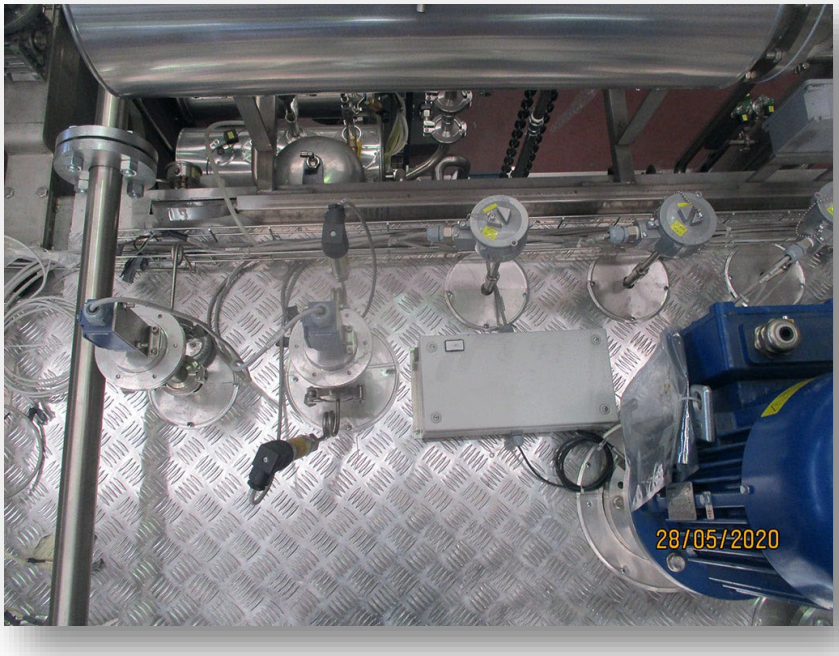
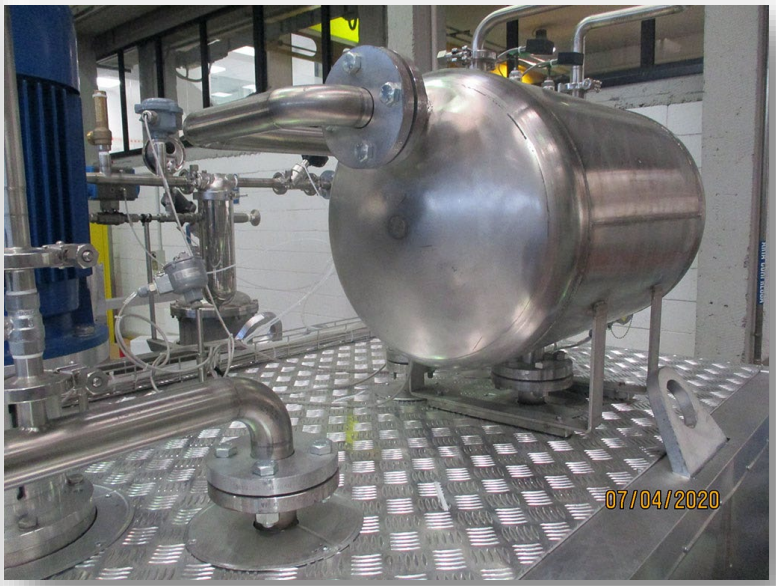
PHARMA WORKS MILANO S.R.L.
TECNOLOGIE REALIZZAZIONE FARMACEUTICHE

Semi-new machine available immediately

ETHYLENE OXIDE GAS (EtO) STERILIZATION AUTOCLAVE
DLOG 40-25 1S NF 4314

PHARMA WORKS MILANO S.R.L.
TECNOLOGIE REALIZZAZIONE FARMACEUTICHE






24/01/2019


26/05/2020


DE LAMA
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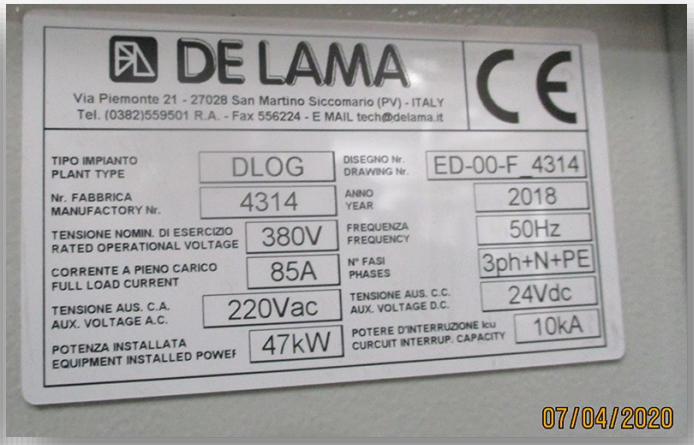
Phone +39 0382 559501 - www.delama.it
CE
INSIEME PED N.F.
PED ASSEMBLY M.N.
4314
CAMERA N.F.
CHAMBER M.N.
LT11176-1
QE NR
4314
GENERATORE N.F.
GENERATOR M.F.
ANNO
YEAR
2018
28/05/2020


DE LAMA
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Tel. (0382)559501 R.A. - Fax 556224 - E MAIL tech@delama.it
CE
TIPO IMPIANTO
PLANT TYPE
DLOG
DISEGNO Nr.
DRAWING Nr.
ED-00-F_4314
Nr. FABBRICA
MANUFACTORY Nr.
4314
ANNO
YEAR
2018
TENSIONE NOMIN. DI ESERCIZIO
RATED OPERATIONAL VOLTAGE
380V
FREQUENZA
FREQUENCY
50Hz
CORRENTE A PIENO CARICO
FULL LOAD CURRENT
85A
N° FASI
PHASES
3ph+N+PE
TENSIONE AUS. C.A.
AUX. VOLTAGE A.C.
220Vac
TENSIONE AUS. C.C.
AUX. VOLTAGE D.C.
24Vdc
POTENZA INSTALLATA
EQUIPMENT INSTALLED POWER
47kW
POTERE D'INTERRUZIONE Icu
CURCUIT INTERRUP. CAPACITY
10kA
07/04/2020

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FLUIDS DATA SHEET STANDARD DATA

TABLE No				FDS-00-F_4314	
CUSTOMER		JOB No.	16667	M.N.	4314
REV	1	DESCRIPTION	As built	DATE	20/09/18
REV	2	DESCRIPTION	As built after internal test	DATE	31/03/20

ITEM	DESCRIPTION	MEAS. UNIT	DIMENSIONS-DATA		
TYPE OF EQUIPMENT			DLOG		
CHAMBER DIMENSIONS		H x W x D mm	1300	900	2500
CAPACITY		liters	2925		
STERILIZING FLUID		type	ETHYLENE OXIDE MIXTURE ETO 10% CO2 90%		
PRESSURE		barg (kPa)	2,5	(350)	
TEMPERATURE		°C (K)	80	(353)	

ITEM	DESCRIPTION	MEAS. UNIT	DIMENSIONS-DATA		
Re. E1	DEMINERALIZED WATER SUPPLY STEAM GENERATOR FOR LOAD CONDITIONING				
	CONNECTION SIZE	ISO	ø	½"	(ø21,3mm)
	PRESSURE ±15%	barg (kPa)		0,5	(150)
	MAX TEMPERATURE	°C (K)		45	(318)
	PEAK REQUIRED FLOW RATE	l/min		0,1	
Re. E4	COOLING WATER SUPPLY VACUUMM PUMP CLOSED LOOP				
	CONNECTION SIZE	ISO	ø	½"	(ø21,3mm)
	PRESSURE ±15%	barg (kPa)		2	(300)
	MAX TEMPERATURE	°C (K)		15	(288)
	PEAK REQUIRED FLOW RATE	l/min		7	
Re. F	SOFTENED WATER SUPPLY VACUUM PUMP / CIRCUITS AND TANKS FILLING				
	CONNECTION SIZE	ISO	ø	½"	(ø21,3mm)
	PRESSURE ±15%	barg (kPa)		1	(200)
	MAX TEMPERATURE	°C (K)		20	(293)
	PEAK REQUIRED FLOW RATE (VACUUM PUMP OPEN LOOP)	l/min		15	
	REQUIRED QUANTITY JACKET AND HEATERS	l		1100	
	REQUIRED QUANTITY VACUUM PUMP CLOSED LOOP	l		35	
Re. J	GAS MIXTURE EtO 10% CO2 90%				
	CONNECTION SIZE	metric	ø	½" NPT	(ø21,3mm)
	PRESSURE ±15%	barg (kPa)		60	(6100)
	MAX TEMPERATURE	°C (K)		50	(323)
	PEAK REQUIRED FLOW RATE			SEE DWG T85082A	
	APPROX CONSUMPTION EACH CYCLE			SEE DWG T85082A	
Re. I	COMPRESSED AIR FOR CHAMBER PRESSURE LEAK TEST				
	CONNECTION SIZE	ISO	ø	½"	(ø21,3mm)
	PRESSURE ±15%	barg (kPa)		3,0	(400)
	PEAK REQUIRED FLOW RATE	n l/min (n m3/h)		300	(18)
Re. L	INSTRUMENTS COMPRESSED AIR				
	CONNECTION SIZE	QUICK CONNEC.	ø	8x6mm	
	PRESSURE ±15%	barg (kPa)		7,0	(800)
	PEAK REQUIRED FLOW RATE	n l/min (n m3/h)		50	(3)

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FLUIDS DATA SHEET STANDARD DATA

	TABLE No		FDS-00-F_4314
CUSTOMER	JOB No.	16667	M.N. 4314
REV 1	DESCRIPTION	As built	DATE 20/09/18
REV 2	DESCRIPTION	As built after internal test	DATE 31/03/20

ITEM	DESCRIPTION	MEAS. UNIT	DIMENSIONS-DATA		
Re. N	**INSTALLED ELECTRICAL POWER**				
	SYSTEM		**3PH+N+PE**		
	VOLTAGE ±5%	V	**400**		
	FREQUENCY ±5%	Hz	**50**		
	VACUUM PUMP POWER (INSTALLED)	kW	**4,0**		
	WATER HEATER POWER (INSTALLED)	kW	**24,0**		
	GAS HEATER or VAPORIZER POWER (INSTALLED)	kW	**10,0**		
	STEAM GENERATOR POWER (INSTALLED)	kW	**4,5**		
	TOTAL POWER (INSTALLED, HEATING TIME 8 h)	kW	**47,0**		
A5	**SEPARATING TANK WATER DRAIN**				
	CONNECTION SIZE	ISO	ø	**3/4"**	**(ø26,7mm)**
	MAX TEMPERATURE	°C (K)		**60**	**(333)**
Re. A6	**VACUUM PUMP DRAIN**				
	CONNECTION SIZE	ISO	ø	**1½"**	**(ø48,3mm)**
	MAX TEMPERATURE	°C (K)		**60**	**(333)**
Re. C	**JACKET AND TANKS WATER DRAIN**				
	CONNECTION SIZE	ISO	ø	**1½"**	**(ø48,3mm)**
	MAX TEMPERATURE	°C (K)		**60**	**(333)**
Re. F2	**COOLING WATER RETURN VACUUMM PUMP CLOSED LOOP**				
	CONNECTION SIZE	ISO	ø	**½"**	**(ø21,3mm)**
	MAX TEMPERATURE	°C (K)		**25**	**(298)**
Re. J1	**GAS EXHAUST TO THE BURNER**				
	CONNECTION SIZE	ISO	ø	**1½"**	**(ø48,3mm)**
	MAX TEMPERATURE	°C (K)		**60**	**(333)**
Re. VS	**CHAMBER GAS MIXTURE SAFETY VALVE OVERFLOW**				
	CONNECTION SIZE	GAS ISO228	ø	**1"**	**(ø33,4mm)**
	MAX TEMPERATURE	°C (K)		**60**	**(333)**
Re. VSG	**GAS LINE SAFETY VALVE OVERPRESSURE**				
	CONNECTION SIZE	GAS ISO228	ø	**1"**	**(ø33,4mm)**
	MAX TEMPERATURE	°C (K)		**60**	**(333)**
Re. VSRG	**GAS MIXTURE PRESSURE REDUCING VALVE LEAKAGE OVERPRESSURE CONNECTION**				
	CONNECTION SIZE	METRIC	ø	**6**	**mm**
	MAX TEMPERATURE	°C (K)		**60**	**(333)**
Re. SS4	**HUMIDIFIER SAFETY VALVE OVERPRESSURE**				
	CONNECTION SIZE	GAS ISO228	ø	**¾"**	**(ø26,7mm)**
	MAX TEMPERATURE	°C (K)		**105**	**(378)**
Re. SS5	**SEPARATING TANK RELIEF VALVE OVERPRESSURE**				
	CONNECTION SIZE	GAS ISO228	ø	**1"**	**(ø33,4mm)**
	MAX TEMPERATURE	°C (K)		**60**	**(333)**
	NOISE LEVEL	db	**<75**		

GENERAL NOTES:

AS BUILT UTILITIES CONNECTION POSITION SHALL BE AVAILABLE AT LEAST 7 DAYS BEFORE FAT DATE

VALUES RECOMMENDED FOR SOFTENED WATER SUPPLY FOR EQUIPMENT GOOD FUNCTIONNING:
HARDNESS: < 3°F (FRENCH DEGREES), MAXIMUM 15 °F(TO PREVENT SCALING)
Ph: MINIMUM 7 MAXIMUM 8. (TO PREVENT CORROSION)
USER HAVE TO INSTALL ON/OFF VALVE AND MECHANICAL/ABSOLUTE FILTER UPSTREAM PROCESS FLUID CONNECTION FOR SAFETY REASONS

CE CONFORMITY STATEMENT No. ECC-00-F_4314

De Lama S.p.A., head office in San Martino Siccomario (PV) - Via Piemonte 21 - V.A.T. number 00166040188, represented by Dr. **Paolo Bianchi** as C.E.O., declares on its own responsibility that the plant:

