



DE LAMA

PHARMA WORKS MILANO
TECNOLOGIE REALIZZAZIONI FARMACEUTICHE

UFFICIO TECNICO E COMMERCIALE
26812 BORGHETTO LODIGIANO (LO) - Via Togliatti, 1
Tel 0039-0371-80344/80392 • Fax 0039-0371-8034
Internet: www.pharmaworks.it
E-mail: info@pharmaworks.it • pharmaworks@libero.it

SEDE: 20126 MILANO - Viale Fuvio Tesli, 39 - tel. 02.6610087

DEPOSITO: 26813 GRAFFIGNANA (LO)
Strada Provinciale 19 - Loc. Porchiroia - tel. 0371.8896

[...] INTRODUZIONE

La sterilizzazione a calore secco è un processo ecologicamente non inquinante, che non genera problemi di rifiuti o di inconvenienti per l'ambiente o per il personale. Nel contempo il processo adempie alle più severe esigenze di riduzione della carica batterica.

Gli sterilizzatori della serie DLST/L sono stati progettati per garantire l'esecuzione dei seguenti trattamenti:

- ◊ sterilizzazione : riduzione dei microorganismi e derivati fino a 12 esponenti (temperatura : 160+180°C)
- ◊ deprogenazione : distruzione dei pirogeni e delle endotossine nei materiali (temperatura : 220+250°C)

Il processo eseguito in un forno a calore secco è idoneo al trattamento dei seguenti materiali:

- vetreria vuota (contenitori tipo fiale/flaconi o altre tipologie di bottiglie in vetro)
- vassoi metallici
- recipienti e materiali metallici
- accessori inox di macchine per la produzione
- materiali vari che temono l'umidità
- prodotti farmaceutici di base che non temono un trattamento termico ad elevate temperature (es. talco, sulfonamidi, ecc.)

[1] PRESCRIZIONI E NORMATIVE

Il forno è progettato, realizzato e collaudato conformemente alle Prescrizioni cGMP e U.S. Federal Standard No.209/E ed è provvisto dell'allestimento aggiuntivo utile a rendere l'impianto in accordo alle Guidelines FDA CFR 21 Parte 212 del 01/06/1976 ed ai Technical Reports della Parenteral Drug Association (vedere quotazione separata nell'offerta economica ed Allegato A).

[2] CONDIZIONI DI PROGETTO ED ESERCIZIO

- Temperatura di progetto : 300°C
- Temperatura massima di esercizio : 250°C

[3] CARATTERISTICHE DIMENSIONALI

CAPACITA' : 2475 litri

3.1] DIMENSIONI INTERNE DELLA CAMERA A PORTE CHIUSE:

ALTEZZA : mm.1800
LARGHEZZA : mm.1100
PROFONDITA' : mm.1250

3.2] DIMENSIONI ESTERNE IMPIANTO : vedere lay-out No.502102B . Rev.A allegato

[4] PRINCIPALI CARATTERISTICHE COSTRUTTIVE

4.1] CAMERA DI STERILIZZAZIONE

La camera di sterilizzazione, di tipo parallelepipedo orizzontale, è in esecuzione a due porte contrapposte ed è progettata per installazione passante verso la zona sterile. Il caricamento del prodotto all'interno della camera avviene da un lato e lo scarico dal lato opposto.

Dry Heat Sterilizers

ISO Class 5 (Class 100) **DLST/L** series
& **DLST** series



 **DE LAMA**

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

Dry heat sterilizers

DE LAMA DLST/L series

 DE LAMA DLST/L ovens are cGMP designed to meet the widest requirements of the Pharmaceutical Industry and to perform following treatments:

sterilization: reduction of microorganisms and their by-products up to 12 log (temperature range: 160÷180°C)

depyrogenation: destruction of pyrogens and endotoxins inside the materials (temperature range: 220÷250°C)

Main applications:

