TECHNICAL SHEET
STEAM STERILIZER MODEL STE1-2-E

1	Manufacturing company:	Mediqua S.r.l.
2	Model:	STE1-2-E
3	CND code:	Z12011304
4	Directory code of the Italian Ministry of Health	2130557
5	Description:	The autoclaves have been designed and built with the aim of guaranteeing repeatable steam sterilization processes over time for: the microbiological result, the treated material, the operators, as well as for the environment, applying the concept of redundancy for process safety and the use of certified safety devices and components. The autoclave, through a safe parametric control, guarantees the conditions of steam sterilization by keeping the material to be sterilized at the correct parameters, such as temperature, pressure and correct saturation of the steam, for a defined time. The door closes/opens with automatic vertical sliding. Functioning with several sterilization cycles with computerized control. Possibility of choosing between one of the following steam productions or from several combined productions (as described in point n.14): - **E**: Self-produced steam supply by means of an integrated electric steam generator (autonomous and separate from the sterilization chamber) built in AISI 316L stainless steel, according to PED 2014/68/EU regulation. - **S**: Steam supply from external mains (clean steam supplied by the customer). - **SE**: Steam supply produced by an integrated heat exchanger and fed by steam from the external network.
6	Classification:	- In accordance with the classification rules set out in Annex IX of Directive 93/42/EC, the sterilizer is classified as a **Class IIb medical device** - In accordance with the classification rules set out in Annex II of Directive 2014/68/EU, the sterilizer is classified as a **Category III Assembly**
7	Followed Directives:	The sterilizer is built according to Directive 93/42/CE and subsequent amendments concerning medical devices (including Directive 2007/47/EC implemented with Italian Legislative Decree 37/2010); according to the P.E.D. Directive 2014/68/EU concerning pressure vessels; according to the Machinery Directive 2006/42/CE; according to the Low Voltage Directive 2014/35/EU; according to the Electromagnetic Compatibility Directive EMC 2014/30/UE.

8	Compliant with Standards:	UNI EN 285 ; UNI EN ISO 17665 ; CEI EN 61010-1 ; CEI EN 61010-2-040 ; CEI EN 61326-1 ; UNI CEI EN ISO 14971 ; CEI EN 62304 ; CEI EN 62366.
9	CE Marking:	According to the European Directives 93/42/CE and subsequent amendments concerning medical devices, and 2014/68/EU concerning pressure vessels.
10	Company quality system:	Mediqua S.r.l. has the quality certification according to ISO 9001:2015; ISO 13485:2016.
11	Year of first placing on the market:	2022
12	Year of placing on the market of the latest version:	2022
13	Intended use:	STEAM line sterilizers are class II b medical devices and are used for the steam sterilization of surgical instruments in general, porous materials in general, rubber materials in general and any material that the medical device manufacturer has tested to be sterilizable using steam.
14	Definition on models:	STEAM line equipment is identified by a code composed on the basis of the construction characteristics of the equipment. The various acronyms and their meanings of the STEAM line for the sterilization of medical devices are listed below. Ex. **STEX-Y-Z** - The letter **X** identifies whether the machine has 1 or 2 doors - The letter **Y** identifies the number of sterilization units of the equipment. - The letter **Z** identifies the type of steam generation Steam generation can be as listed below: - **E** = electric steam generator inside the machine. - **S** = steam coming from the external network. - **ES** = electric steam generator inside the machine and steam coming from the external network (E mode + S mode). - **SE** = clean steam produced by heat exchanger fed from the external mains. - **ESE** = electric generator inside the machine and clean steam produced by a heat exchanger powered by the external mains (E mode + SE mode).
15	Model:	STE1-2-E
16	Number of doors:	Single door (N.1 for the loading/unloading of material)
17	Machine overall dimensions (mm): (WxHxD)	1050x1850x970
18	Loading height (mm):	around 850