Ethylene Oxide sterilization autoclave DLOG type

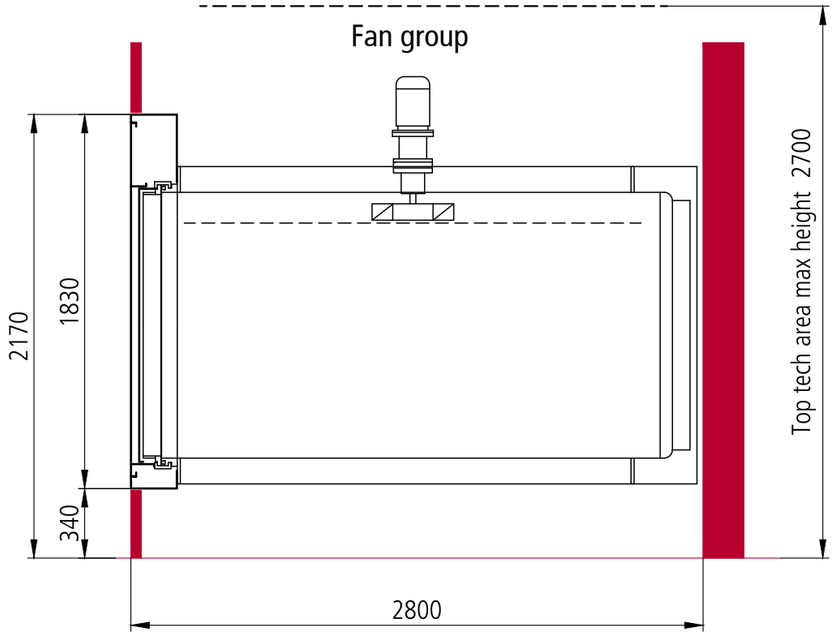
M.N. : 4314

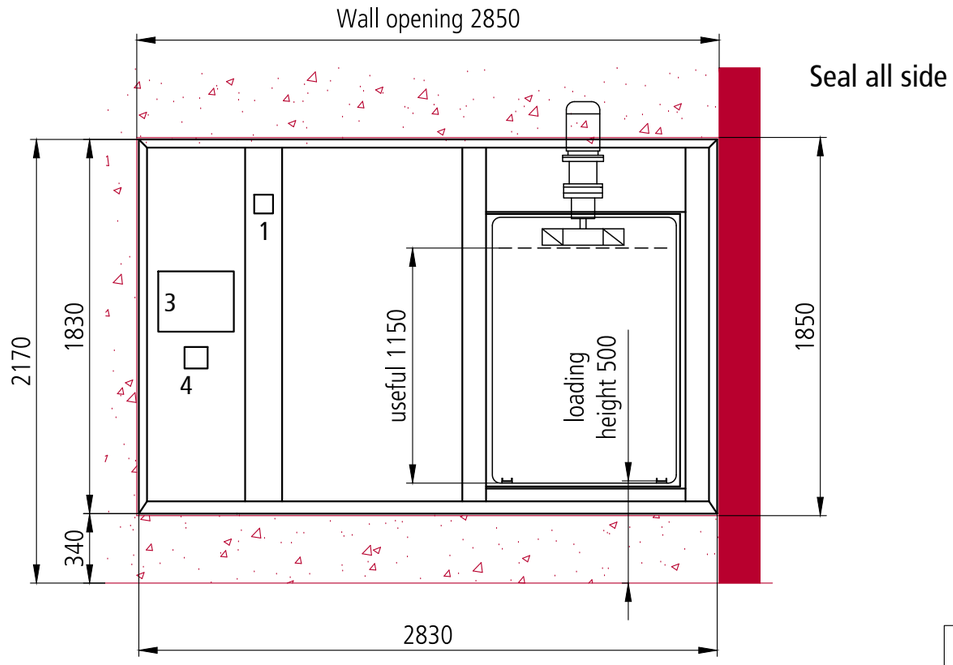
Job Nr. : 16667

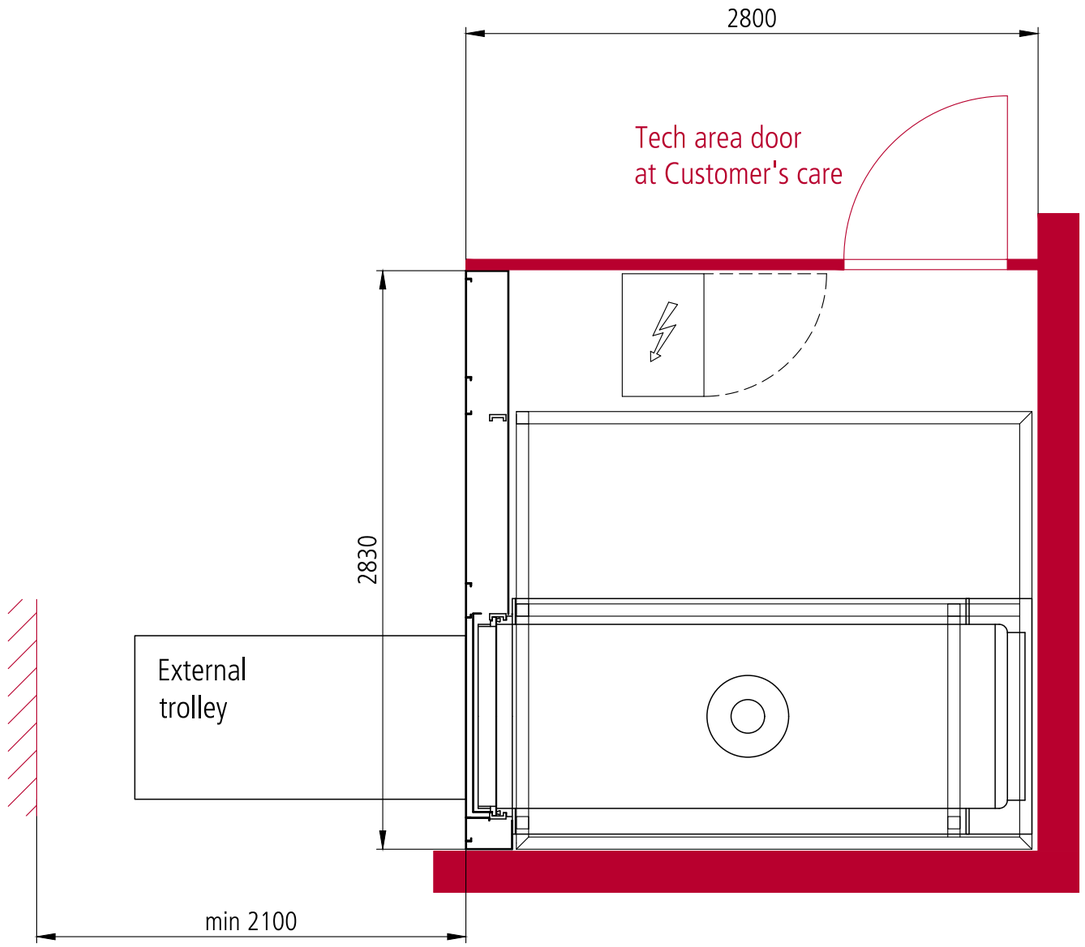
which this statement refers to, has been manufactured as hereunder described.

2006/42/EC - Machinery Directive
Directive 2014/30/UE - EMC Directive
Directive 2014/35/UE - Low Voltage Directive
UNI EN ISO 12100-1:2010 – Safety of Machinery
UNI EN ISO 13857: 2008 - Safety of Machinery – Safety distances …
UNI EN ISO 14738:2009 – Safety of Machinery – Anthropometric requirements …
UNI EN 349:2008 – Safety of Machinery – Minimum gaps to avoid crushing of ….
CEI EN 60204-1:2006 – Safety of Machinery – Electrical equipment …
CEI EN 61439-1:2011-10 – Low voltage switchgear and controlgear assemblies …
CEI EN 60445:2011-07 – Basic and safety principles for man-machine interface, marking, ... - Identification of equipment terminals …
Directive 2014/68/EU – Pressure Equipment Directive
UNI EN 1422:2014 Sterilizers For Medical Purposes – Ethylene Oxide Sterilizers….
UNI EN ISO 11135:2008 (where applicable) Sterilization Of Medical Devices. Validation And…
ATEX 2014/34/EU - European Directive Concerning Equipment And Protective Systems Intended For Use In Potentially Explosive Atmospheres

On Mandate of C.E.O.







Panel Instruments and equipments legend:
1 Pressure gauges
3 HMI
4 Keyboard
5 Printer to be placed at Customer's care

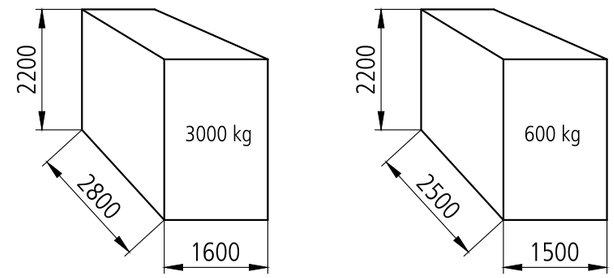
GENERAL NOTES:

Theoretical empty weight: 3600 kg
Theoretical hydraulic test weight: 6525 kg

The position of components inside tech area (e.g. fans, steam generator, electric board etc) could change upon detail design completion, even after Customer's approval.
Red colored elements are out of De Lama scope
For connections see fluids data sheet standard data

⚠ Safety devices

MINIMUM SIZES FOR PLANT ACCESS



Parts of the plant disassembled before shipment or to be reassembled on site to allow the plant entry into the installation room are not indicated in the above dwg

Dimensions (mm)	>0÷100	>100÷500	>500÷1500	>1500÷3000	≥3000
	±1	±5	±10	±20	±30

General tolerances

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Denomination
DLOG 1300x900x2500 1PSO
EQUIPMENT LAYOUT

Customer

Man.No. 4314

Job No. 16667

Draw. No. LAY-00-F_4314

Draw by CB
Contr by AMU
Appr by GB
Rev. 02
Scale 1:30

Rev.	Date	Rev. by	Revision description
01	25/07/18	CB	Issue
02	17/12/18	CB	As built
03			
04			

DE LAMA

Process & Sterilization Solutions since 1949

ETO STERILIZERS

DLOG & DLOG/V Series

The industrial low temperature autoclaves for treatment of temperature sensitive packed medical products (e.g. empty syringes, catheters, sutures etc.), antique books and furnitures

Parapharmaceutical Industry

Antiques

Archives

MAIN FEATURES

Wide range of chambers sizes and configurations

Heavy duty construction for industrial use

No-proprietary, high quality components

Compliant with the current International standards

SCADA Windows OS control system, CFR 21-Part 11

DESIGN, CONSTRUCTION & FUNCTIONAL FEATURES

- capacity from 640 lts up to 50 m^3
- design for installation on the floor or pit-mounted (for load direct introduction into the chamber)
- parallelepiped chamber in stainless steel
- jacket to optimize the temperature uniformity into the chamber through an original system for hot water circulation
- single or double door, hinged or automatically sliding, eventually heated through circulation of hot water coming from the jacket
- ventilator system, with revolution detector, to favour the best sterilant distribution inside the chamber and prevent sterilant stratification
- chamber piping and fittings in stainless steel
- circuit to heat water circulating inside the jacket
- sterilant pre-conditioning group for sterilant controlled evaporation from liquid to gas status
- steam generator for load humidification/ conditioning, prior to sterilant injection into the chamber, to allow sterilant best penetration into the load
- group for ETO and water separation on the exhaust line, inclusive of reduction and stabilization group for the gas conveyed to a combustor system
- air inlet absolute filter with 0,22 micron cartridge for chamber vent
- gas inlet filter with 50 micron cartridge for sterilant injection into the chamber
- entry connections for thermometry, vacuum test and sampling port to determine ETO concentration or RH value
- high grade thermal insulation
- built-in or separate electrical cabinet
- external panel/s in stainless steel
- pressure transmitter for pressure monitoring inside chamber
- thermoresistances Pt 100 Ohm class A EN 60751 for temperature monitoring/ regulation inside the chamber
- humidity/temperature transmitter for humidity monitoring inside the chamber
- wide range of alarms and safety devices to assure Operator protection and proper equipment operation
- thermal combustor system for exhausted gas elimination for enviromental protection (available on request)
- gas detector set up at different locations to monitor and alarm any leak of ETO (available on request)

DLOG EN 05/18

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DE LAMA

Process & Sterilization Solutions since 1949

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DESCRIPTION	PRICE EURO
AUTOCLAVE + ACCESSORIES	
1) No.1 ethylene oxide gas (EtO) sterilization autoclave **DLOG 40-25 1S** type working above atmospheric pressure - in pickled AISI 304 stainless steel execution - nominal internal dimensions mm.1300(h)x900(w)x2500(d) – gross volume 2925 lts. – one automatic horizontally sliding closing door. Features and concentration of sterilant : **up to 20% max. of EtO concentration**	INCLUDED
2) Body (chamber & door) execution in highly satin finish (Ra < 0,375 µm) AISI 316L stainless steel instead of pickled AISI 304 stainless steel (De Lama's standard)	INCLUDED
3) EXTRA for sterilizer execution with tight sealing system (bioseal) to isolate loading side from technical area (service door for access to technical area is at Customer's charge and care) **NOTE** : Sterilizer will be fitted with external panel on loading side only. External panels made of AISI 304 stainless steel even on the two sides will be eventually foreseen according to installation lay-out	INCLUDED
4) EXTRA for sterilizer demountable version (two-piece construction) to allow transport to Customer's facilities (delivered to site disassembled)	INCLUDED
5) EXTRA for autoclave configuration with application of a ventilator system useful to favour the best sterilant distribution inside the chamber and to assure a suitable effect preventing sterilant stratification. Group, located in the chamber upper sector, is composed of high efficiency magnetic fan/s, compliant with Ex execution, equipped with relevant accessories and ancillary devices. **NOTE** : Installation of ventilator group involves an housing space in chamber upper sector with consequent reduction of nominal internal height	INCLUDED
6) Steam generator for load humidification/conditioning, prior to sterilant injection into the chamber to allow sterilant best penetration into the load itself, with all relevant ancillary devices/accessories for a correct operation	INCLUDED
7) Control and management system **OLIMPYA/EXP9-TS** type, fitted with relevant ink-jet process printer and integrated touch screen, provided with standard S/W package to perform following automatic standard programs: ▪ **PROGRAM I** : control/utility program "chamber vacuum leakage test according to European Standard UNI EN 1422" ▪ **PROGRAM P** : control/utility program "chamber pressure leakage test according to	INCLUDED

DESCRIPTION	**PRICE EURO**
European Standard UNI EN 1422” ▪ **PROGRAM A_IP** : sterilization ▪ **PROGRAM B** : degassing System, composed of industrial PC + microprocessor based electronics (De Lama PLC), is CFR-21 Part 11 compliant. Thanks to system H/W configuration and S/W modularity, **Customer can store as many cycles as he wants with virtually no limits,** within installed programs. It is possible, therefore, to create a Customized library of cycles, stored with identification file names, with different parameters which can be selected by the Operator according to type of load. **NOTE** : System in standard configuration features a Ethernet I/F which allows the connection to existing remote PCs (or servers) or network printers. No additional S/W is required since the process controller runs under Windows® operating system. Network configuration has to be performed by the Customers on their own remote PC (or server).	
8) EXTRA for integrated DAS (Data Acquisition System), carried out directly by the PLC via an additional dedicated analogue board, to comply with European Standard EN 1422 (recording instrumentation independent from the automatic controller) : No.1 measuring point for pressure inside the chamber + No.2 measuring points for temperature inside the chamber + No.1 measuring point for humidity inside the chamber. Pressure, temperature and humidity recording will be performed by dedicated instruments: one pressure transmitter, two temperature sensors Pt 100 Ohm and one humidity transmitter fitted with relevant sensor	INCLUDED
9) Rails, made of AISI 316L stainless steel, placed inside the chamber, for trolleys/shelf racks rolling	INCLUDED
10) One set of loading/unloading accessories composed of: 10.1) No.2 in-chamber trolleys, made of AISI 316L stainless steel, CCA2 type - approx. dimensions mm.1110(h)x860(w)x1220(d) – suitably designed to support trays on adjustable levels and fitted with a number of brackets sufficient to house the purchased number of trays only. PRICE of each trolley is EURO 10.2) No.24 multipurpose perforated trays, made of AISI 316L stainless steel, MIC type - approx. dimensions mm.810(w)x1220(d)x50(h) PRICE of each tray is EURO 10.3) No.2 transfer trolleys, made of AISI 304 stainless steel, ETASS/A type – approx. dimensions mm.900(h)x800(w)x1620(d) PRICE of each trolley is EURO **NOTE** : Trolleys/trays load has been calculated on information available at present. Before issuing final offer (prior to Purchase Order), the load (quantity, dimensions and weight)	INCLUDED INCLUDED INCLUDED