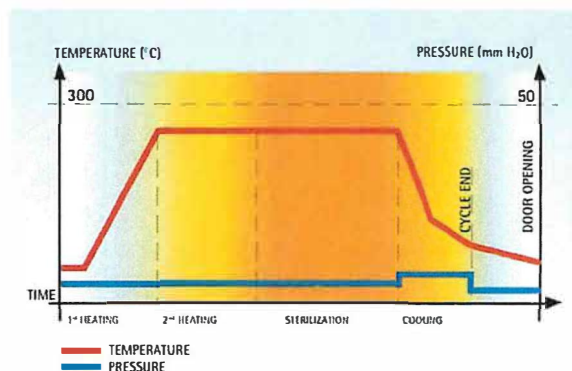
- empty glassware (e.g. vials, ampoules, bottles)
- inox equipment (e.g. trays, machine parts)
- materials sensitive to humidity
- thermostable basic pharmaceutical products and chemical compounds
- non-acqueous liquid materials (e.g. oils, glycerines, etc.)

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

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

OPERATING TEMPERATURE

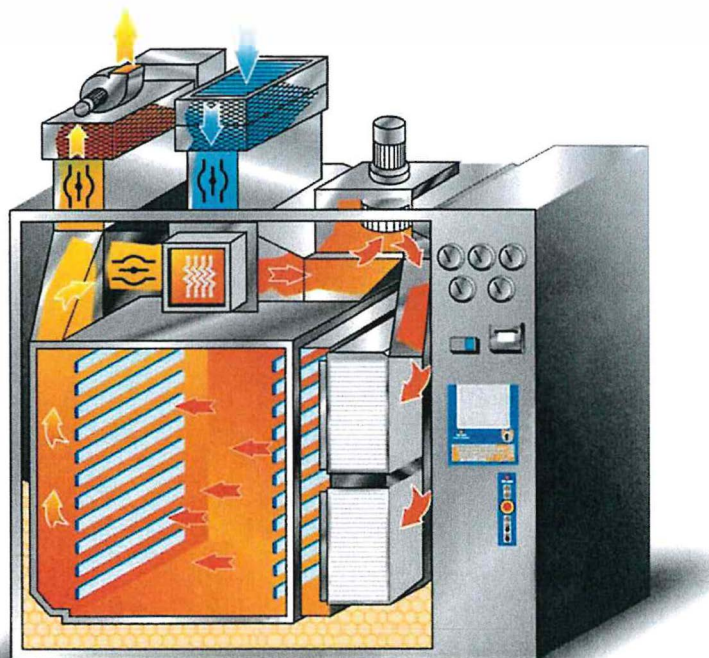
Operating temperature ranges between 250°C (standard design) and 300°C according to Customer request.