19	Type of steam generation:	Electrical (E)
20	Autoclave weight (kg):	Total weight: 700 kg Specific load: 413 kg
21	Machine information:	The autoclave consists of: a **load-bearing structure** that supports the sterilization chamber, and an **access module** on which the touch-screen monitor is installed. This allows for easy transport, balanced load distribution and easy passage through the access doors to the installation rooms. The machine is therefore composed of two elements: the main element on the left measuring WxHxD 580x1850x990 mm and the secondary element on the right measuring WxHxD 470x1850x990 mm, joined together with different panel shapes. It is possible to compose the machine in a mirrored configuration (main element on the right and secondary element on the left). In the main element there is the chamber with N.1 automatic vertical sliding doors and closing control device. The plumbing systems (steam inlet, condensate drain, general drain, etc.) are made below and above the chamber, always on the main element. Inside the module (secondary element) there is an electrical panel with the control and management system of the autoclave and the steam generator (if present). The steam generator can also be placed above and below the main element. If necessary, the structure can be disassembled and can be shipped in 2 modules (main element and secondary element) that can be easily re-assembled on site.
22	Control panel:	The control panel is placed on the front surface of the sterilizer. This represents the operator interface for the operation of the sterilizer and shows all the components for the command and control and for safety. It consists of a tactile graphic screen (touch-screen), a printer, a power button, an emergency button with key reset, a door closing button, a door opening button, a USB port and three pressure gauges for displaying the **generator/jacket/chamber** pressure. The touch screen control panel provides the following displays and commands: • Second button for closing the doors • Program selection buttons • Buttons for changing program parameters • Process stage indicators • Alarm indicators • Text indication of alarms • Indication of the maintenance schedule • Room temperature • Chamber pressure • Jacket temperature • Generator pressure • Time and date • Remaining cycle time
23	Thermal insulation:	- Thermal insulation has been a goal on which we have invested and worked to obtain a significant reduction in heat dissipation, to have significant energy savings.

		- Chamber, jacket, door and generator adequately insulated with high-efficiency insulation materials. - A mat in expanded melamine (Fonitek®) and highly insulating, self-extinguishing glass wool with thermal conductivity **< 0.035 W/m*K** are used - The surfaces to be insulated have been designed to have perfect adherence of the insulating material and to eliminate possible conduction towards the other external and internal parts of the appliance in compliance with the reference standards. - The steam and condensate pipes are insulated with a sheath (textile glass), this allows to maintain the same parameters of heat transmission and external temperature.
24	Thermal Dissipation: - Loading/unloading side front surface - Internal compartment	 1200 kJ/h 6000 kJ/h *(Indicative model values that can be found on the equipment of this family)*
25	Average noise in accordance with the Standard UNI EN 285:	<65 dBA
26	Ease of access to the machine system for maintenance operations:	Access for maintenance and validation can be done from the front by opening the front and rear inspection doors (if double door) and removing the side panels on both the right and left sides of the equipment. The hydraulic circuits, valves, components, electrical and wiring are easily accessible from the front by opening the inspection doors on the control side and on the unloading side if double door. Access for maintenance is further facilitated thanks to the completely extractable electrical panel by means of telescopic guides. Maintenance can also be done laterally on both the right and left sides of the machines by removing the side panels. The front inspection doors and side panels are equipped with a key or other locking system that does not allow access to unauthorized personnel. The internal and external components (and doors) of the autoclave are protected in order to prevent accidental direct access by unauthorized personnel.
27	Precautions to facilitate the loading and unloading of the material:	Steam sterilizer arranged and equipped in such a way as to guarantee an ergonomic position for the operator both during loading and unloading.
28	Transport and installation:	The autoclave is completely assembled on the assembly line and tested as a whole. It can be shipped in a single piece or if there is a need for smaller overall dimensions for reasons of space or routes, it is possible to ship the autoclave divided into two parts (chamber part and module part, as described in point n.21 - OPTIONAL) The autoclave is designed and built as a single unit and comes off the assembly line complete with all the components, thus avoiding the need to assemble parts during the installation phase.