DESCRIPTION	PRICE EURO
needs to be confirmed by the Customer in order to enable De Lama to perform the final verification of trolleys/trays actual loading capacity.	
OPTIONAL ACCESSORIES	
11) Gas feeding group typically composed of distribution manifold complete of high pressure on/off valves and flexible pipes between bottles and manifold	out of De Lama's scope of work
12) Thermal combustor system for exhausted gas elimination	out of De Lama's scope of work
DOCUMENTATION	
13) De Lama's standard FAT protocol "Factory Acceptance Test – Doc. ID : FAT-00-G_xxxx", in **English** language, to be filled out during FAT. FAT execution is separately indicated at ITEM 15).	INCLUDED
14) De Lama's standard IQ/OQ validation protocols, procedures and blank set of forms "Installation Qualification - Doc. ID : IQ-00-G_xxxx" and "Operational Qualification - Doc. ID : OQ-00-G_xxxx", in **English** language, to be filled out during IQ/OQ. IQ/OQ activities execution is out of De Lama's scope of supply.	INCLUDED
FAT / PACKING	
15) Factory acceptance test (FAT) by De Lama's premises in San Martino Siccomario (Pavia), prior to delivery of the sterilizer, witnessed by max. No.2÷3 Customer's inspectors: ▪ FAT execution with empty chamber, without load and with compressed air (instead of EtO) according to De Lama's standard document "Factory Acceptance Test – Doc. ID : FAT-00-G_xxxx" : No.2 days max. (No.8 working hours/day max.) ▪ De Lama's internal costs to perform FAT (including use of necessary accessories, instrumentation and utilities arrangement) ▪ Travel charges and hotel accommodation (board and lodging expenses) for Customer's inspectors ▪ Lunch expenses **NOTES** : a) In case staff in charge of FAT attendance is composed of more than No.2÷3 Customer's inspectors, De Lama reserve the right to decide to charge additional costs for management of such activities b) Should Customer require FAT execution with load/s, De Lama is available to supply relevant additional quotation (in this case, Customer has to specify number of loads	EXCLUDED

DESCRIPTION	PRICE EURO
and type/number of tests they are willing to perform). The supply of load/s and eventual consumables necessary to perform FAT at De Lama's workshop will be at Customer's full charge (such items will have to be sent to De Lama approx. 1 month before FAT beginning). Charges to send load/s to De Lama's premises and subsequent return are at Customer's charge. c) De Lama's staff involved in FAT activity will carry out : ✓ a training session to Customer's inspectors on equipment final positioning at site and on mechanical re-assembly ✓ a short training to Customer's inspectors on equipment working and maintenance	
16) Plant disassembling by De Lama's factory to allow transport to Customer's facilities	INCLUDED
17) Packing charges for autoclave with all quoted accessories	INCLUDED
TRANSPORT / ACTIVITIES ON SITE	
18) Equipment transport to Customer's factory (with relevant insurance), off-load and handling activities inside Customer's premises, eventual storage, unpacking, eventual lifting operations to bring equipment to final installation area, disposal of packaging materials and final positioning at site	at Customer's charge/ out of De Lama's scope of work
19) Equipment re-assembly on site (according to De Lama's instructions, indications and dwgs.)	at Customer's charge/ out of De Lama's scope of work
20) Equipment installation and connection of utilities to delivery points (according to De Lama's instructions, indications and dwgs.)	at Customer's charge/ out of De Lama's scope of work
21) IQ/OQ activities execution	out of De Lama's scope of work
22) PQ & Biological Qualification protocols writing/activities execution	out of De Lama's scope of work

EXCLUSIONS

Following additional items are out of De Lama's scope of supply:

- general construction works including civil, structural and architectural
- utilities inlet piping
- discharge/drain piping and vents
- external conveying system of the safety valve
- silicone sealing of eventual air tight system/s (bioseal/s) to walls and floor of the Customer's building
- connection cables, ducts and pipes between the autoclave and the gas feeding group (either if included or if out of De Lama's scope of supply), the autoclave and the thermal combustor system (either if included or if out of De Lama's scope of supply) and the autoclave and the air cooled chiller for vacuum pump closed loop circuit (either if included or if out of De Lama's scope of supply), together with relevant laying
- hydraulic and electrical connections between the autoclave and the air cooled chiller for vacuum pump circuit (either if included or if out of De Lama's scope of supply)
- optional equipment, accessories and activities not specifically indicated in the offer

ADDITIONAL REMARKS

◊ All documentation will be issued in English language on De Lama's forms and according to De Lama's templates. Should Customer require customized documentation involving overhauls of De Lama's standard documents or compliance with specific needs, De Lama is available to supply relevant additional quotation

◊ Unless differently specified by the Customer or in the URS, documents that will be submitted to Customer for their approval are the lay-out and the fluids data sheets

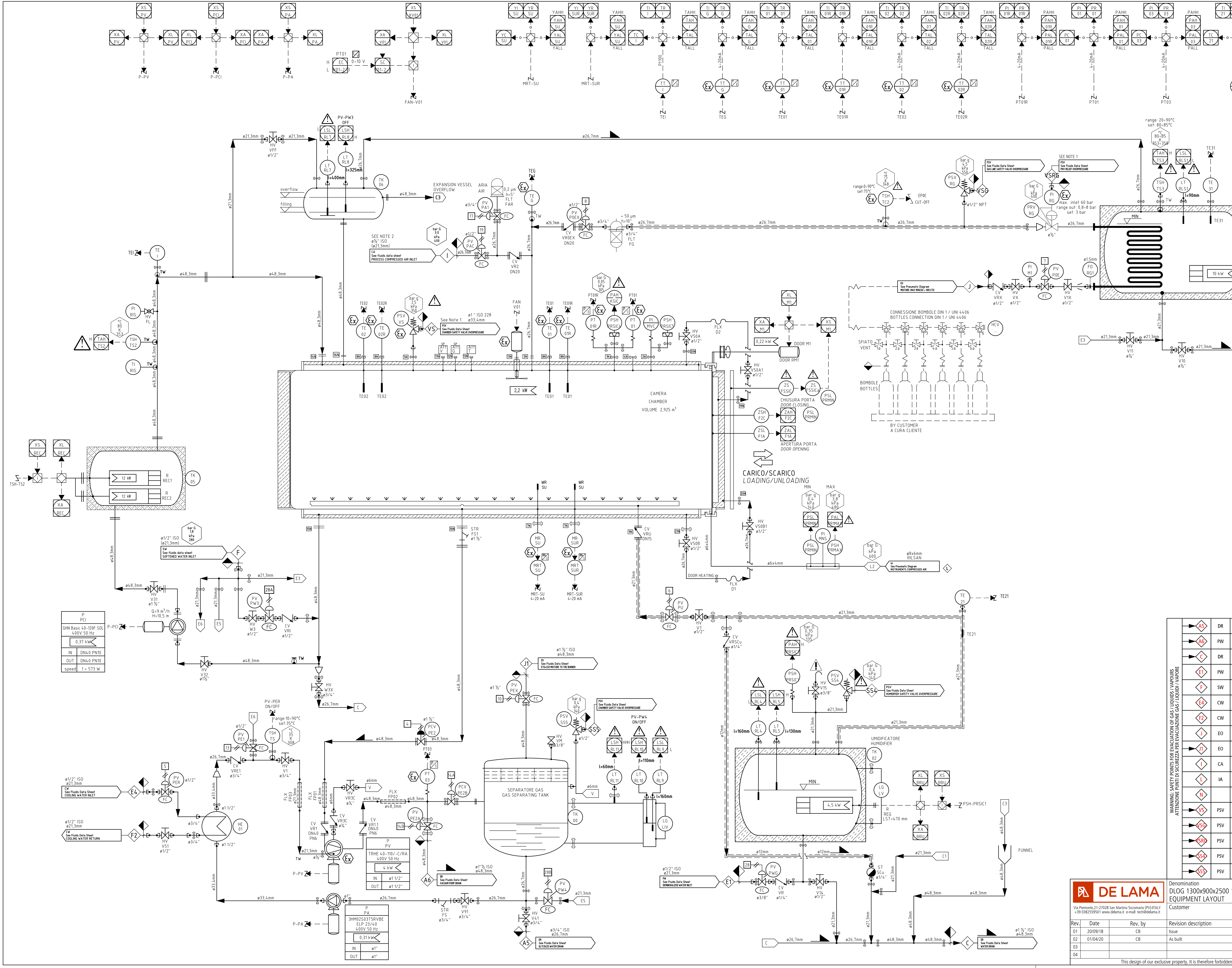
◊ De Lama will provide to inform Customer, suitably in advance, about plant ready for FAT. In case such activity cannot be performed within 30 days from De Lama notification, owing to Customer impossibility to be present, FAT will be carried out by De Lama engineers. In this case, such activities, not witnessed by the Customer, will have full contractual value.

◊ Activities on site (commissioning, start-up, etc.) performed by De Lama will be carried out according to De Lama's standard protocols. Should Customer require activities execution according to customized procedures involving overhauls of De Lama's standard protocols, De Lama is available to supply relevant additional quotation

◊ Any kind of activity included in the present offer, both free of charge or for a valuable consideration, has to be deemed tacitly no more feasible, at terms indicated in the offer itself, if it is not required and performed, for reasons not imputable to De Lama, within 24 months from shipping date. This is valid unless clauses otherwise agreed with Customer.
In case of performances already paid, payment has to be considered no more refundable.

SPECIAL TERMS OF SALE

DELIVERY TERM	EXW (Incoterms® 2010)
PACKING	as indicated in the priced offer



DE LAMA — CUSTOMER / CLIENTE: LIMIT OF SUPPLY / LIMITI DI FORNITURA

= TRICLAMP

= FLANGE

= THREAD

SLOPE / PENDENZA

NOTE

THE TYPOLOGY OF THE INDICATED CONNECTIONS IN THE DRAWING HAS THE PURPOSE TO IDENTIFY THE PRINCIPAL DISCONNECTION POINTS OF THE COMPONENTS (VALVES AND MAIN PIPE LINES) AND IT IS NOT REPRESENTATIVE OF THE AS BUILT PLANT PIPING.

LA TIPOLOGIA DELLE CONNESSIONI INDICATE NEL DISEGNO HA LO SCOPO DI IDENTIFICARE I PRINCIPALI PUNTI DI DISCONNESSIONE DEI COMPONENTI (VALVOLE E PRINCIPALI TRATTI DI TUBAZIONE) E NON E' RAPPRESENTATIVA DEL PIPING AS BUILT DELL'IMPIANTO.

CROSS-REFERENCE TO DOCUMENT / RIFERIMENTO AL DOCUMENTO

SAFETY DEVICES / DISPOSITIVI DI SICUREZZA

..N — REFERENCE TO CHAMBER CONSTRUCTION DRAWING / RIFERIMENTO DISEGNO COSTRUTTIVO CAMERA

NOTE:
FOR THE DESIGN AND SYMBOLS STANDARD APPLIED SEE DOC. PIDRK-00-G_0000 "P&ID READING KEY"
PER SIMBOLI E DESIGNAZIONI STANDARD APPLICATI VEDERE DOC. PIDRK-00-G_0000 "CHIAVE DI LETTURA SCHEMI P&ID"

WARNING: SAFETY POINTS FOR EVACUATION OF GAS / LIQUIDS / VAPOURS
ATTENZIONE PUNTI DI SICUREZZA PER EVACUAZIONE GAS / LIQUIDI / VAPORE

A5	DR	GLYCOLED WATER DRAIN SCARICO ACQUA/GLICOLE SEPARATORE
A6	PW	VACUUM PUMP DRAIN SCARICO POMPA A VUOTO
C	DR	WATER DRAIN SCARICO ACQUA
E1	PW	DEMINERALIZED WATER INLET INGRESSO ACQUA DEMINERALIZZATA
F	SW	SERVICE WATER INLET INGRESSO ACQUA DI RETE
E4	CW	COOLING WATER INLET INGRESSO ACQUA DI RAFFREDDAMENTO
F2	CW	COOLING WATER RETURN RITORNO ACQUA RAFFREDDAMENTO
J	EO	ETO+CO2 MIXTURE INLET INGRESSO MISCLEA ETO+CO2
J1	EO	ETO+CO2 MIXTURE TO THE BURNER MISCELA ETO+CO2 AL BRUCIATORE
I	CA	PROCESS COMPRESSED AIR INLET INGRESSO ARIA COMPRESSA PROCESSO
L	IA	INSTRUMENTS COMPRESSED AIR INLET ARIA COMPRESSA INDUSTRIALE
N		ALIMENTAZIONE ELETTRICA ELECTRIC SUPPLY
VS	PSV	CHAMBER SAFETY VALVE OVERPRESSURE SOVRAPRESSIONE VALVOLA SICUREZZA CAMERA
VSG	PSV	GAS LINE SAFETY VALVE OVERPRESSURE SOVRAPRESSIONE VALVOLA SICUREZZA LINEA GAS
VSRG	PSV	PRV RELIEF OVERPRESSURE SOVRAPRESSIONE PRV GAS
SS4	PSV	HUMIDIFIER SAFETY VALVE OVERPRESSURE SOVRAPRESSIONE VALVOLA SICUREZZA UMIDIFICATORE
SS5	PSV	GAS SEPARATOR SAFETY VALVE OVERPRESSURE SOVRAPRESSIONE VALVOLA SICUREZZA SEPARATORE GAS

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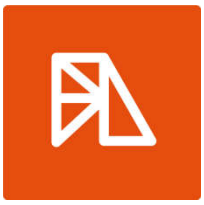
Denomination
DLOG 1300x900x2500 1PSO
EQUIPMENT LAYOUT

Customer

Rev.	Date	Rev. by	Revision description
01	20/09/18	CB	Issue
02	01/04/20	CB	As built
03			
04			

Man.No. 4314 — Job No. 16667 — Draw. No. PID-00-F_4314 — Rev. 02 — Scale n/a

Draw by CB — Contr by AMU — Appr by GB



User Manual

DLOG

JOB:n/a M.N.:n/a

Document ID : UM-00-G_DLOG
Revision: 6
Revision date: 30-Mar-18

Prepared by:

Your signature indicates that the document has been prepared in compliance with existing project standards and accurately reflects the requirements to be fulfilled for the operation of the system.

Name	*Title*	*Company*	*Signature*	*Date*
A. Dragoni	*Process Engineer*	*De Lama S.p.A.*		30/03/2018

Reviewed by:

Your signature indicates that, as a content expert, you have reviewed this document and it accurately and completely reflects the requirements necessary to implement the system

Name	*Title*	*Company*	*Signature*	*Date*
A. Muggiasca	*Technical Manager*	*De Lama S.p.A.*		30/03/2018

Approved by:

Your signature indicates that you have approved the document

Name	*Title*	*Company*	*Signature*	*Date*
G.Botteri	*Q.A.*	*De Lama S.p.A.*		30-03-2018

Customer's Review and Approval

Your signature indicates that you have reviewed the document and that you agree that this document is found to be complete and accurate for the referenced equipment and that you approve the document.

Name	*Title*	*Company*	*Signature*	*Date*

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Applicable documents

[1] N/A

Revision History

Issue	Date	Revised by	Revised chapters	Revision Description
1	26-11-2008	C. Bordoni	N/A	First Emission
2	28/07/2011	A. Monegato	All	General Revision
3	04/02/2013	C. Bordoni	All	General Revision
4	17/12/2014	A. Dragoni	All	Residual risk added Routine plant maintenance Added notes installing safety valves
5	28/07/2017	A. Monegato	All	Updated Pressure Vessel codes
6	30/03/2018	A. Dragoni	Chapter 7.3	Added ID 62

Any difference between this document and any previous document must be resolved in favor of the current version.

CONTENTS

1. Introduction

This document describes the operating and maintenance modes for the series of sterilizers known as "DLOG".
The technical and design specifications for the plant are given in the *'Equipment Data Sheet'* document.
While reading this document we strongly recommend consulting all the relevant contract documents included in the relevant Technical Folder.

1.1. Purpose

This manual provides instructions on using the DLOG series of sterilizers and it specifically describes:

- The make-up of the equipment
- Installing and starting the plant
- The safety devices used
- Maintenance

All the information contained in this manual is of use for defining correct use of the machine.