GUARANTEED ISO CLASS 5 (CLASS 100) CONDITIONS

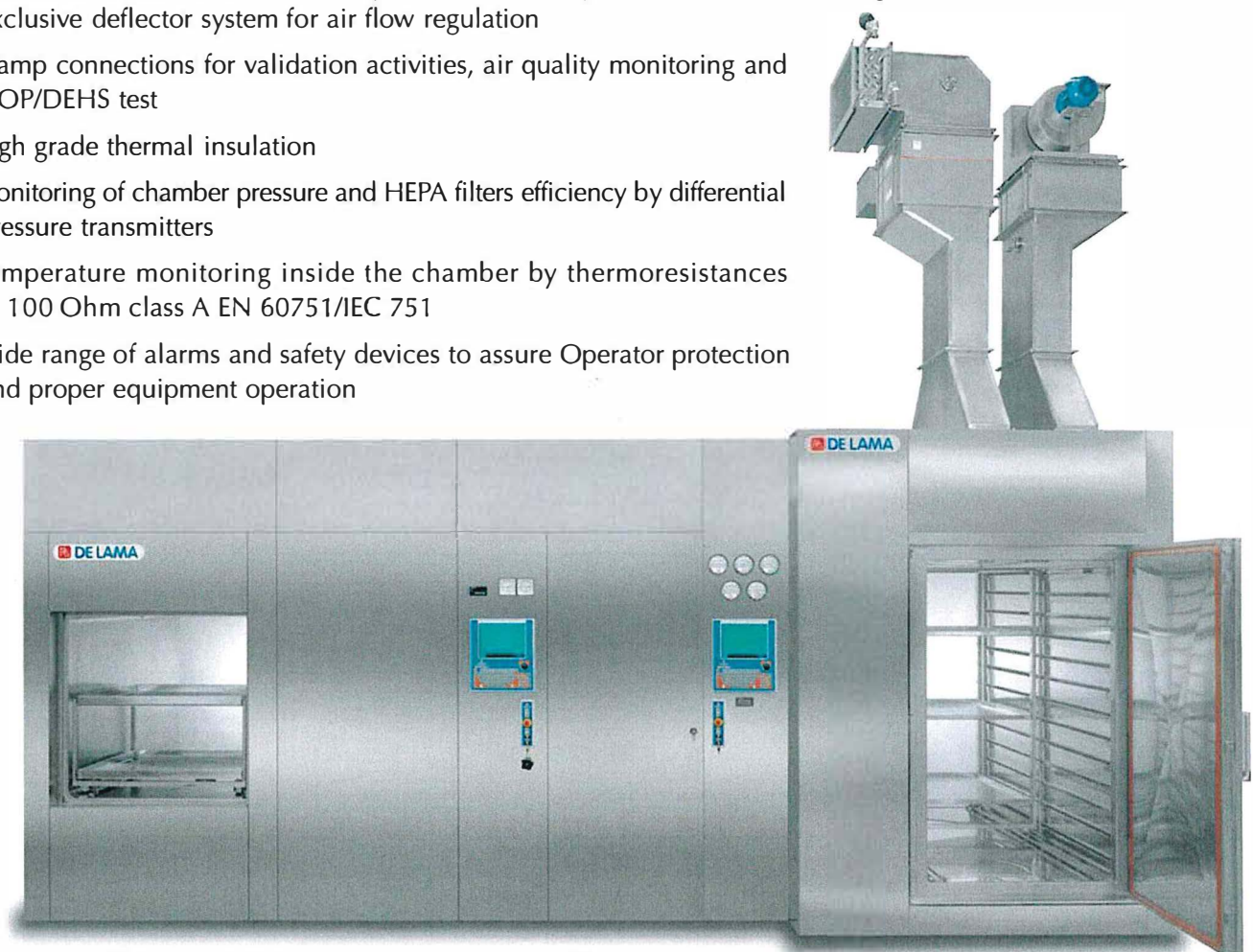
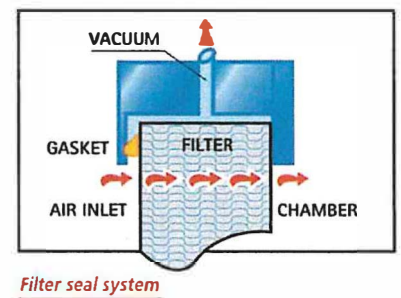
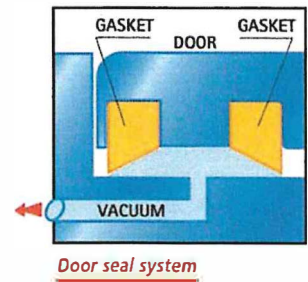
The HEPA filters installed on air intake, exhaust and recirculation wall together with the accurate execution for no cross-contamination guarantee ISO 14644-1-2 Class 5 (U.S. Federal Standard 209E Class 100 referred to 0,5 micron particle size) quality throughout the process chamber.