		For the installation of the autoclave, the place must be prepared with the utilities envisaged in the installation drawing. The specialized technicians will position the autoclave, carry out the hydraulic and electrical connections, carry out commissioning, functional testing and staff training.
29	Electric steam generator: (present in case of steam generation E, ES, ESE)	- Automatic electrically heated steam generator (integrated, separated from the sterilization chamber and jacket), built in **AISI 316L** stainless steel (Optional AISI 316Ti), produces and accumulates the steam to be used for the sterilization cycles. - The circular section generator is made in a single piece by assembling from various semi-finished products through certified welding procedures. Dimensional calculations for project approval of 4 relative bars. Documentation certifying the welding parameters of the generator and the hydraulic test. The steam generator consists of an automatic water supply device via an AISI 316 stainless steel electric pump, controlled by two AISI 316 steel minimum and maximum level probes. The level probes control both the heating elements and the electric pump with minimum filling operations to keep the generator pressure stable. - Automatic regulation of the pressure through a pressure transducer and a pressure switch for the control of the heating elements - Automatic resistance temperature control device to avoid overheating - Automatic and programmed generator drain device with time control to generate mechanical self-cleaning by eliminating any mineral deposits that could solidify. - Pressure gauge for pressure control. - A "Y" filter with stainless steel mesh is installed at the inlet of the water supply pipe to the generator, which serves to protect the pipes and components from any impurities present in the mains water. - Automatic change to Stand-by position if the autoclave is not used, this implies a reduction in energy consumption (the operator can choose the time for the start of **Stand-by** and the type of **energy saving**). - The heating elements (resistors) are made of a special alloy (incoloy 800).
30	Dimensions of the Internal steam generator: (Diameter x Depth)	219x460mm
31	Steam generator capacity:	16 l
32	Heat exchanger: (only for SE, ESE models)	The steam used to feed the autoclave is produced by a plate exchanger with different sizes based on the model of the machine, where two fluid currents (primary element and secondary element) exchange their thermal content through plates thus generating steam. In the first element of the exchanger the steam coming from the network is connected via a pneumatic valve and in the second element the water present in the generator is connected. The heat exchange of the fluids (network steam and generator water) generates steam at the

		exchanger outlet which is transferred to the generator via a pneumatic valve and is used to feed the autoclave.
33	Construction materials of the sterilization chamber:	- The sterilization chamber with a rectangular section is made in a single piece by assembling various semi-finished products with a reduced number of welds, subjected to radiographs. The internal corners are perfectly rounded. The bottom of the sterilization chamber is inclined towards the drain, to allow for optimal drainage of the condensate and to achieve perfect drying. - Material constituting the walls and bottom of the sterilization chamber: stainless steel **AISI 316L** (1.4404 X2CrNiMo 17-12) (Optional version in AISI 316 Ti) of first quality (certified) highly resistant to corrosion and with a high percentage of chromium-molybdenum, which guarantees greater resistance in the welding and bending areas. Sterilization chamber made with 5 mm thick stainless steel profiles and plates. Generous internal dimensions in relation to the load; this promotes the flow of vapor and the elimination of air. Approval of dimensional calculations for design pressure from -1 to +3.5 bar relative. Design temperature up to 148° C. - The front of the chamber is made with a high thickness 316 stainless steel profile with incorporated gasket seat and with fixed guides, all worked with numerical control machines. Direct connections in the chamber welded flush with the surface, connections for thermometric tests and vacuum tests as required by the EN285 standard. The introduction of steam into the chamber is carried out laterally and takes place through optimized diffusers to ensure better diffusion of the steam. This allows to obtain a homogeneous temperature profile in all points of the chamber. - Documentation certifying parameters and certifications of chamber welding and the hydraulic test. - Mechanical polishing with roughness less than 0.2 µm. The finishing processes of the polishing take place through the use in different processes with abrasive machines until a perfect mirror polishing is obtained with a roughness lower than (RA) 0.2 µm. - The chamber is manufactured in compliance with the European Pressure Equipment Directive (PED) 2014/68/EU and related CE marking
34	Load capacity in sterilization units:	N.2 Sterilization units
35	Chamber volume (litre):	160 l
36	Sterilization chamber dimensions: W x H x D (mm)	350 x 680 x 690
37	Construction materials of the jacket:	- The jacket is in stainless steel AISI 304 (1.4301 X5CrNi18-10) (Optional version in AISI 316L or AISI 316Ti) - Made with profiles and sheets in first quality AISI 304 stainless steel (certified) with a thickness of 5 mm. - The jacket completely envelops the chamber with a system called "full-jacket system". This system promotes better heat uniformity in the chamber, reducing the coldest areas where condensation could form. The full-jacket system guarantees maximum coverage of the directly heated chamber surface. The operating pressure is 3.5 relative bars, maximum working temperature 148° C. The jacket is assembled and welded on the chamber by assembling the various semi-finished products (sheets)