1.2. Acronyms

This manual provides instructions on using the DLOG series of sterilizers and it specifically describes:

PPE: Personal Protection Equipment
GMP: Good Manufacturing Practice
PCS: Process Control System
PWM: Pulse Width Modulation
PLC: Programmable Logic Controller
URS: User Requirement Specification
UPS: Uninterruptible Power Supply

1.3. Symbols Used

The document uses symbols that are used to highlight and/or help the reader to understand the manual better. They are used to indicate the following:

*The **Stop** sign highlights all information that must be read carefully to avoid possible risks to people and/or equipment.*

*The **Warning** sign indicates all operations that could damage the equipment and, in some cases, the operators.*

*The **Lamp** highlights all instructions that are useful for better running of the equipment.*

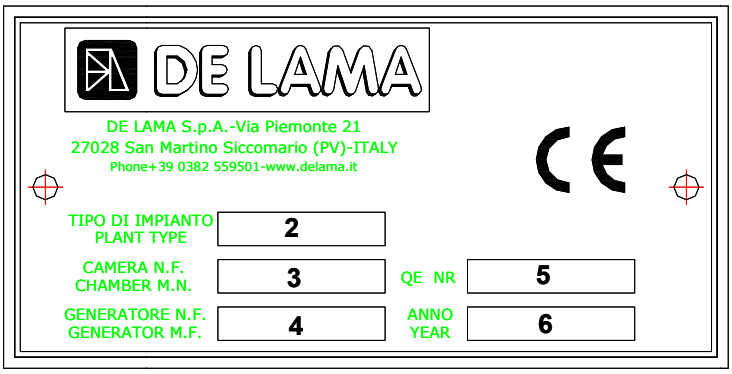
2. Identification of the equipment

The following plates are fixed on the plant:

- Plant data plate
- Data plate for the pressure vessel – **sterilizer body (2014/68/EU)**
- Data plate for the pressure vessel – **steam generator, if fitted (2014/68/EU)**
- **Electrical panel** data plate.

2.1. Plant data plate

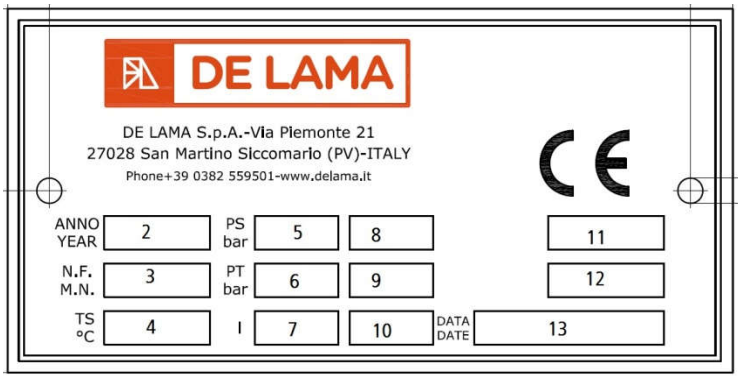
This plate contains all the essential data for recognising and tracing the critical components that make up the plant. It is fitted on the plant in the technical room and is used to identify the product / equipment as a whole, and indicates:



- (2) Plant TYPE identity
- (3) Sterilizer CHAMBER Manufacturer's Number
- (4) STEAM GENERATOR'S Manufacturer's Number (if fitted)
- (5) ELECTRICAL PANEL Serial Number
- (6) Year of Construction

2.2. Data plate for pressure vessel (97/23/CE)

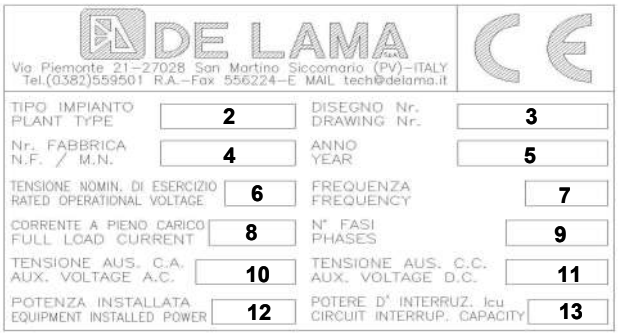
The pressure vessel /equipment (**sterilizer** or **steam generator**) is fitted with a data plate in compliance with European Directive 97/23/CE. It is fixed to the pressure vessel in a visible position using rivets. This plate bears the following information:



- (2) Year of Construction
- (3) Pressure vessel Manufacturer's Number
- (4) Design temperature in °C
- (5) Chamber design pressure in bar
- (6) Sleeve design pressure in bar
- (7) Chamber hydraulic test pressure in bar
- (8) Sleeve hydraulic test pressure in bar
- (9) Chamber volume in litres
- (10) Sleeve volume in litres
- (11) not applicable (blank field
- (12) Identity number for the Notified Body for Directive 2014/68/EU
- (13) Pressure vessel hydraulic test date

2.3. Electrical panel data plate.

The electrical panel is fitted with a data plate that contains all the basic electrical data.
It is positioned on the door or fixed cover of the panel, and indicates:



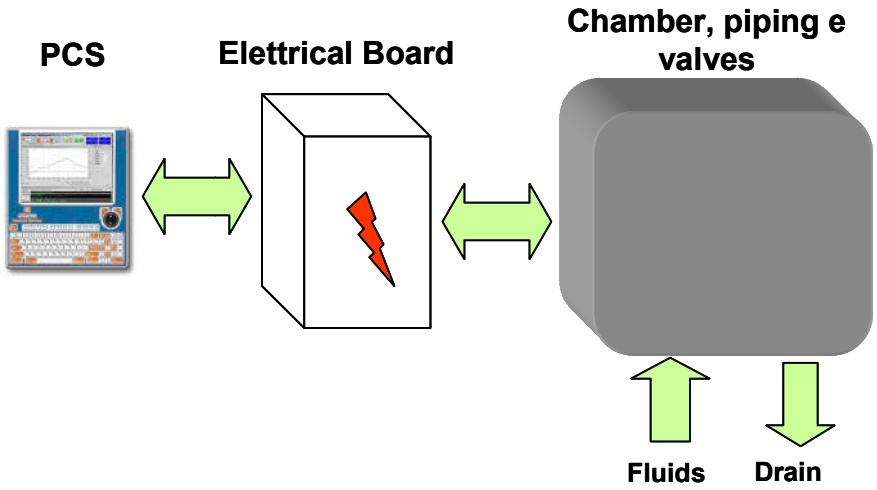
- (2) Plant TYPE identity (e.g. DLOV)
- (3) Wiring diagram number
- (4) (Sterilizer) Plant Manufacturer's Number
- (5) Year of Construction
- (6) Working voltage
- (7) Working frequency
- (8) Maximum current absorption
- (9) Number of power supply phases
- (10) Voltage of alternating current auxiliary circuits
- (11) Voltage of direct current auxiliary circuits
- (12) Plant power rating in kW
- (13) Maximum permissible short-circuit current in kA

3. Equipment description and use

The DLOG series of sterilizers can be used to sterilize products in compliance with the most recent national and international directives.
They are essentially made up of a chamber of suitable thickness fitted with connections and the relevant valves for managing the planned fluids in the chamber.
The figure below gives an example of a typical DLOG series machine.

Note:
See your construction drawings for further details (layout, P&ID, etc.).

- The figure below shows the principal parts that make up the sterilizer.



3.1. Sterilisation chamber and connected plumbing system

The sterilisation chamber is a pressure vessel used to house the product that must be treated.
It is made of stainless steel plating, the thickness of which is defined on the basis of structural calculations, and a suitable finish.
The product is fed into the chamber via a loading port and drawn off after the sterilisation cycle via the discharging port in a suitably classified room.
Where the sterilizer only has one port, the product to be sterilized is fed in and removed on the same side.
Access to the process fluid chamber and the related discharges is controlled on the basis of the sterilisation process by means of suitable actuators and other suitable devices.
The piping that makes up the plant is made of stainless steel, with a suitable interior finish.
See the mechanical construction drawings and P&ID diagram for further details.

3.2. Electrical panel

The power electrical panel contains all the parts required for controlling the devices used to control the process to be carried out.
All the control logics are run by the PCS process controller. The electrical panel is therefore used to convert the control signals into power implementations.
Another important function of the electrical panel is that of managing all safety aspects by means of specific systems type-approved for these purposes.

3.3. Control system

The sterilizer is controlled fully automatically by a special control system. The following range of control systems can be installed:

- Master-6
- Olimpya EXP-9
- Olimpya EXP-5
- OlimpyaWP
- OlimpyaWP-TS
- WinPlus
-

Having identified which system is fitted on your machine, see the specific User Manual provided.

4. Installation

This section provides the sterilizer installation instructions.

4.1. Ambient and working conditions

This sterilizer is designed to be able to work correctly under the following ambient conditions.
Ambient conditions:

Working temperature	0 to + 40°C
Working relative humidity	8 to 85% N.C.
Working altitude	max 2400 metres
Storage temperature	-10°C to +60°C

Important Notes:

(a)
We strongly recommend installing the equipment where the ambient temperature will be between 15°C and 30°C. Installing it under these conditions makes it possible to minimise errors due to temperature fluctuations.
(b)
The installation must be such that the correct air changes are guaranteed in the technical room. This makes it possible to keep the temperature of all electrical, electronic, or instrumentation devices within the correct temperature range.

4.2. Removing the packaging and positioning

The plant is packed in a special container that must be removed.

Pay maximum attention to safety aspects when removing the packaging and positioning the machine.
Handling and levelling operations are ONLY to be carried out by expert personnel using adequate equipment that is in good condition, as well as the necessary PPE.

Once the packaging has been removed, the following operations must be carried out:

- Check that the maximum permissible load for the installation area is greater (with a reasonable safety coefficient) than the weight of the sterilizer (see layout).
- Handle the plant safely using adequate lifting equipment that is in good condition. Use the lifting lugs provided on the upper part of the sterilizer to lift the unit.
- Position the plant in the work area marked out.
- Level the plant correctly using the adjustable feet and alignment spacers that are to be placed under the feet.
- Remove all mechanical stops on the doors, used to prevent unplanned movements in transit and during handling.
- Remove all plastic films used to protect the panelling.
- Check the position of the electrical connection according to the layouts.
- Check all the process fluid connections and the related pneumatic connections according to the layouts.

For general indications on installation conditions and process fluid connections, see the Installation Layout.

4.3. Fluid connections

In order to form the process fluid connections correctly, reference must be made to the following design documents:

- Fluid table provided with the plant
- Plant P&ID

Comply with all the indications relating to the physical and chemical characteristics of the feed fluids and the diameters of the lines shown in the documents referred to above.

From a safety point of view and on the basis of obligatory norms, the Employer is responsible for correct installation of the plant and the feed fluids on the basis of the information contained in this manual and the relevant technical documents.

4.4. Electrical connections

In order to form the electrical connection correctly, reference must be made to the following design document:

- Plant wiring diagram

Comply with the indications relating to cable sections given in the document referred to above.

The electrical connection is ONLY to be made by qualified personnel.

5. Starting the plant

5.1. Preliminary operations

All the fluids have been connected up as indicated in the plant P&ID and the electrical connections have been formed according to the requirements laid down in the wiring diagram. The following preliminary checks must now be carried out.

5.1.1. Fluid check

Open the operating fluids and check that there are no leaks. Also check that the clamps for the process fluids are connected correctly.
Use the plant P&ID and the fluids table for further details.

THE SYSTEM IS NOT SUPPLIED OF MANUAL SHUT-OFF VALVES FOR ALL FLUIDS LOCKABLE. SHUT-OFF VALVES, IF ANY, ARE REPRESENTED ON THE P&I PROVIDED IN THE DOCUMENTATION. BEFORE BEGINNING MAINTENANCE WORK MAKE SURE THE VALVE POWER OF ALL FLUIDS ARE CLOSED TIGHTLY

5.1.2. Power supply and UPS system

Check that the mains power is on and the UPS power supply (*Note #1*) with the help of the plant wiring diagram.

These operations are ONLY to be done by qualified personnel.

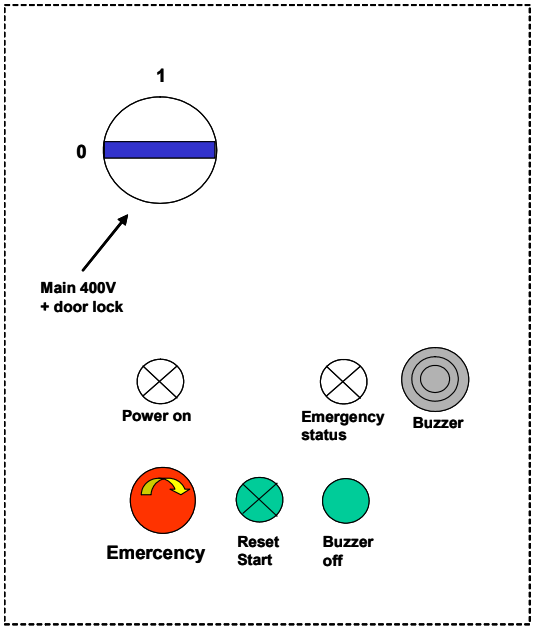
The power supply to the control system runs via a UPS that can be set up in the following ways:

- A built-in UPS with batteries inside the panel.
- A centralised building (220 Vac) UPS

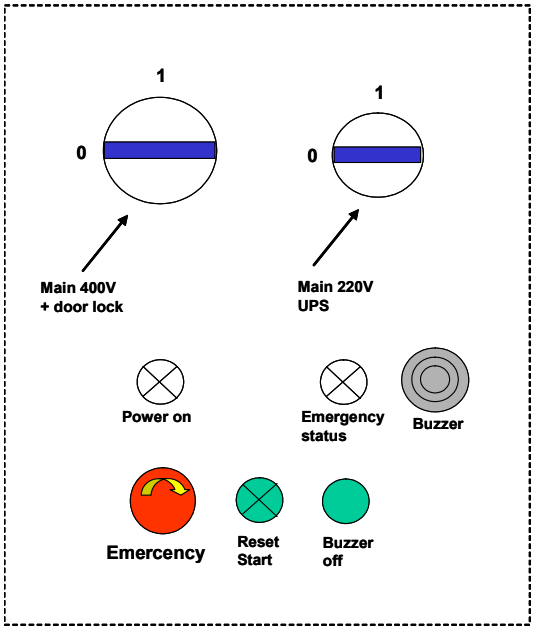
In the first case check the correct connection of the battery(ies) inside the electrical panel, while kin the second case check that there is a centralised 220 Vac line connected to a two-pole switch on the electrical panel.

The figures below show the devices normally installed in the machine's electrical panel inside the technical room.

Built-in UPS:



Centralised building UPS:



STOP

WARNING: The general UPS can be on even when the electrical panel door is open. Be very careful

Description of controls:

Device	*Description*
Main 400 v + door lock	*Switches on the mains power to the electrical panel. When in position '1' the door cannot be opened.*
Main 220 V UPS	*Switches on the 220V UPS power (only for the centralised UPS option)*
Emergency	*Emergency button with reset release*
Reset Start	*Lit button for starting the emergency safety unit (must be pushed after each emergency event)*
Buzzer off	*Used to silence the buzzer (not always included)*
Power On	*LED that switches on when the power is on.*
Emergency status	*LED that switches on when an emergency status arises*

5.1.3. Motor rotation check

Once the main switch on the electrical panel has been switched on, check that the motors rotate in the correct direction, using the controls provided.
The plant wiring diagram must therefore be used to identify the motor remote controls and these must be activated manually for a few seconds. If the check reveals that the rotation direction is wrong, invert two cables in the three-phase power supply triad on the machine input terminals.