Air flow diagram



DESIGN, CONSTRUCTION & FUNCTIONAL FEATURES

- chamber execution in AISI 316L or AISI 304 stainless steel fully welded, with rounded edges
- pass-through execution for no cross-contamination with interlocked doors
- semi-automatic hinged doors or automatically sliding doors
- door seal system: special double gaskets system (FDA approved) to avoid any air release or cross contamination between the chamber and the external environment
- bioseal flange to seal the sterilizer into the facility wall at the “clean side” ensuring a barrier preventing particulate from entering the room from the maintenance area
- HEPA filters installed in the air intake, air exhaust and recirculation wall
- filter seal system: internal filters seal frames kept at a pressure lower than the chamber pressure
- two fan groups: one for air circulation into the chamber and one for exhausted air extraction and cooling
- electrical or steam/electrical heating
- chamber constant overpressure control through the inverter on the air circulation fan
- adjustable heating up ramp with internal humidity evacuation
- cooling by external fresh air flow optionally improved through coil exchanger
- enhanced air distribution and temperature uniformity into the chamber through exclusive deflector system for air flow regulation
- clamp connections for validation activities, air quality monitoring and DOP/DEHS test
- high grade thermal insulation
- monitoring of chamber pressure and HEPA filters efficiency by differential pressure transmitters
- temperature monitoring 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



Autoclave  DE LAMA DLOV 35-20 2S type + dry heat sterilizer  DE LAMA DLST/L 60-27 2H type

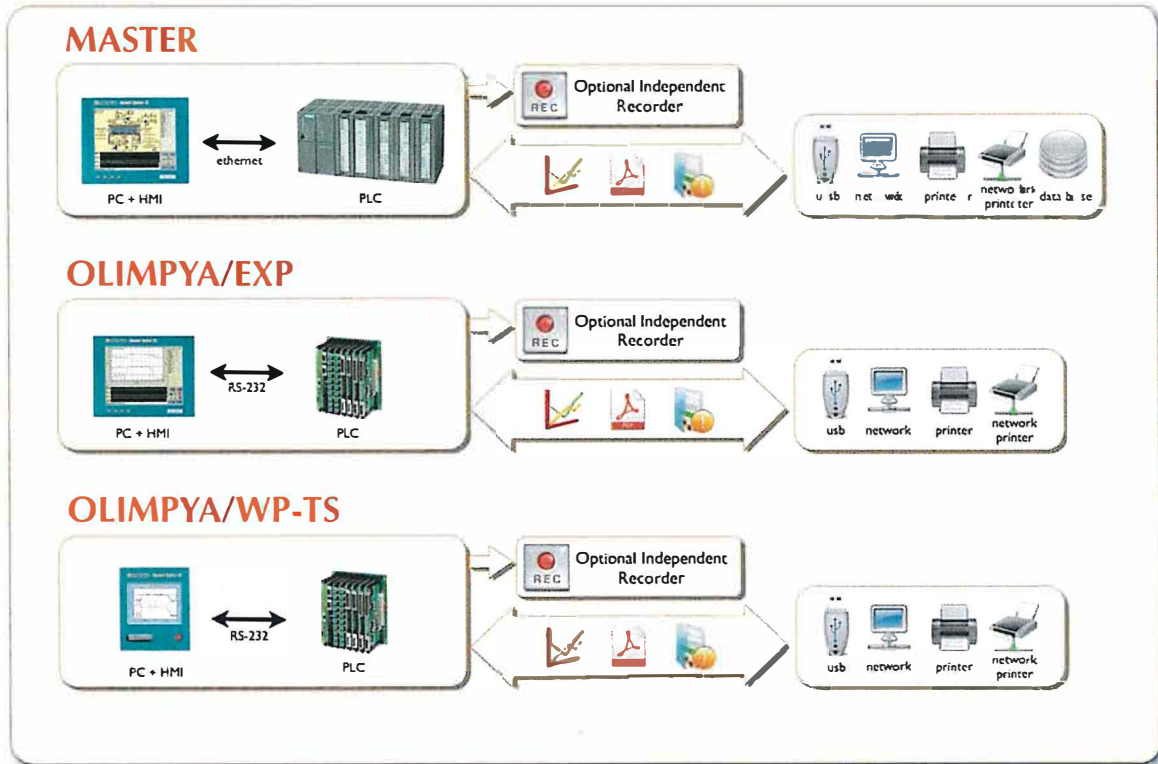
PROCESS CONTROLLERS

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.