		and connections (for loading the steam and draining the condensates). The modular assembly allows you to carry out a qualitative control of the welds carried out. The welds are radiographed. - Documentation certifying the parameters of the jacket welds and the hydraulic test.
38	Jacket capacity (litre):	27 l
39	System for the vacuum formation in the sterilization chamber:	- High capacity liquid ring type vacuum pump, capable of achieving a vacuum level performance in line with the reference standard. The system is equipped with a cooling system implemented through an AISI 304 steel water-steam exchanger. The large capacity of the pump to produce vacuum, due to the hourly flow rate, actively contributes to the reduction of the sterilization cycle time. A special condenser/cooler equipped with a cooling fluid control valve is installed between the chamber discharge valve and the vacuum pump. This system allows the temperature of the fluids coming from the chamber to be lowered before entering the vacuum pump. All this combined with an anti-cavitation system that allows for highly efficient vacuum production with low noise emissions, the vacuum system in the sterilization chamber is implemented through the use of a liquid ring vacuum pump. The cycles foresee as a first phase the execution of the fractionated vacuum (vacuum and injection of steam to eliminate the formation of air pockets in the material to be sterilized) and the elimination of the steam after the sterilization phase through the vacuum pump. The vacuum pump cooling water supply is regulated so as to minimize consumption. - The vacuum pump is equipped with its own silencer and is mounted on anti-vibration supports to ensure absolute silence. - A "Y" filter with stainless steel mesh is installed at the inlet of the vacuum pump cooling water supply pipe to protect the pipes, components and vacuum pump from any impurities present in the mains water. As OPTIONAL a system to reduce water consumption of the vacuum pump can be added (water recovery system) OR another OPTIONAL is the ECOPUMP system, that uses a dry vacuum pump, and with this there is no need of water at all for the vacuum pump.
40	Connection for validation use:	There are two connections for validation use: TT temperature cap, TV vacuum/pressure cap. They are located in the upper part of the machine and can be accessed for validation use via the inspection door.
41	Construction materials of the hydraulic system and electrical circuit (distribution, shut-off, regulation and discharge system for the steam, condensate, water, air fluids used and/or produced during the sterilization process, electrical panel and electrical components):	The hydraulic system is made entirely of **AISI316L** stainless steel designed together with the electrical system to allow easy maintenance through panels that can be opened on the right and left sides, front and rear sides of the machine. The material for the fluid shut-off valves and the pipes are made of stainless steel from primary leading companies worldwide. On the groups and sub-groups are installed

		tri-clamp connections, fittings with cut ring and sealing thread with Teflon tape (PTFE), hydraulic unions to facilitate disassembly, maintenance and improve sealing. The treated water pipes for the mains water, steam and condensate generator are made to drain perfectly and are insulated with insulation (textile glass sheath) to avoid heat dispersion into the environment and prevent direct contact with the operators in charge of maintenance. The shut-off valves are made of **AISI316** stainless steel and are built with materials that do not transmit polluting components and installed with a stainless steel body and components actuated by pneumatic servo controls. All valves are equipped with a silencer. A **0.01 µm** air filter is installed to allow air to enter the sterilization chamber at the end of the cycle. The electrical panel is separate from the equipment and connected to it, has an IP55 degree of protection, and is installed laterally inside the equipment. The panel can be extracted by means of telescopic guides to allow easy maintenance. A disconnector and a key lock are installed in it to allow maintenance in complete safety. The electrical panel includes: - PC - Command and control cards - Switch/disconnector - Motor protection thermal contactors - Electronic levels for water and resistance control - Relay with light indicators - Protection fuses - Clamps - Wiring in raceway. The electrical system of the autoclave complies with current European regulations (CEI EN 62208). All the electrical components installed are from leading companies worldwide, are connected to a terminal block and enclosed in a cabinet with IP55 protection, with the exception of the control components which are provided on the front panel and protected by a protective casing.
42	Method of connection between the various sections of the circuit:	Hydraulic connection via tri-clamp fittings, unions, cut ring fittings and Teflon tape (PTFE) sealing thread.
43	Compressed air system:	- The compressed air system (serving the operation of the pneumatic actuators of the shut-off valves and actuation of the sliding doors) is made with Teflon (PTFE) or Rilsan pipes. - The air used to control the pneumatic valves is made to pass through pressure reduction units complete with air filtering and anti-condensation filter. - The system is complete with all the instruments necessary for operation and control, generating an **alarm in the absence of compressed air**.
44	Construction materials of other components:	- Frame: the frame structure is designed with a load-bearing structure to support the sterilization chamber and an access module designed for anchoring all the