These operations are ONLY to be done by qualified personnel.

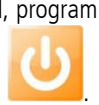
5.1.4. Removing mechanical door blocks

To avoid unexpected movements of the doors in transit, blocking devices are fitted in the factory and must be removed before the plant is commissioned. Check for them and, if they are still in place, remove them.

Failure to remove ALL the mechanical blocks may cause serious damage to the movement and safety systems fitted on the plant.

5.2. Switching on the control system

After power on electric panel, it's possible to turn on the machine using key-switch  placed on system sterilization frontal panel or on remote control rack; after inserting operating system password, program will be started automatically.

Power on is done by pressing more than 3 seconds the ON-OFF key-switch  .
The possibility of turning on is shown by the led on power on key-switch (blinking every 5 seconds). During the turning on the led blink quickly together with a buzzer sound. The correct powering on is shown by the led always on.

*For further details see the specific manual for the **Control System** fitted in your plant.*

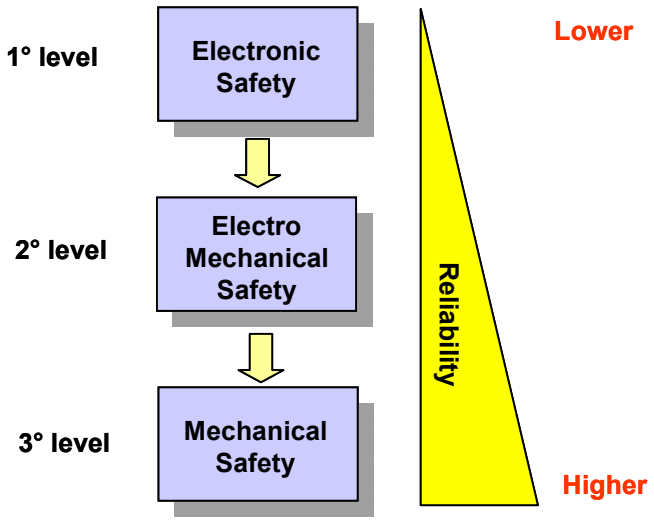
6. Detailed plant description

This section of the manual provides a detailed description of the plant, especially as regards all safety aspects.

6.1. Safety devices

The sterilizer is fitted with all the safety devices required to avoid possible risks to the operators. Generally, there are three levels of safety that are always active, that is:

- Electronic safety managed by the control system
- Electrical safety managed electro-mechanically by the electrical panel.
- Mechanical safety managed by devices that are able to work even when the power supply is off.



6.1.1. Electronic safety devices

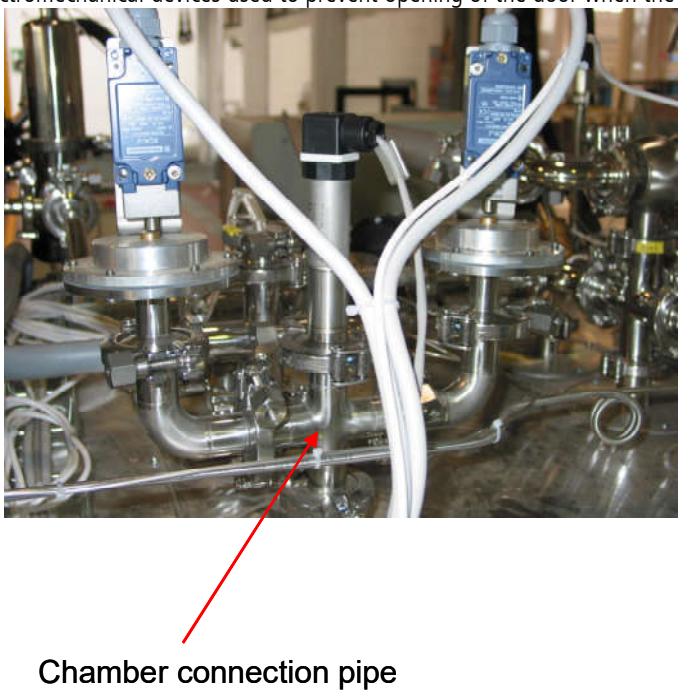
The first group of safety devices is managed directly by the control system. If these devices are activated, the control system does not allow the action requested and provides the relevant alarm message.

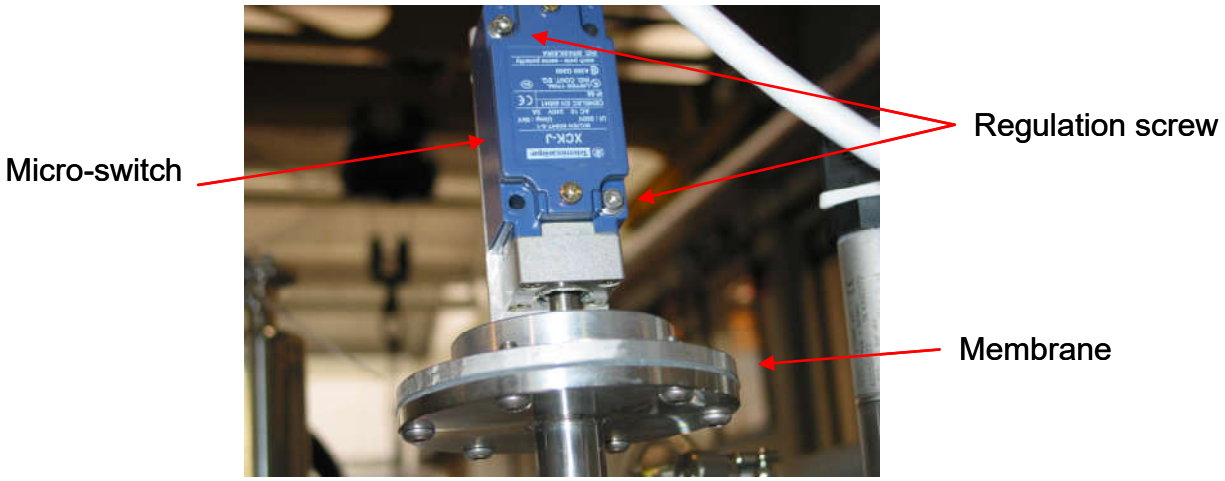
6.1.2. Electro-mechanical safety devices

The second group of safety devices is made up of suitable interlocking devices that are able to directly manage safety actions autonomously. In this case too, the device activated sends an alarm message to the control system.

6.1.2.1. High chamber pressure

The figure below shows the electromechanical devices used to prevent opening of the door when the chamber pressure is high.





This system is made up of two micro-switches activated by a membrane. If the chamber pressure is more than 5 mbar higher than the atmospheric pressure, the system prevents the doors being opened. If the devices are activated, the PCS displays the relevant message.

Regulation of the activation threshold is done by adjusting the screws indicated in the figure.

Warning! The setting on the high pressure system must be checked every six months. The pressure regulation must not exceed 40-50 mbar. It is also important to check the condition of the membranes periodically and, if necessary, to replace them.

6.1.3. Mechanical safety devices

The third group of safety devices is activated by the mechanical force generated by the pressure in the chamber, and activation of these devices is signalled by the control system. The only device of this type is the safety valve that can intervene when there is high pressure in the chamber.

6.1.3.1. Safety valves

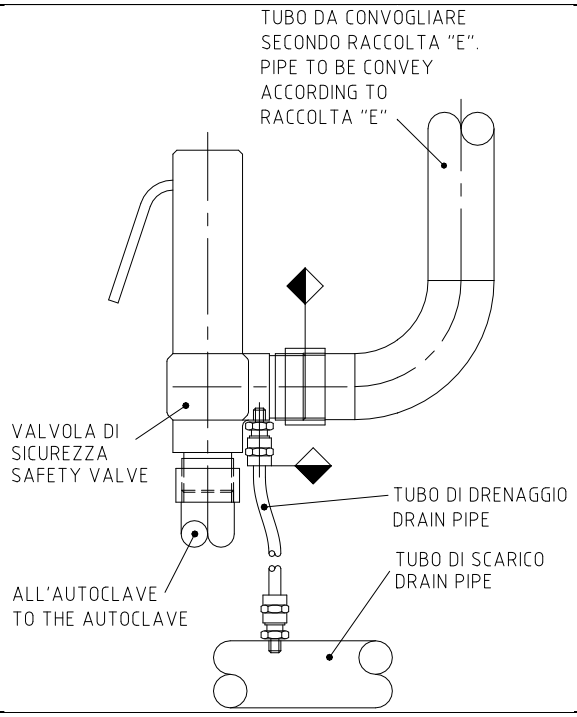
The plant is fitted with safety valves that are suitably sized to comply with regulations in the sector.
A safety valve has been installed for each pressure vessel.
More specifically, the plant is fitted with the following valves:

- Chamber safety valve
- Sleeve safety valve (if fitted).
- Steam generator safety valve (if fitted).

The safety valves fitted are certified according to the PED directive (97/23/CE), have a manufacturer's serial number, and are covered by a certificate with the same number. The valve setting is strictly related to the design pressure for the pressure vessel.
The documents for the safety valves fitted (sizing calculations, certificates, and "OPERATING AND MAINTENANCE MANUAL") are included in the "PED Conformity Declaration" dossier that is included among the annexes to this manual.

6.1.3.1.1. Installing the safety valves

For installation instructions for the safety valves see the valve Manufacturer's "OPERATING AND MAINTENANCE MANUAL".
To connect the discharges correctly, proceed as indicated below.



The discharge from safety devices MUST be set up to prevent damage to people or property.

In cases in which the chamber is used to treat highly polluted material (HP cycle), the discharge from the valve must be conveyed into a suitable chemical trap, installed by the user. The steam excess pressure discharge pipe MUST be connected to the outside air in order to avoid excessive transfer of heat into the area in which the plant is installed.

The safety valve's excess pressure discharge pipe MUST be securely fixed to the construction's structure.

The piping used to convey the discharge must be as short as possible (maximum 4 times the diameter of the safety valve connection).

If the discharge piping is longer than the maximum dimension, suitable supports must be fitted (so as not to impose loads on the valve due to external forces), in order to support the weight of the piping itself and the reaction forces caused by the discharge pressure.

EXHAUST SAFETY VALVES MUST BE CONVEYED, INDIVIDUALLY OR THROUGH MANIFOLD, IN A SAFE PLACE IN COMPLIANCE WITH THE LAW. PIPE CONVEYING MUST HAVE A PROPER SECTION SO AS NOT TO GENERATE BACKPRESSURE ON THE EXHAUST.

THE CALCULATIONS CONCERNING THE PRESSURE AND THE RESPECT OF THE COLLECTION "E", ARE NOT RESPONSIBILITY OF DE LAMA.

UNDER NO CIRCUMSTANCES MUST THE SEAL BE TAMPERED WITH TO CHANGE THE SETTING OR OPEN THE VALVE ITSELF.

6.1.3.1.2. Routine checks

The safety valves must be checked and maintained periodically to guarantee that they function correctly.
For further details see the valve Manufacturer's "OPERATING AND MAINTENANCE MANUAL", indicated on the back of the valve certificate.

These checks are ONLY to be done by qualified personnel.
These tasks are ONLY to be done:

- *After having disconnected the service fluids.*
- *When the chamber and sleeve pressure is equal to the atmospheric pressure.*
- *After the ports to the chamber have been opened.*
- *At a plant temperature of less than 25°C.*

6.1.3.1.3. Changing safety valves

The safety valve is the most important safety component on the plant. It is chosen and sized in relation to the physical characteristics of the feed fluid to the sterilizer and the design characteristics of the pressure vessel.
If it has to be changed, follow the instructions below.

When changing a safety valve ONLY use certified devices that have the same technical characteristics as the original valves.
In case of doubt, contact De Lama S.p.A's Technical Department.
De Lama S.p.A. IS NOT RESPONSIBLE if the valve is changed by anyone else.

Changing is ONLY to be done by qualified personnel.
This task is ONLY to be done:

- *After having disconnected the service fluids.*
- *When the chamber and sleeve pressure is equal to the atmospheric pressure.*
- *After the ports to the chamber have been opened.*
- *At a plant temperature of less than 25°C.*

6.1.4. Visual safety devices

Along with the automatic safety systems, the plant is fitted with instruments that display the pressure of the various devices installed.
These instruments are considered to be safety accessories and as such are chosen by the manufacturer on the basis of their functional characteristics.
More specifically, the following pressure gauges are fitted to measure:

- Chamber pressure
- Sleeve pressure (if fitted).
- Steam generator pressure (if fitted).

Instruments installed:

THE RANGE OF THE PRESSURE GAUGES INSTALLED MUST BE BETWEEN 1,5 AND 2 TIMES THE DESIGN PRESSURE AND THE SETTING FOR THE SAFETY DEVICES.

IF A PRESSURE GAUGE HAS TO BE CHANGED ONLY USE CALIBRATED DEVICES WITH THE RELEVANT CERTIFICATES AND THE SAME TECHNICAL CHARACTERISTICS AS THE ORIGINAL PARTS. IN CASE OF DOUBT, CONTACT DE LAMA S.P.A'S TECHNICAL DEPARTMENT.
DE LAMA S.P.A. IS NOT RESPONSIBLE IF THE PRESSURE GAUGE IS CHANGED BY ANYONE ELSE.

6.1.5. Emergency system

All equipment in the DLOG series is fitted with suitable emergency buttons that are connected to the relevant safety units (Pilz or equivalent).
The emergency buttons are normally positioned on the front of the machine's panels and on the electrical panel.

If the emergency button is pushed under '*off cycle*' conditions, the '**RESET START**' button must be pushed on the electrical panel.

All emergency situations must be handled by expert personnel that have been trained on how the plant works. Remember that sterilizers are essentially made up of pressure vessels that are potentially dangerous for personnel working with them. In case of doubt, or for explanations, contact De Lama S.p.A. directly.

6.1.6. Blackout

A blackout status arises every time the main power supply to the plant is interrupted. To avoid this problem the entire PCS part is powered via a suitable UPS.

6.1.6.1. Managing blackouts

The (PCS) control system continuously monitors the main power supply (400 Vac). Should this power supply fail a blackout strategy must be adopted.

The PCS is therefore powered by the UPS and continues to correctly record all the analogue process values.
When the power supply is restored, the PCS automatically resets the emergency safety unit to allow the equipment to start up again.
The following information is also recorded by the PCS:

…
Start blackout <date_and_time>
…
End blackout <date_and_time>
…

NOTE:
<Date_and_time> indicates the date and time of events.

If the blackout continues for a time that is longer than the batteries' capacity, be very careful before opening the doors.

Never attempt to force the safety devices that prevent the doors being opened after a blackout.

