ETHYLENE OXIDE GAS (EtO) STERILIZERS

DE LAMA holds the Quality System certificates
ISO 9001 and EN 46001

more than fifty years of experience in sterilization
Ethylene oxide gas (EtO) sterilizers

DE LAMA DLOG and DLOG/V

Ethylene oxide sterilizers of DE LAMA DLOG and DE LAMA DLOG/V series have been specifically designed for sterilization of products sensitive to high temperatures and to humidity (syringes, defluxers, catheters, cartridges for dialysis, plastic articles, bandages, sutures, etc.). Such autoclaves can be used even for sterilization of powders which deteriorate by heating exposure. For the wide range of product that can be treated, such sterilizers find application in parapharmaceutical and pharmaceutical industry, in laboratories and hospitals.

Ethylene oxide autoclaves can be realized in two versions to satisfy different requirements:

- **DE LAMA DLOG** series for working under pressure (3.5 abs. bar + vacuum) with mixtures of ethylene oxide and carbon dioxide (usual composition 10% EtO + 90% CO2)
- **DE LAMA DLOG/V** series for working under vacuum (1.45 abs. bar + vacuum) with mixtures of ethylene oxide and carbon dioxide (usual composition 90% EtO + 10% CO2) or with 100% ethylene oxide.

On request, DE LAMA can supply EtO sterilizers which are able to perform even saturated steam cycles.

**MAIN CONSTRUCTION FEATURES**

Sterilizers are designed, manufactured and tested according to current Directives for construction of pressure vessels (PED), in full compliance with cGMP Guidelines, European Standards and EN 1422, with procedures fixed by ISO 9001 and Quality Systems and are suitable to be validated according to European Standard EN 550.

DE LAMA DLOG (equipment under pressure) and DE LAMA DLOG/V (equipment under vacuum) are distin-

- front panels and eventual side walls in satin finish AISI 304 stainless steel
- piping and valves directly connected with the chamber in stainless steel
- loop for heating and circulation of water inside the jacket, complete of pump
- efficient insulation with minimum heat loss and high power economies

Sterilizers are available with single or double door, hinged or automatic sliding type.
**PROCESS CONTROL**

All **DE LAMA** control systems are provided with **CE** marking and are in compliance with European Directive **EMC 89/336** relevant to electromagnetic compatibility.

To satisfy Customers’ several production needs, **DE LAMA** has realized different and flexible control system configurations. All controllers give the possibility of data processing and to issue detailed process documentation.

**DE LAMA MASTER 6**
Distributed architecture modular control, processing and recording system with industrial PC connected to a PLC

- VGA colour LCD monitor (TFT 800x600)
- multifunction keyboard membrane type
- track-ball
- colour graphic printer with printout size A4
- interface Ethernet IEEE 802.3 and Profibus
- self-diagnostic and self-test
- graphic programming
- configurable dynamic synoptic panel
- human / machine interface (HMI) with graphic management
- Windows-NT® / 2000 Professional® operating system
- integrated management of all process parameters and sequences

**STERILIZATION PROGRAMMES**

High flexibility of control systems mounted on autoclaves **DE LAMA DLOG** and **DE LAMA DLOG/V** allows to perform cycles, automatic control cycles (vacuum leak test pressure leak test) and cycles free programmable by it is possible to choose operating parameters (time, humidity, gas concentration, etc.) according to type load, packaging and product placing inside the chamber.

Standard operating values are the following:

**Sterilization time**: usual gas exposure time is 3÷4 hours. Sterilization time depends on both type of packaging and other process parameters.

**Product temperature**: 40÷60°C
Set temperature value is non-stop holded by forced circulation of water inside the jacket and, optionally, inside the

This system is very reliable with no risk of overheating and temperature differences by steam use.

**Product humidity**: 40÷70 RH%
Such value is obtained with sterilizer under vacuum condition to allow best conditioning of sterilization load.

Gas concentration inside the sterilizer: variable on the basis of used gas mixture and operating pressure.

<table>
<thead>
<tr>
<th>Gas concentration inside the sterilizer</th>
<th>Pressure (kPa)</th>
</tr>
</thead>
<tbody>
<tr>
<td>C= 600 mg/l 3.6 bar (360 kPa)</td>
<td></td>
</tr>
<tr>
<td>C= 500 mg/l 3 bar (300 kPa)</td>
<td></td>
</tr>
<tr>
<td>C= 400 mg/l 2.4 bar (240 kPa)</td>
<td></td>
</tr>
<tr>
<td>C= 300 mg/l 1.8 bar (180 kPa)</td>
<td></td>
</tr>
<tr>
<td>C= 250 mg/l 1.5 bar (150 kPa)</td>
<td></td>
</tr>
<tr>
<td>C= 200 mg/l 1.2 bar (120 kPa)</td>
<td></td>
</tr>
<tr>
<td>C= 150 mg/l 1 bar (100 kPa)</td>
<td></td>
</tr>
</tbody>
</table>

**DE LAMA OLIMPYA/EXP3**
Control, regulation, management and recording system equipped with high speed microprocessor:
- monitor LCD
- multifunction keyboard membrane type
- synoptic panel
- colour graphic printer with printout size A4
- serial interface
- wide programming and management of all process parameters

- up to 35 standard storable programmes
- self-diagnostic
- data holding in case of black-out
- possibility of connection to an external PC for real-time logger and data storage functions

On Customer’s request, **DE LAMA** can supply:
- customized systems able to interface with supervisors (SCADA) and external control facilities
- independent recording system for process data (according to European Standard **EN 1422**)

**Graphic of changes in mixture consumption (10% EtO + 90% CO₂) to different concentrations**
**CYCLE BASIC PHASES**

- Load of product to be sterilized
- Product heating by heated water circulating inside the jacket and by internal fans preventing stratification which make heat exchange easier.
- Pre-vacuum with value that can be automatically set up to 40 mbar (4 kPa) max.
- Vacuum leak test of the chamber before gas inlet
- Product conditioning by humidification up to a preset value
- Inlet of preheated and vaporized gas up to selected pressure value
- Sterilization with gas pressure constant holding for a preset time (up to 24 hours)
- Flushing by gas evacuation through vacuum pump and sterile air inlet (pulsations) for a prefixed number of times.