		electronic and hydraulic parts and other components. The frame, in addition to supporting all the mechanical and non-mechanical details, also delimits the size of the equipment, making it robust and thanks to the rigidity of the frame, unloading the weight on the entire base, reducing the load on the floor. The frame is made with AISI 304 stainless steel tubulars. - External paneling (external cabinet: side and front panels): the external paneling is made of AISI 304 stainless steel with a "scotch-brite" finish. For safety, the panels are made with metal sheets without sharp edges and sharp angles. The control panel with the tactile graphic screen (touchscreen) and the technical control and safety instrumentation of the device is installed on the paneling of the module door. The front panels can be opened with hinges and are equipped with a lock with a dedicated key. The side panels are bolted to the frame with screws. - Door sliding guides: AISI 304 stainless steel
45	Garanzie accessorie per alcune parti componenti l'autoclave: - chamber - jacket - door	 - see warranty period in the sales conditions; - see warranty period in the sales conditions; - see warranty period in the sales conditions.
46	Doors features: - Number of doors: - Closing system:	 - N.1 vertical automatic sliding doors, opening downwards with pneumatic control and tactile buttons arranged on the control panel and on the touch screen (operated by pneumatic actuators). - The doors are designed and built with vertical sliding movement, pneumatically operated with a system that guarantees precision, silence and safety. - Door closing is enabled by n.2 buttons (n.1 tactile button on the touch-screen and n.1 button on the control panel). The distance between the two buttons does not allow them to be operated by just one hand, therefore it is necessary to use both hands to operate the door closing safely. Safe door closing by continuously pressing the dedicated buttons and double button closing control. - The perfect seal against vacuum and pressure is guaranteed by a special silicone perimeter gasket with dynamic seal. The gasket is inflated by the steam and ensures a perfect seal between the doors and the chamber. The gasket is made in a single profile with a circular section to adapt to continuous dynamic stresses. - Door equipped with suitable safety devices to protect operators and loads.

	- Construction materials:	- It is impossible to open the door as it is mechanically blocked for the entire duration of the cycle. The door opening consent will be active when, upon completion of the cycle, the chamber pressure is at atmospheric pressure. The autoclave is equipped with control devices and mechanical block against the opening of the door in the presence of pressure in the chamber: pressure switch, mechanical device with sensor which signals the correct functioning of the mechanical block, overpressure devices. - When the door is closed, a mechanical lock intervenes which prevents it from being opened until it is reopened by the operator (mechanical safety device for door locking which is always active when the door is closed). - **AISI 316L** stainless steel (OPTIONAL version in AISI 316Ti highly resistant to corrosion).
46	Door structure description: Door interlock:	- The doors are made out of a single homogeneous piece of steel, with approval of dimensional calculations; the sheet is 10 mm thick; the doors are designed to work at a design pressure of -1 +3.5 relative bars. Design temperature of 148°C. The surface of the door is polished through the use of different processes with abrasive machines until a perfect mirror polish is obtained with a degree of roughness lower than 0.2 µm. - Type of material used for insulation: melamine expanded foam panel. The thick insulation makes it possible to guarantee a maximum external temperature that is always **lower than 45 °C** (personal protection). - It is not possible to open both doors at the same time: for double door machines (loading door and unloading door) the doors are interlocked; this avoids contamination between environments. The doors are controlled by the control system and, based on the selected cycle, it enables the door that can be opened (for test cycles and work cycles that are not terminated regularly or in the event of alarms, only the opening of the loading door is enabled). When the cycle ends regularly, only the unloading door (sterile) can be opened.
47	Sealing system between door and chamber:	- The gasket in silicone between the door and the chamber is an important element and is essential for the correct execution of the sterilization cycle. The gasket is made in a single tubular mold in high quality silicone, and allows perfect adherence in the gasket seat and on the door until it becomes integral with the chamber, and thanks to the circular section and its high elasticity, maintains it throughout the cycle of sterilization and in particular in the phases of dynamic