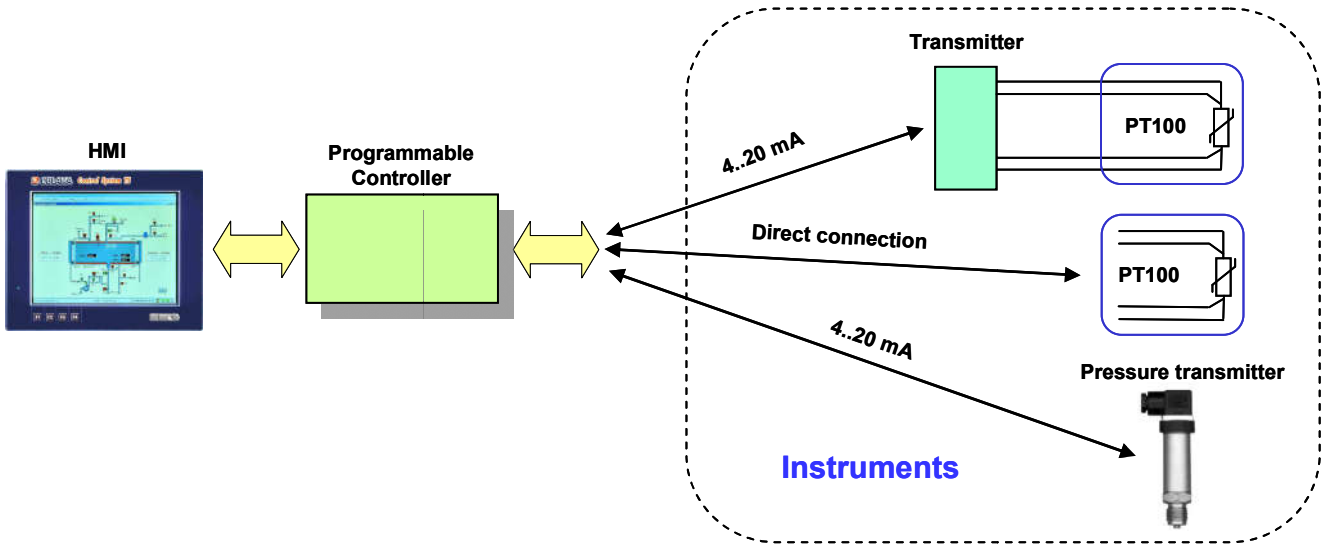
6.2. Instruments connected to the PCS and positioning of the same

The control system uses various types of sensors and transducers to manage the process. The instruments used in the DLOG series of equipment can be divided into two groups as indicated below:

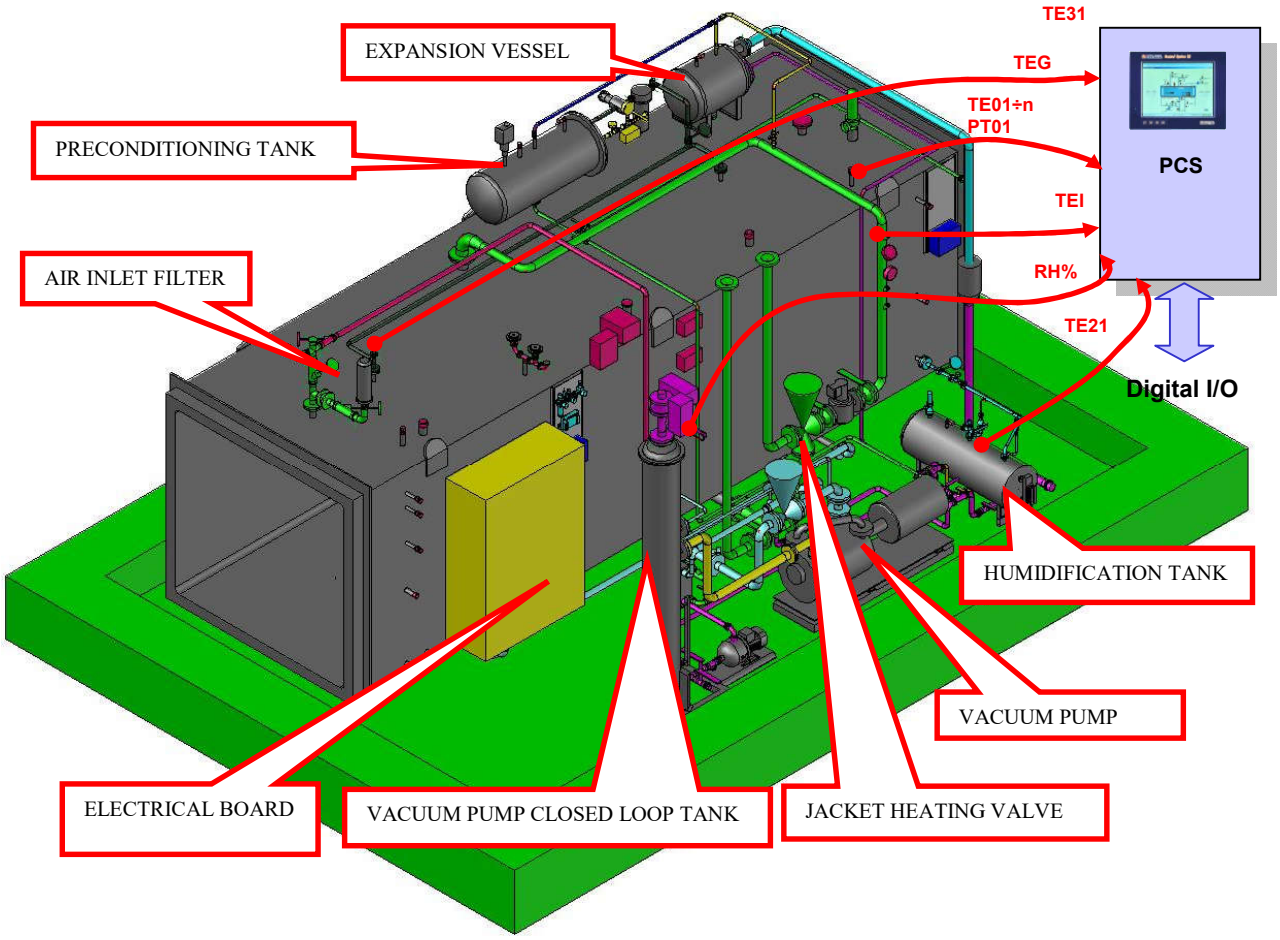
- Principal instruments with a GMP impact.
- Auxiliary instruments

6.2.1. Principal instruments

The principal instruments used in the DLOG series of sterilizers are shown in the figure.



The process instruments are positioned inside the chamber or in functional sub-groups when it is necessary to measure or control the process parameters.
Using the instrument and P&ID diagrams makes it possible to better understand the measuring systems used in the sterilizer.
The below figure shows a typical autoclave with the main important functional blocks.



LEGENDA:

- All red arrows are related to the analog signals to be read (GMP relevant data)
- Into functional blocks all related valves and ancillary devices are included.

Generally, the positioning of the instruments is as indicated in the table below:

Measuring loop	Positioning
Chamber temperature	*Flexible PT100s in the chamber*
Gas temperature	*Flexible PT100 in the gas line thermowell*
Chamber pressure	*Absolute pressure sensor connected to the chamber*
Chamber Humidity	*Humidity sensor connected to the chamber*
Jacket temperature	*PT100 installed in the jacket heating circuit*
Steam generator temperature	*PT100 installed in the steam generator outlet pipe (if the relevant device is installed)*
Preconditioning tank temperature	*PT100 installed in the preconditioning water tank thermowell (if the relevant device is installed)*
Gas separator outlet pressure	*Absolute pressure sensor connected to the gas separator outlet, for exhaust regulation to the neutralization system*

6.2.2. Auxiliary instruments

The auxiliary instruments are mainly devices that are useful for detecting particular plant statuses, such as:

- Fluid level sensors
- Fluid presence sensors (pressure switches)
- Etc.

The detailed documents supplied can provide further details on the actual composition of the equipment.

6.3. Positioning of the electrical panel

The electrical panel is normally positioned inside the sterilizer's technical space, although in some cases, in agreement with the client URS it may be located in a remote position.

Check the specific documents for your plant for further details.

6.4. Moving the doors

The DLOG series of equipment can be fitted with the following types of doors:

- Horizontal sliding doors
- Vertical sliding doors
- Semi-automatic folding doors

NOTE:
In all three cases seal gaskets are used that are activated by a pneumatic thrust.
Moving the doors is always done by an electric actuator controlled by a specific pushbutton panel.

Example of buttons for opening and closing doors

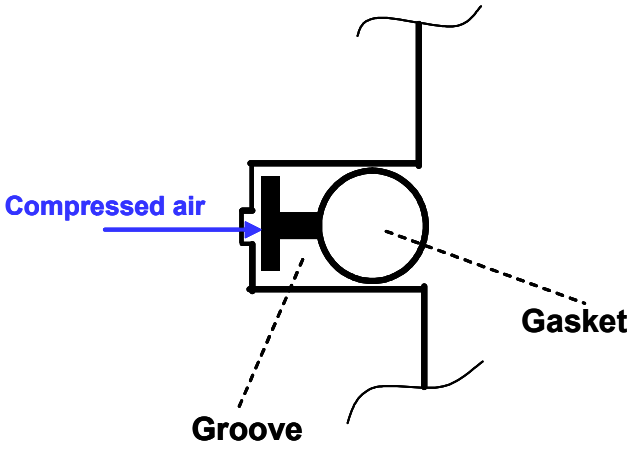
Correct closure of the door with an inflated gasket is shown by a green LED switching on in the key.

RESIDUAL RISK OF SHEARING

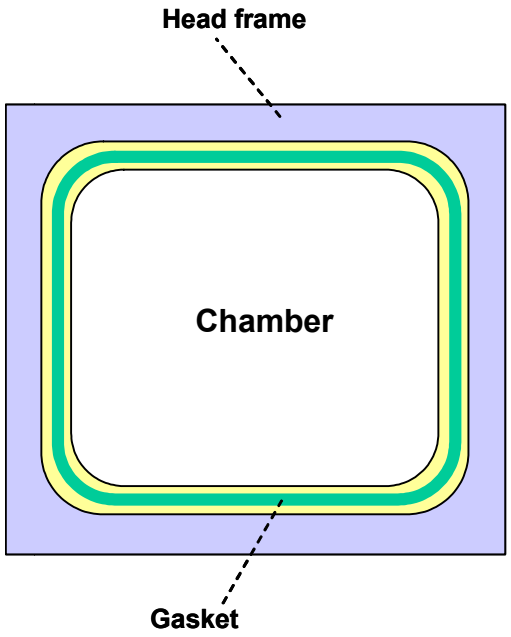
IS ADVISED OF THE PRESENCE OF A RESIDUAL RISK OF SHEARING IN TWO POINTS, ABOVE AND BELOW THE DOOR.
DURING CLOSING THE DOOR, THE OPERATOR MUST PERFORM THE ACTION BY HOLDING THE BUTTON ON THE RESERVATION BUTTON AND POSITIONING THE OTHER HAND ONLY ON THE FRONT OF THE DOOR FOR THE COMBINATION OF THE SAME.
MAKE SURE THAT THERE IS NO OTHER PERSONAL CORRESPONDENCE IN THE AREA OF REPORTED RISK.

6.5. Door seal gasket

Irrespective of the type of closing, the DLOG series of machines uses air thrust pneumatic type gaskets.
The profile of the gasket is designed to guarantee perfect sealing of the chamber, and is shown in the figure below.



The next figure shows an example of the positioning of the gasket in its slot.



6.5.1. Gasket maintenance

It is essential to carry out an inspection at least once a month, during which the following must be checked:

1 The shape and condition of the gasket. It must not have any permanent deformation. It must not be broken. It must be suitably elastic (N.B. hardened gaskets do not guarantee a proper seal).

2 The presence of any metal, glass or other particles compacted in the body of the gasket.

3 No signs of sticking of the gasket (phenomena due to use of solvents for cleaning the machine for example).

4 If any of the conditions indicated above arise, the gasket must be replaced.

5 For better conservation and a longer lifespan of the gasket it must be systematically lubricated using silicone grease (able to withstand 150°C / 423K).

6 It is advisable to replace the gasket each working year the machine is used for.

6.5.2. Changing the gasket

To replace the gasket, we recommend adopting the following procedure. It is taken as given that the doors (whether they be sliding or semi-automatic) must be perfectly aligned with the sterilizer head when closed and moving (sliding or closing).

1 Having removed the old gasket, proceed to clean the sides and bottom of the groove thoroughly. Especially remove any debris (glass or other) or slag, and any signs of rust. Use a scourer soaked with quick-evaporating solvent with high degreasing power.

2 Rinse thoroughly using a cloth soaked in water.

3 Remove the new gasket from its packing and pull it at the two ends to identify its two mid points Mark these points with a marker pen or soft tipped pencil.

4 If the sterilizer has a parallelepiped opening position these points (inserting the gasket in its slot) near the mid points of the upper and lower sides.

5 The push the gasket into its slot without any particular elastic elongation. (The length of the gasket is equal to the average geometric size of the slot).

We recommend compliance with the following instructions:

- Leave the gasket in its packaging until it is to be used.
- Do not leave the gasket out of its packaging for long times in dusty places.
- Do not use grease of any kind (including silicone grease) to facilitate putting the gasket into its seating. If necessary, use soap and water to facilitate insertion.

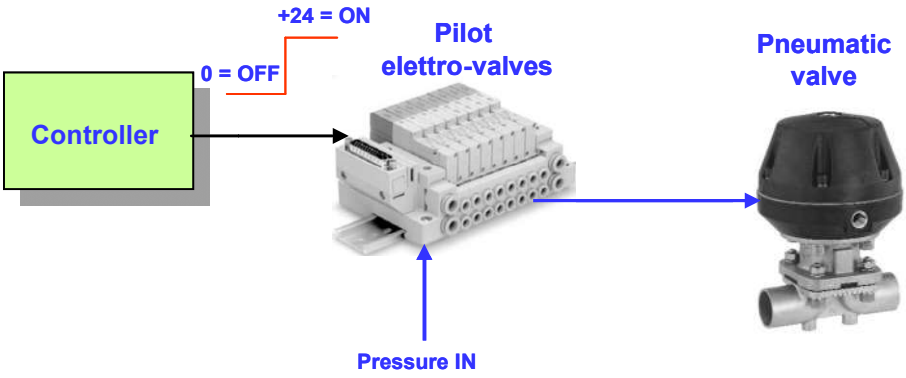
6.6. Vacuum pump

The vacuum in the chamber is produced by a liquid ring vacuum pump connected to the chamber via suitable valves.

The minimum vacuum level that can be reached in the chamber is proportional to the temperature of the water in the liquid ring. High H_2O temperatures do not allow the correct degree of vacuum to be achieved. See the manufacturer's manual for the pump installed in your plant for further details.

6.7. Pneumatic and electric valves

Most of the valves on the fluid intakes on the chamber are pneumatically activated. Depending on the layout of the plumbing system they may have an inclined seat or be of a sanitary type.
The valves are activated as shown in the figure below:

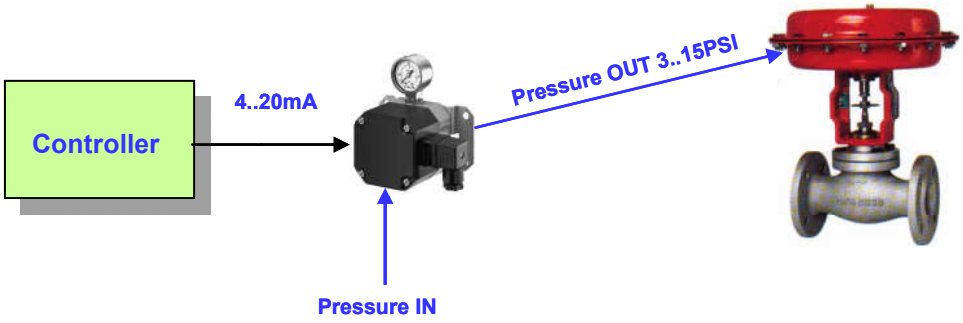


6.8. Chamber vacuum operation

The vacuum inside the chamber is controlled by suitable valves.
A modulating valve is fitted in the vacuum line in order to regulate the gas outlet to the gas neutralization system.

6.8.1. Modulating valve

The modulating valve, is controlled by a 4-20 mA electric signal that is converted into a 3-15 PSI pressure signal for actuating opening of the valve.



