NEW AUTESTER FDA/GMP

REGULATIONS:

EU GMP – ANNEX 1:	STERILE MANUFACTURING, ENVIRONMENTAL CONTROL AND RISK MANAGEMENT.
EU GMP – ANNEX 15:	QUALIFICATION & VALIDATION (IQ/OQ/PQ)
ISO 17665-1 / 17665-2:	STEAM STERILIZATION – PROCESS VALIDATION AND CONTROL
EN 285:	REQUIREMENTS FOR LARGE STEAM STERILIZERS
ISO 13485:	QUALITY MANAGEMENT SYSTEMS FOR MEDICAL DEVICES
21 CFR PART 11:	DATA INTEGRITY AND SECURITY (FOR EQUIPMENT WITH DIGITAL RECORDING)
GAMP 5:	SOFTWARE AND AUTOMATION LIFECYCLE MANAGEMENT

BLOCKCHAIN SECURITY

CLOUD CONNECTIVITY

CER.21 - APAR.11

DESIGNED ACCORDING TO THE MOST DEMANDING INTERNATIONAL STANDARDS

OUR AUTOCLAVES ARE DESIGNED TO MEET THE KEY REGULATORY REQUIREMENTS OF THE PHARMACEUTICAL INDUSTRY, ENSURING FULLY TRACEABLE, REPEATABLE, AND VALIDATABLE PROCESSES IN ACCORDANCE WITH INTERNATIONAL STANDARDS.

Each unit is delivered with complete technical documentation to facilitate audits and IQ/OQ/PQ validations if required, ensuring that the process is fully demonstrable.

SATURATED STEAM TECHNOLOGY FOR A FULLY VALIDATABLE STERILIZATION PROCESS

SELECTA autoclaves use pressurized saturated steam as the sterilizing agent, combining precise control of temperature, pressure, and exposure time to ensure the destruction of resistant microorganisms, with automatic monitoring of the F_0 value.

PRINCIPLES OF PROCESS OPERATION

- Internal or external steam generation
- PID control of temperature and pressure
- Independent probe for cycle verification
- Programmable cycles according to load type, including liquids
- Vacuum systems for optimal steam penetration
- Drying by vacuum, filtered air, and radiation
- Automatic parameter recording

ADVANTAGES FOR PHARMACEUTICAL APPLICATIONS:

- Full alignment with EU GMP, FDA, and quality audits
- Digital recording compliant with 21 CFR Part 11
- Hygienic design in AISI 316L stainless steel
- Process repeatability under audit conditions
- Full support for IQ/OQ/PQ validations
- Load (core) probe for real product temperature control

THE SAME MODELS ARE AVAILABLE WITHOUT GMP CONNECTION



“Steril Pres” autoclaves for liquid sterilization.

PLC CONTROL OF TEMPERATURE AND PRESSURE.
THE AUTOCLAVES ARE DESIGNED FOR A VARIETY OF APPLICATIONS IN THE FIELDS OF INDUSTRIAL PROCESSES, QUALITY CONTROL AND MICRO-BIOLOGY. THESE AUTOCLAVES ALLOW STERILIZATION PROCESSES OF SOLIDS, LIQUIDS AND CULTURE MEDIA.
FOR ADJUSTABLE TEMPERATURES FROM 80 °C TO 128 °C (0.21 TO 2 BAR). MAXIMUM PRESSURE: 2.5 BAR.
CONFORMS TO THE PRESSURE EQUIPMENT DIRECTIVE 2014/68/EU.
VERTICAL MODEL. CAPACITIES: 80 / 150

CONFORMITY

EN 61010-1	SAFETY REQUIREMENTS FOR LABORATORY EQUIPMENT.
EN 61010-2-040	SAFETY FOR STERILIZER EQUIPMENT FOR LABORATORY USE
EN 61326-1	ELECTROMAGNETIC COMPATIBILITY FOR EQUIPMENT FOR LABORATORY USE.
AD2000	MERKBLATTER PRESSURE EQUIPMENT DESIGN CODE.

FEATURES

Exterior cabinet and countertop in stainless steel.
Tank and lid in stainless steel (AISI 316L).
Purging by fractionated vacuum and atmospheric pump.
Steam generator.
Water tank to supply the boiler.
Possibility to supply the boiler from an external water source.
6 operating modes.
Connection for a second control probe.
10 fully configurable user programs.
Lateral port for external probe (except for 150-liter autoclave).
Internal memory for storing 200 cycles.



NEW

EU GMP Annex 11

FDA 21 CFR Part 11

Wi Fi

Fo

USB

SAFETY

Device that prevents the lid from opening while the chamber is under pressure.
Safety valve. Prevents the pressure from exceeding the maximum limit.
Safety pressure switch. Disconnects the heating in case of overpressure.
Thermal protective cover for the lid.
Closed-door detection sensor.
Atomatic generation of reports in PDF and CSV.
Safety thermostat.
Overheating alarm.
Error alarm during cycle.
Level alarm.
Sterilization failure alarm.

INTEGRATED BACK PRESSURE SYSTEM

MODELS	Code	Capacity liters	Ø / High (usable) cm	Height / Width / Depth (external) cm	Temp.° C H_2O dest.	Capacity Tank	Capacity Basket	Consumption W	Weigth Kg
Steril Pres USB-80	4002442	80	40 60	119 58 72	80 a 128	10	2	4850	136
Steril Pres USB-150	4002443	150	50 70	118 80 95	80 a 128	10	3	7500	250
Steril Pres GMP-80	4002444	80	40 60	119 58 72	80 a 128	10	2	4850	136
Steril Pres GMP-150	4002445	150	50 70	118 80 95	80 a 128	10	3	7500	250



They are supplied without basket and without drums.

PLC FUNCTIONS

The PLC controls the air extraction, sterilization and drying process by executing the procedures and commands selected by the operator, regulating the following parameters:

- Sterilization temperature from 105 °C to 128 °C
- Sterilization time from 3' to 59'.
- Up to 60 user-configurable programs.
- Configuration
  - Units -Languages (Spanish, English, French)
  - On/Off printer. - Clock: date/time.
  - External water inlet: on/off.
- Password for user level configuration.
- Calibration (offset adjustment)
  - Probe 1 temperature - Probe 2 temperature
  - Water dosage - Pressure.
- Visual alarm of over-temperature and under-temperature.
- Detection and memorization of mains failures.
- Safety thermostat (TS) by software.
- Sterilization cycle data logging with capacity for more than 500 cycles.
- Graphic representation of the process in real time

Any error in operation or execution results in a message on the control panel and an acoustic warning, automatically shutting down the steam generator.

COMPLEMENTS AND ACCESSORIES

Code	Ø cm	Height cm	Number of baskets
1000496	36	28	2
1000785	47	28	2

*AISI 304 stainless steel blind baskets.