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**Functional diagram**

- **DE LAMA DLOG 931 type**
- Sterilizer DE LAMA DLOG 931 type, capacity 37734 lts., with hinged motorized door

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**Typical sterilization cycle**

- Conditioning 240'
- Sterilization 360'
- Flushing 60'

<table>
<thead>
<tr>
<th>Pressure</th>
<th>Temperature</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 bar (300kPa)</td>
<td>60°C (333 K)</td>
</tr>
<tr>
<td>2 bar (200kPa)</td>
<td>50°C (328 K)</td>
</tr>
<tr>
<td>1 bar (100kPa)</td>
<td>40°C (313 K)</td>
</tr>
<tr>
<td>0.2 bar (20kPa)</td>
<td>30°C (303 K)</td>
</tr>
</tbody>
</table>

**Diagrams:**
- Magnetic coupling fan
- Chamber
- CPU
- Steam generator
- EtO gas mixture bottle
- Heater of water recirculating inside the jacket
- Gas heater
- Air inlet
- Pressure transducer
- Temperature probes
- Humidity probe
- Separating tank
- Drain to be conveyed to neutralization system

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**Definitions:**
- **CPU:** Central Processing Unit
- **TE:** Temperature Elements
- **TP:** Temperature Probes
- **RH %:** Relative Humidity Percentage
- **Jacket:** Insulated outer shell of the sterilizer
- **Chamber:** Inner space where the sterilization process takes place
- **GAS INLET:** Point where gas is introduced into the system
- **HUMIDIFICATION:** Process of adding moisture to the air
- **VACUUM LEAK TEST:** Check for leaks in the system
- **AIR REMOVAL:** Process of evacuating air from the system
**AUXILIARY EQUIPMENT**

- Gas feeding, vaporizing and preconditioning equipment
- Microprocessor system for control of relative humidity
- Exhausted gas neutralization equipment
- Device for continuous monitoring of EtO pollution arising from eventual escapes of gas indoor

**OPTIONALS**

- Doors heating through hot water flushing
- Doors motorization system with electronic control
- Automatic translation system for doors opening/closing
- Internal ventilation system, with magnetic coupling fan groups, to optimize homogeneity conditions throughout the chamber (according to European Standard EN 1422)
- Gas injection pipes washing system by nitrogen flux
- Exhaust hoods for suction of eventual residual gas on doors opening
- Electronic gas weighing system
- ADPE explosion-proof execution for sterilizers under vacuum (DE LAMA DLOG/V)

**QUALITY CONTROL AND VALIDATION**

Equipment and relevant supervision systems are designed and manufactured to be easily validable in compliance with European Standard EN 550 and with quality standards for pharmaceutical processes required by FDA. Careful tests, specific controls and high technical professionalism in pre-validation activities assure that plants are fully in compliance with highest required standards.

**TECHNICAL DOCUMENTATION AND ADDITIONAL ACTIVITIES**

To complete the supply, plants are always provided with following basic documentation:
- installation and operation manuals
- P&I and technological diagrams
- dimensional drawings and lay-out
- bill of materials and components
- materials and calibration certificates

On request, DE LAMA supplies:
- FAT and SAT protocols/documentation for pre-validation
- Validation documentation customizable by the end-users
- Full documentation for EN or FDA activity of validation
- Theoretical/practical trainings reserved to Customers’ production and maintenance staff.

**ASSOCIATED EQUIPMENT AND ACCESSORIES**

TO COMPLETE THE PLANT

- Stainless steel trolleys for internal loading and external moving, trays and boxes
- Idle/motorized rollers internal conveyor for europallets
- Full customized systems for loads handling
DE LAMA advises that technical data and features indicated in this folder are subject to without notice, owing to the continuous development of the technology and the research in the field.

### TECHNICAL DATA

**ETHYLENE OXIDE (EtO) GAS STERILIZERS**

DE LAMA DLOG and DLOG/V type

<table>
<thead>
<tr>
<th>MODEL</th>
<th>CAPACITY lts.</th>
<th>CHAMBER INTERNAL DIMENSIONS</th>
<th>MAXIMUM WORKING PRESSURE abs. bar</th>
<th>LOADING CAPACITY IN EUROPALLETS (dimensions mm.800x1200)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>HEIGHT mm</td>
<td>WIDTH mm</td>
<td>DEPTH mm</td>
</tr>
<tr>
<td>DLOG 101</td>
<td>640</td>
<td>800</td>
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<tr>
<td>DLOG 201</td>
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<td>9000</td>
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</tbody>
</table>

**Notes:**
- Models indicated in above table are only some of standard sizing for DE LAMA DLOG and DLOG/V.
- Apart from the standard configurations indicated in the table, sterilizers can be proposed even with other dimensions, on request, according to Customer's production needs.
- Working parameters are for indication only and can be modified in relation to Customer’s working requirements.

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