Electric signal	Pneumatic conversion	% valve opening
4 mA	*3 PSI*	*0% (valves closed)*
12 mA	*9 PSI*	*50%*
20 mA	*15 PSI*	*100%*

6.9. Putting steam into the chamber

The humidity is regulated by feeding steam into the chamber via suitable valves. The method used to feed steam into the chamber is using an ON/OFF valve operated by a PWM technique

The regulation parameter is the relative humidity

See the P&ID and other technical documents for further details.

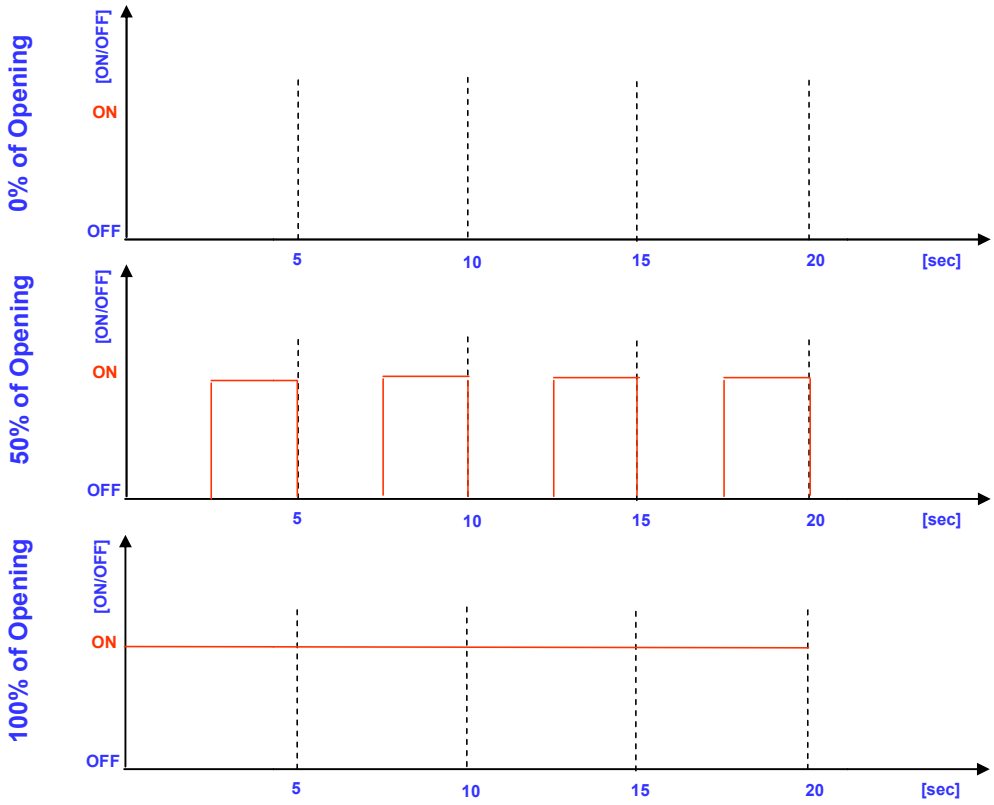
6.10. Putting gas mixture into the chamber

The method used to feed Gas Mixture into the chamber is using an ON/OFF valve operated by a PWM technique.

See the P&ID and other technical documents for further details.

6.10.1. ON/OFF valve using a PWM technique

A normal ON/OFF valve can be used to obtain good regulation by means of the PWM technique.
The figure below shows the PWM operating mode.



7. Routine plant maintenance

This chapter describes the activities involved in maintaining a DLOG model sterilizer.

THE SYSTEM IS NOT SUPPLIED OF MANUAL SHUT-OFF VALVES FOR ALL FLUIDS LOCKABLE. SHUT-OFF VALVES, IF ANY, ARE REPRESENTED ON THE P&I PROVIDED IN THE DOCUMENTATION. BEFORE BEGINNING MAINTENANCE WORK MAKE SURE THE VALVE POWER OF ALL FLUIDS ARE CLOSED TIGHTLY

WE RECOMMEND CONSULTING THE USER MANUALS FOR THE INDIVIDUAL COMPONENTS IN QUESTION BEFORE UNDERTAKING MAINTENANCE OPERATIONS IN ORDER TO AVOID INCORCRECT SETTINGS OR INVOLUNTARY TAMPERING.

THE ELECTRICITY SUPPLY AND FLUID FEED LINES MUST BE SHUT OFF.
BEFORE BEGINNING WORK INDICATE THAT MAINTENANCE IS IN PROGRESS BY MEANS OF SUITABLE SIGNS AND FIT SOME INTERLOCKS ON THE POWER SUPPLY LINES TO PREVENT UNWANTED RE-ACTIVATION OF THE ENERGY SUPPLY THAT WAS TURNED OFF PREVIOUSLY.

RESIDUAL RISK OF SHEARING
IS ADVISED OF THE PRESENCE OF A RESIDUAL RISK OF SHEARING IN TWO POINTS, ABOVE AND BELOW THE DOOR.
DURING CLOSING THE DOOR, THE OPERATOR MUST PERFORM THE ACTION BY HOLDING THE BUTTON ON THE RESERVATION BUTTON AND POSITIONING THE OTHER HAND ONLY ON THE FRONT OF THE DOOR FOR THE COMBINATION OF THE SAME.
MAKE SURE THAT THERE IS NO OTHER PERSONAL CORRESPONDENCE IN THE AREA OF REPORTED RISK.
.

RESIDUAL RISK - AREA OF OPERATION IN THE TECHNICAL COMPARTMENT
THE TECHNICAL COMPARTMENT IS DESIGNED TO CORRECT ACTIVITIES OF MAINTENANCE.
IT IS 'REPRESENTED ON THE DESIGN LAYOUT ANNEX TO THE DOCUMENTATION WHERE ARE INDICATED SPACES AVAILABLE, THE NECESSARY LIGHTING, ETC.
OFTEN, HOWEVER, THE INSTALLATION REQUIREMENTS OF END USER INVOLVE THE LIMITATION OF THE OPERATIVE SPACE
BE SURE TO OPERATE WITHIN THE TECHNICAL COMPARTMENT WITH GREAT CARE TO PREVENT FALLS OR RAISE IMPROPERLY OF PARTS OF THE SYSTEM WORK EQUIPMENT.

7.1. Monthly checks

THESE OPERATIONS CAN BE CARRIED OUT ON THE PLANT UNDER NORMAL WORKING CONDITIONS THAT DO NOT REQUIRE SPECIFIC MAINTENANCE. THE ESSENTIALLY INVOLVE VISUAL INSPECTIONS THAT CAN BE CARRIED OUT BY SUFFICIENTLY EXPERT, TRAINED PERSONNEL ON PLANT USE. THE TRAINING HAS TO BE CARRIED ON AND RECORDED BY THE USER RESPONSIBLE.

ID	OPERATION – INSPECTION – CHECK DESCRIPTION
1.	Functional check of the external state of the door gasket and its condition (see description in point …).
2.	Check and cleaning as necessary of fluid supply filters (installed by the Customer: steam, water, air, etc.).
3.	Check air filter efficiency
4.	Check steam inlet filter and cartridge (if fitted).
5.	Check of the chamber drain strainer filter (external and internal)
6.	Visual check for any leaks on the equipment piping.
7.	Checking the efficiency of the buffer battery in the electrical panel. If replaced, reset the parameters.
8.	Visual check of correct working of the signal LEDs.
9.	Visually check the door movement belt and tension.
10.	Check the efficiency of the door opening / closing switches.
11.	Check pressure seal on the compressed air line / door gasket by switching off the power supply and compressed air when the door is closed. The pressure drop (ΔP) over a 20 minute period (the pressure drop must be zero).
12.	Visual check of the gasket air pressure value (5 bar g)
13.	Check the integrity of the door counter bar and that it is working.
14.	Check that the green door opening consent LED on the electric panel is on when there is no pressure in the chamber.
15.	Check the integrity of analogue measuring instruments (pressure gauges)

7.2. Quarterly checks

The suggested operations to be carried out at three-monthly intervals are listed below.

THESE CHECKS CAN BE DONE BY EXPERT AND TRAINED PERSONNEL. ON PLANT USE AND GENERAL MAINTENANCE. TRAINING HAS TO BE PERFORMED BY SPECIFIC INSTRUCTION DONE BY MANUFACTURER PERSONNEL OR QUALIFIED TEACHER. TRAINING HAS TO BE RECORDED.

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ID	OPERATION – INSPECTION – CHECK DESCRIPTION
1.	Check the efficiency of the two membrane safety devices that allow the door to be opened only when there is no pressure in the sterilizer.
2.	Visually check for movement of the pin on membrane safety devices that results in activation of the micro-switch.
3.	Check the efficiency of the membrane inside the safety devices.
4.	Check that the activation pressure value for the two membrane safety devices is lower than that allowed (0,05 bar).
5.	Check and clean the filter-reducer unit on the instrumentation compressed air line. Do not use solvents for cleaning the cartridge. Drain off any condensate.
6.	Check for any lime build up in the vacuum pump discharge pipe.
7.	Check that the gasket returns to its rest position and that there are no compressed air leaks from the dynamic vacuum device that brings about this return.
8.	Check that the door open / closed LEDs are working properly.
9.	Visually check alignment of the stops for the door when open. Check the related mechanisms.

7.3. Half-yearly maintenance

These activities include checks, adjustments, and settings using sample instruments in order to guarantee the efficiency and safe functioning of the plant.

THESE CHECKS CAN BE DONE BY SUPERVISOR AND TRAINED PERSONNEL THROUGH SPECIFIC TRAINING ON PLANT USE. MAINTENANCE AND VALIDATION DONE BY MANUFACTURER PEOPLE OR BY VERY QUALIFIED PEOPLE. BESIDES AU INSTRUMENTS USED KNOWLEDGE IS REQUIRED. ALL TRAINING HAS TO BE RECORDED.

BEFORE BEGINNING MAINTENANCE WORK INDICATE THAT WORK IS IN PROGRESS BY MEANS OF SUITABLE SIGNS AND FIT SOME INTERLOCKS ON THE POWER SUPPLY LINES TO PREVENT UNWANTED RE-ACTIVATION OF THE ENERGY SUPPLY THAT WAS TURNED OFF PREVIOUSLY.

ID	OPERATION – INSPECTION – CHECK DESCRIPTION
1.	Functional safety valve check.
2.	Check water and ballast regulation on the vacuum pump. Visually check for any water leaks from the vacuum pump body. Check functioning of the vacuum pump (ballast and water regulation). Check for any lime build up in the vacuum pump and its discharge pipe. Check the vacuum seal on the chamber.
3.	Check and clean the chamber discharge filter (externally and internally) and the sleeve discharge filter.
4.	Check and clean the other filters (fitted on the sterilizer).
5.	Check and clean the inside of the condensate and air dischargers.
6.	Check functioning of the non-return valves fitted on the sterilizer.
7.	Check for compressed air leaks in the pneumatic system's pipes and valves. Check correct tightening of all connection elements.
8.	Check the line pressure and proper functioning of all the compressed air reduction filters.
9.	Check and clean filter unit reducers on the compressed air instrument line, removing any condensate.
10.	Check pneumatic valve and solenoid valve seals and gaskets.
11.	Visually check the modulating pneumatic valve membranes. Check that they are working properly and there are no leaks.
12.	Check for any fluid leaks on the plumbing system piping. Check correct tightening of all connection elements.
13.	Check the seal on all pneumatic and manual valves.
14.	Check the efficiency and activation point of the compressed air instruments / solenoid valve unit pressure switch.
15.	Visually check the functioning of all the LEDs on the pushbutton panel, electrical panel, front panels, and microprocessor.
16.	Check the good functioning of all the levels.
17.	Check the integrity and clear view of the visual levels.
18.	Check the efficiency of the buffer battery and check the battery charger. In the case of the PLC, change the battery once a year.
19.	Check that the emergency buttons are working properly.
20.	Check the pneumatic valve piloting solenoid valves.
21.	Check the activation values for the thermal relays and the absorption of electric motors in Ampere, compared to the wiring diagram.
22.	Check correct tightening of all electric conductor connecting elements to the electrical panel on the equipment. Change any cables found to be worn or partially cut.
23.	Check the printer, paper stock, condition of the cartridges, and cleanliness of the print heads.

ID	OPERATION – INSPECTION – CHECK DESCRIPTION
24.	Zero the maintenance alarm
25.	Check that the safety devices are in good condition, efficient, and have not been tampered with.
26.	Check the cleanliness of the internal chamber only by looking for pieces of glass / plastic / or liquids in the drain sump at the bottom of the chamber. Remove the protective mesh and clean.
27.	Regulate the valves: Condensate discharge, chamber discharge, and steam injection.
28.	Check fluid pressure switched, check electric contact switching at the activation point.
29.	Check that when the door is open the cycle cannot start (if during running of the cycle do to some fault the door remains open, the cycle must stop immediately).
30.	Check the cycles installed on the plant.
31.	If fitted, check the efficiency of the smoke damper located on the general discharge pipe. (Max outlet temperature 60-70°C).
32.	Check the activation points on the electrical contacts (NO ◂ ▸ NC) for the digital display indicator, set in the factory using the in-house DL procedure.
33.	Internal / external movement maintenance
34.	Check the mechanical seal on the movement motor.
35.	Check the movement safety devices
36.	**Functional check of the external condition of the door gasket.** Check: ✓ Correct positioning of the gasket in its seating. ✓ Shape and consistency of the gasket. ✓ Absence of permanent deformation. ✓ Absence of breakage. ✓ Absence of areas without elasticity or with cracks (hardened gaskets do not guarantee a proper seal) ✓ Absence of metal, glass or other particles embedded in the body of the gasket. Absence of adhesion of the gasket (due to the product treated inside the chamber).
37.	Visually check the condition of the belt / chain.
38.	Check the belt / chain tension. Check greasing and wear on mechanical parts.
39.	Check the pressure on the door gasket air reducer filter.
40.	Check the efficiency of the door opening / closing limiting switches for completed movements.
41.	Check the efficiency of the min/max compressed air feed pressure switches connected to the door gasket seat circuit.
42.	Inspect and check the efficiency of the gasket compressed air feed to the door gaskets.
43.	Use the MS-MNS pressure gauge reading to check the gasket air pressure.
44.	Check the good functioning of the door safety system. If an obstacle enters the door stopper bar working area the door must stop immediately (also check the friction system).
45.	Check the efficiency of the PRSIC4 and PRSIC5 membrane safety devices that allow the door to be opened only when there is no pressure in the chamber.
46.	Visually check for movement of the pin on membrane safety devices that results in activation of the limiting switches.
47.	Check the efficiency of the pressure switch for the air unit for the PR ALL doors.
48.	Check that the activation pressure value for the two membrane safety devices is lower than that allowed (0,05 bar). This check is done by fitting a sample pressure gauge on the sterilizer and readign the value it indicates and the LED on the electrical panel door switching on ($\geq$ 0,05 bar proceed with door locking, $\leq$ 0,05 bar proceed with door release).
49.	Check the efficiency of the membrane inside the safety devices.
50.	Check that the gasket returns to the rest position and correct functioning of the dynamic vacuum device that effects this return.

