2106	1300	900	1800
DLOV 40-20	2340	1300	900	2000
DLOV 40-24	2808	1300	900	2400
DLOV 45-20	2900	1450	1000	2000
DLOV 45-25	3625	1450	1000	2500
DLOV 45-30	4350	1450	1000	3000
DLOV 70-25	6500	2000	1300	2500
DLOV 73-18	3780	2100	1000	1800
DLOV 73-22	4620	2100	1000	2200
DLOV 75-31	6820	2200	1000	3100
DLOV 80-22	8712	2200	1800	2200

Tables show standard sizes. Other dimensions available on request.
The technical contents of present brochure are not binding and can be varied by **DE LAMA** without any prior notice.