Dry heat sterilizer **DE LAMA** DLST/L 40-15 2H type
Capacity 1800 lts.

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

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

Further information in a separate leaflet.





Dry heat sterilizer  **DE LAMA DLST/L 22-10 2H type**
Capacity 1000 lts.



Dry heat sterilizer  **DE LAMA DLST/L 50-20 2H type**
Capacity 2700 lts.

Dry heat sterilizers

DE LAMA DLST type

 **DE LAMA DLST** ovens are used where ISO Class 5 (Class 100) is not necessary. The same high quality construction features and performances of  **DE LAMA DLST/L** series remain unchanged.



The main difference is the filtration system: HEPA filters are installed on the air intake only and, optionally, on the air exhaust to prevent particles backflow to the chamber. No HEPA filters on air recirculation wall are installed.


For more information refer to  **DE LAMA DLST/L** sterilizers.



Dry heat sterilizer  **DE LAMA DLST 20-12 2H type**
Capacity 1000 lts.

TECHNICAL DATA

MODEL	CHAMBER CAPACITY	CHAMBER INTERNAL DIMENSIONS			INSTALLED POWER	LOADING CAPACITY (HINGED DOORS)	
		HEIGHT	WIDTH	DEPTH		Ampoules 2 ml.	Vials 10 ml.
		mm.	mm.	mm.		No.	No.
	Its.				kW		
DLST/L 05-06	152	480	480	660	10	4260	2000
DLST/L 08-06	287	660	660	660	13	12480	5080
DLST/L 10-08	544	800	800	850	28	24840	11340
DLST/L 10-10	640	800	800	1000	28	31500	14500
DLST/L 20-10	800	1000	800	1000	30	44100	18850
DLST/L 20-12	1000	1000	800	1250	30	56420	24570
DLST/L 20-15	1200	1000	800	1500	44	67340	29490
DLST/L 30-10	1080	1200	900	1000	30	57800	28560
DLST/L 30-15	1620	1200	900	1500	46	84100	41620
DLST/L 40-10	1200	1200	1000	1000	30	61830	29920
DLST/L 40-15	1800	1200	1000	1500	46	94720	46520
DLST/L 50-10	1350	1500	900	1000	42	75770	35200
DLST/L 50-12	1688	1500	900	1250	44	96100	44880
DLST/L 50-15	2025	1500	900	1500	65	115640	53860
DLST/L 50-20	2700	1500	900	2000	78	157000	73920
DLST/L 50-22	3038	1500	900	2250	79	178070	81840
DLST/L 50-25	3375	1500	900	2500	89	197610	92400
DLST/L 60-10	1500	1500	1000	1000	42	84480	37760
DLST/L 60-12	1875	1500	1000	1250	44	108240	50160
DLST/L 60-15	2250	1500	1000	1500	65	130240	60200
DLST/L 60-20	3000	1500	1000	2000	78	174240	80260
DLST/L 60-22	3375	1500	1000	2250	80	200640	90290
DLST/L 60-25	3750	1500	1000	2500	89	221760	101640
DLST/L 60-27	4050	1500	1000	2700	89	242880	110360
DLST/L 70-16	2880	1500	1200	1600	65	169360	77620
DLST/L 70-20	3600	1500	1200	2000	79	214500	99800
DLST/L 70-25	4500	1500	1200	2500	101	274700	129360
DLST/L 70-27	4860	1500	1200	2700	101	297530	140450

Models indicated in the table are only some of the standard sizing for  DE LAMA DLST/L.

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



 Dry heat sterilizer
DE LAMA DLST/L 70-25 2S type
Capacity 4500 Its.

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

 **DE LAMA**
PHARMACEUTICAL EQUIPMENT

Via Piemonte, 21 - 27028 San Martino Siccomario (Pavia) - Italy
Phone +39 0382 559501 (12 lines) - Fax +39 0382 556224 - <http://www.delama.it> - e-mail (Sales Dept.): sales@delama.it