ID	OPERATION – INSPECTION – CHECK DESCRIPTION
51.	Check the pressure seal on the compressed air / door gasket line. Switch off the power supply and compressed air with the door closed. Use a pressure gauge to check for a drop in pressure (ΔP) over 20 minutes (the pressure drop must be zero).
52.	Check the efficiency of non-return valves downstream of the pressure reducer on the door pneumatic circuit.
53.	Check the pressure on the door gasket air reducer filter.
54.	Clean the door gasket compressed air filter fitted on the reducer filter unit.
55.	Check that the LEDs and door opening / closing buttons and the LEDs on the machine are working properly.
56.	Check absorption of the electric motors for moving the doors or door levers.
57.	Check that the door seals airtight.
58.	Check the tensioning on the bolts on the door plating.
59.	Check alignment, fixing, and correct functioning of the door contrast bar limiting switch.
60.	Check that the safety devices are in good condition, efficient, and have not been tampered with.
61.	Check that the cycle cannot restart with the door is open.
62.	**Functional check RECIRCULATION FAN/s (if fitted)** Perform the following checks: ✓ visual check of the fan functionality ✓ check noise due to interference or wear on bearings ✓ verification of absorption of the electric motor ✓ visual verification of the structural integrity of the fan blades ✓ visual check for any clearance on the fan shaft ✓ visual check for dust in the chamber near the fan ✓ verification of the correct functioning of the electric motor acceleration ramp. The electric motors must be started slowly and without blows and / or jerks until reaching the normal rotation revolutions. If one of the above points is NOT compliant, or, the fan seal was in use for about 500/600 cycles, and therefore needs revision / replacement, it is essential that the fan be forwarded to the De Lama Company.

9. Particular prescriptions for installation and use in potentially explosive atmospheres at the presence of ETO gas plant maintenance

IMPORTANT:
This chapter must be read together with the working instructions manual of the installed sterilizer

Plant ATEX Classification
Zone 2 Category 3Gc

9.1. Conformity statement

Each sterilizer is fitted with a conformity statement according to laws, European Directives and harmonized rules.

DE LAMA	Equipment Conformity Certificate			
Doc ID: ECC-00-F_XXXX	Job: XXXXX	M.N.: XXXX	Issue: 1	Date: DD-MMM-YY

De Lama S.p.A., head office in San Martino Siccomario (PV) - Via Piemonte 21 - V.A.T. number 00166040188, represented by Dr. **Paolo Bianchi** as C.E.O., declares on its own responsibility that the plant:

Ethylene Oxide sterilization autoclave DLOG series

M.N. : XXXX

Job Nr. : XXXXX

which this statement refers to, has been manufactured as hereunder described.

2006/42/EC - Machinery Directive
Directive 2014/30/UE - EMC Directive
Directive 2014/35/UE - Low Voltage Directive
UNI EN ISO 12100-1:2010 – Safety of Machinery
UNI EN ISO 13857: 2008 - Safety of Machinery – Safety distances …
UNI EN ISO 14738:2009 – Safety of Machinery – Anthropometric requirements …
UNI EN 349:2008 – Safety of Machinery – Minimum gaps to avoid crushing of ….
CEI EN 60204-1:2006 – Safety of Machinery – Electrical equipment …
CEI EN 61439-1:2011-10 – Low voltage switchgear and controlgear assemblies …
CEI EN 60445:2011-07 – Basic and safety principles for man-machine interface, marking, … - Identification of equipment terminals …
Directive 2014/68/EU – Pressure Equipment Directive
UNI EN 1422:2014 Sterilizers For Medical Purposes – Ethylene Oxide Sterilizers…. (where applicable)
UNI EN ISO 11135:2008 (where applicable) Sterilization Of Medical Devices. Validation And…
ATEX 2014/34/EU - European Directive Concerning Equipment And Protective Systems Intended For Use In Potentially Explosive Atmospheres – Marking: CE Ex II 3 G Ex h T3 Gc

On Mandate of C.E.O.

1 of 1

9.2. Premise

This appendix to the working instructions manual has been issued to satisfy the safety requirements against explosions as demanded by laws, European Directives and reference rules.
Personnel properly trained about explosion risks, only, can be authorized to act in areas ATEX classified.
Extract of Italian Governmental Act 81/2008 dated April 9, 2008 – Title XI - Annex L

1. Organization measures.
1.1. Workers professional training.
The employer is obliged to give the workers a proper and adequate training about protection measures against explosions in areas classified as potentially explosive.
1.2. Written instructions and working permissions.
When established by the protection document against explosions:
a) the activity in risk areas considered at risk is carried out according to the written instructions given by the employer;
b) a working permission system applies to all activities considered dangerous or to the ones that can become dangerous if interfering with other working operations.
The working permissions are released by authorized people before starting activities.

9.3. Summary of the marking data

Each sterilizer is fitted with an identification plate showing its main operating data.

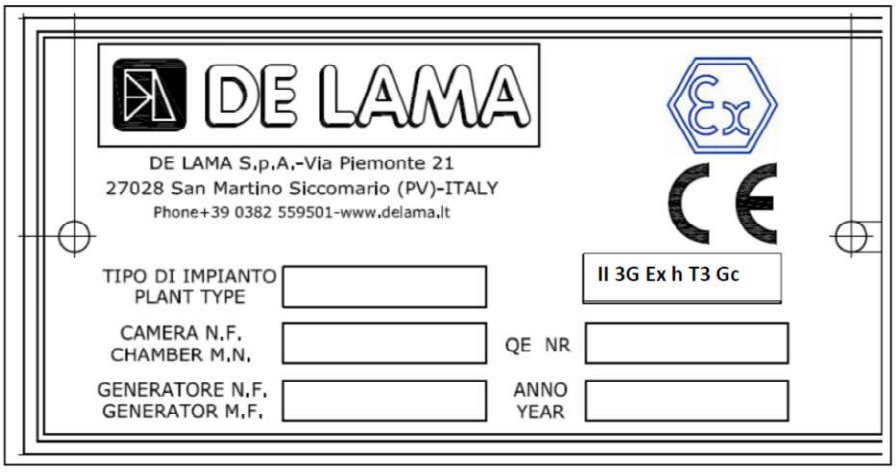

Fig. 2 – Example of nameplate

ATEX CE Ex II 3G Ex h T3 Gc

Additional marking for Zone 2

9.4. ATEX marking

The safety marking must specify unambiguously the product category for the relevant reference zone, as demanded by the European Directive ATEX Directive n. 2014/34/UE and the relevant harmonized rules.
The identification of an ATEX sterilizer can be observed through the main plate containing:

The content is:

- The reference of the manufacturer
- The CE mark
- The Ex logo to identify Atex equipments
- The group (**II** = surface industry; **I** = mines)
- The category (2 o 3)
- The type of atmosphere (G= gas; D= Dust)
- The temperature class (T1 ÷ T6 or. Tmax)
- The reference of the technical file
- The symbol R if the equipment has been modifier or repaired
- The year of the marking CE Ex

9.5. Laws

The sterilizers execution conforms to the laws in force in the European Union and in Italy.
Here under, a list of reference laws and directives.

- GOVERNMENT ACT April 9, 2008, n. 81 - Actuation of article 1 - Law n.123, Agoust 3, 2007, concerning the health and safety preservation on working places

Decrees cancelled and included in D.Lgs. 81/2008
• DPR n°547 dated 27/4/1955 - Rules for prevention of injuries in working places
• DPR n°303 dated 27/04/1956 - General rules for health in working places
• D.lgs. n°626/94 dated 19/9/1994 - Actuation of directives 89/391/CEE, 89/654/CEE, 89/655/CEE, 89/656/CEE, 90/269/CEE, 90/270/CEE, 90/394/CEE, 90/679/CEE, 93/88/CEE, 95/63/CE, 97/42/CE, 98/24/CE, 99/38/CE, 99/92/CE, 2001/45/CE, 2003/10/CE and 2003/18/CE concerning the improvement of workers' health and safety during working time.

- Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on the machinery, and amending Directive 95/16/EC (recast) (Italian Governmental DecreeNo.17 dated 27.01.2010)
- Directive n. 2004/108 "Electromagnetic compatibility"

9.6. Reference rules

This sterilizers series have been built according to the following technical rules:

- **Directive 2006/42/EC** of the European Parliament and of the Council of 17 May 2006 on the machinery, and amending **Directive 95/16/EC** (recast) *(Italian Governmental Decree No.17 dated 27.01.2010)*
- **Directive 2014/30/UE** of the European Parliament and of the Council of 26 February 2014 on the approximation of the laws of the Member States relating to electromagnetic compatibility
- **Directive 2014/35/UE** of the European Parliament and of the Council of 26 February 2014 on the harmonization of the laws of Member States relating to electrical equipment designed for use within certain voltage limits
- **UNI EN ISO 12100:2010**
  Safety Of Machinery. Basic Concepts, General Principles For Design. Risk evaluation and reduction
- **UNI EN ISO 13857: 2008**
  Safety Of Machinery – Safety Distances To Prevent Danger Zones Being Reached By The Upper Limbs
- **UNI EN ISO 14738:2009**
  Anthropometric Requirements for the design of Workstation at Machinery
- **UNI EN 349:2008**
  Safety Of Machinery – Minimum Gaps To Avoid Crushing Of Parts Of The Human Body
- **CEI EN 60204-1:2006**
  Safety Of Machinery – Electrical Equipment Of Machines – Part 1 : General Requirements
- **CEI EN 61439-1:2011-10**
  Low-Voltage Switchgear And Controller Assemblies – Part 1 : General requirements
- **CEI EN 60445:2011-07**
  Basic And Safety Principles For Man-Machine Interface, Marking And Identification – Identification Of Equipment Terminals And Of Terminations Of Certain Designated Conductors, Including General Rules For An Alphanumeric System
- **Directive 2014/68/EU**
  Pressure Equipment Directive for design and fabrication, the following Standards & Guidelines are applicable
- **UNI EN ISO 11135-1:2014 (where applicable)**
  Sterilization Of Medical Devices. Validation And Routine Control Of Ethylene Oxide Sterilization
- **•ISO 80079-36:2016**
  Explosive atmospheres -- Part 36: Non-electrical equipment for explosive atmospheres -- Basic method and requirements
- **ISO 80079-37:2016**
  Explosive atmospheres -- Part 37: Non-electrical equipment for explosive atmospheres -- Non-electrical type of protection constructional safety ''c'', control of ignition sources ''b'', liquid immersion ''k''
- **IEC-60364 (WHERE APPLICABLE)**
  Electrical Installation for Buildings

9.7. Installation in potentially explosive atmosphere

The sterilizers installation in potentially explosive atmosphere is at the User's complete charge (unless otherwise specified by technical/commercial documents).

- Dangerous Zones

In order to grant the plant safety, all the sterilizer adjacent area within a 2 meters ray in the 3 orthogonal directions must be considered "Zone 2", unless otherwise specified.

- No smoking

Smoking and free fires are strictly prohibited around the sterilizer working area.

Fig. 3 – No-smoking warning

- Earth connection

The sterilizer structure must be mandatorily connected to an efficient earth connection system and a residual current operated circuit-breaker must be provided up-stream the plant, against the explosion ignition risks.

Fig. 4 – Earth connection symbol

9.8. User's obligations

As a conclusion, the user (employer) is obliged to up-grade the plant according to the following laws:

- **European Directive 99/92/EC**

"Minimum prescriptions improving the health and safety of all workers who may be exposed to the explosive atmospheres risk"

- **Governmental Act n. 233/03 dated June 12, 2003**

The D. Lgs (Governmental Act) n. 233/03 added the Title VIII bis to the D. Lgs. n. 626/94 named: "Protection from explosive atmospheres" then changed into Title XI of D.Lgs. 81/2008 entered into force on May 15, 2008.

a. **Reference rules actuating the Directive 99/92/EC and the D.Lgs. 81/2008, Title XI**

IEC 60079-10 - Classification of areas with Gas

IEC 60079-14 - General rules for installation

IEC 61241-17 - Rules for maintenance and inspection in areas with dust

IEC 61241-19 - Rules for safety equipments review and repairing

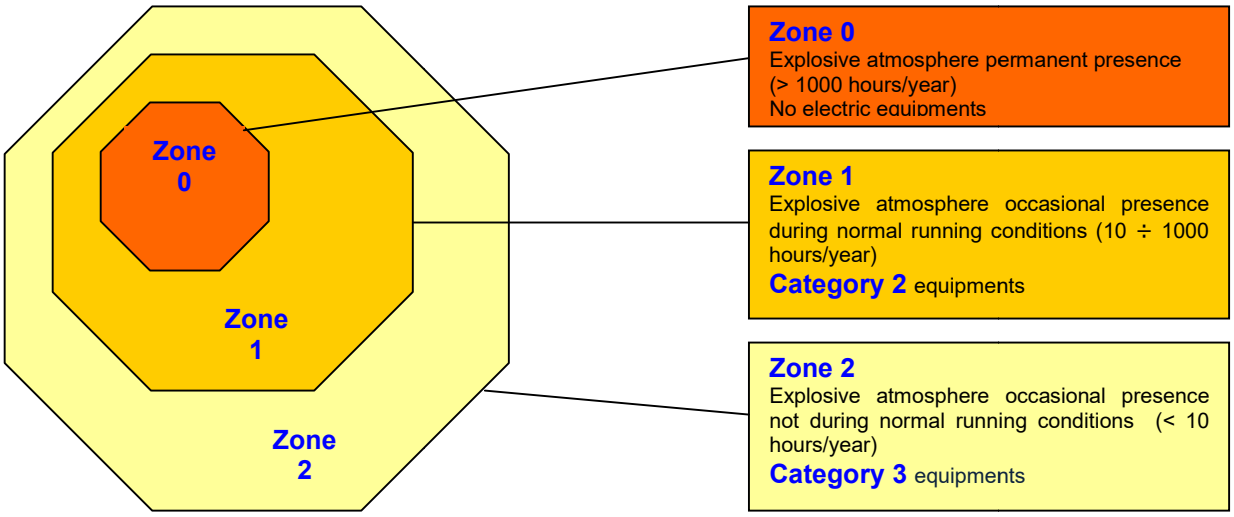

Fig. 5 – Atex Zones classification

b. Start-up and use

All potentially explosive areas must be indicated by the following warning:

Annex III
(Directive 99/92/EC)

Fig. 6 – Indication warning for ATEX areas

Before going on with the sterilizer starting-up the user must issue the "Document about Protection against explosions".

Here, the text of Art. 294 - D.Lgs. 81/2008.

Document about Protection against explosions

1. Observing the obligations established by the article 290, the employer must issue and up-date a document named «Document about Protection against explosions».

2. The document as per comma 1, must specify:
a) the explosion risks have been identified and analyzed;
b) adequate measures to achieve this title aims will be taken;
c) the indication of all places classified in Zones as per Annex XLIX;
d) the indication of all places where the minimum prescriptions as per Annex L apply;
e) the working places and the equipments are designed, used and efficiently maintained taking safety into good consideration, first, alarm devices included;
f) all means for the working equipments safe use have been carried out according to Title III

3. The document as per comma 1 **must be released before starting the activities** and reviewed when working places, equipments or organization change significantly.

4. The document as per comma 1 is integral part of the Risks evaluation document, as per the article 17, comma 1, D.Lgs. 81/2008

9.9. Manual use and preservation

Subjects

All people involved in the sterilizer direct control and management, included all other people allowed to operate with it, are the subjects of this manual, copy of which is supplied together with the plant.

Aims

DE LAMA S.p.A. suggests the people responsible for the sterilizer management to read the whole manual before starting any action and to properly inform and train the personnel involved in operational activities with the plant.

Start-up, use, assembling, disassembling, routine maintenance, installation and adjustment operations are described by the manual issued according to the installed sterilizer type.

9.10. Changes and repairings

Any change and repairing involving all plants classified according to Atex directives must be carried out by the manufacturer or by other parts authorized and duly trained by the manufacturer about explosion risks.

Spare parts must be original type, certified and supplied by the manufacturer.

All repairing must be reported by:

- the Manufacturer
- the Troubleshooter
- the Customer/User

Any change or repairing performed unlike what above mentioned will invalidate the safety certification and warranty, considering