		movement of the gasket during the phases of vacuum and introduction of steam into the chamber. The gasket is positioned inside a slot obtained on the front of the machine. - Thrust mode: steam (taken from the generator) is used as a means of force for the seal and guarantees the dynamic movement of the gasket.
48	Safety devices:	- Servo-assisted closing and opening of the door (closing with continuous pressure of 2 tactile buttons). The movement of the door takes place via a pneumatic device. The door slides between two side guides. By sliding vertically, the door moves in safety conditions. The system has safety limit switches, via proximity sensors, for closure. Anti-crushing protection system and obstacle protection on the door, with thrust force control not exceeding 150 N (Newton). - Certified safety valve on the door closing compressed air line. - Dynamic seal by steam pressure. - Check the pressure in the gasket groove by means of a pressure switch. - Impossibility to open the door if the chamber is not at atmospheric pressure controlled by a pressure switch installed directly in the sterilization chamber. Inability to start programs if the door is not perfectly closed and hermetically sealed. - Impossibility to open the sterile side door following Test cycles or cycles with negative results (only for double door versions). The loading side door (for double door versions) opens only when the limit switch of the sterile side door gives the door closed signal. In this case, one of the two doors is always closed, allowing the two clean side and sterile side environments not to communicate. - When the door is closed, it is blocked by a mechanical safety device. - Control of overpressure and overtemperature of saturated steam using the following devices: pressure transducers, PT1000 class A temperature sensor. - Double chamber temperature control device using class A PT1000 probes. - Jacket temperature control via PT1000 class A probe. - Chamber pressure control element via 4-20 mA pressure transducers. - Device against the introduction of steam into the chamber if the door is open or not perfectly closed.

		- Element for controlling the temperature of the electric heaters. - Water level control elements inside the generator via 2 minimum and maximum level probes with conductivity control relay. - Use of manual reset magneto-thermal switches on the various utilities (water pump, vacuum pump). - Analog pressure gauges for displaying the pressure in the generator, in the jacket and in the chamber, even when the machine is off. - Emergency mushroom button on the front panel of the machine (also on the sterile side for pass-through versions). To restart, the button must be reset by turning the key given to the responsible authority to the ON position. - Safety valve with maximum working pressure of 3.5 bar, certified in accordance with the PED 2014/68/EU standard, installed on the body of the steam generator. - Steam generator overpressure control via pressure transducer, pressure switch and safety thermostat. - Pressure control of the door gasket by means of a pressure switch. - Control of lack or lowering of compressed air by means of a pressure switch. - Release switch/disconnector on the electrical power panel.
49	Number of temperature control probes:	N.3 Probes PT 1000 class A
50	Number of pressure control transducers:	N.2 electronic pressure transducers in the chamber 0-6 bar 4-20 mA N.1 Transducer/electronic pressure switch for the steam generator 4-20 mA 0-5 Bar
51	Number of pressure switches for pressure control:	N.4 pressure switches for gasket pressure control, compressed air, generator and chamber pressure.
52	Possibility of calibrating temperature probes and pressure transducers:	Possibility of accessing the setting pages via a **maintenance password** where the offset and range can be entered for the calibration of the temperature probes and pressure transducers.
53	Active alarms:	- Fluids control (water and air), - power supply, protections; - Heating operation control; - Door locking and unlocking control; - Gasket pressure check - Door sealing and closing control;

		- Cycle phases control; - Pressure and temperature control in the sterilization chamber - Sterilization chamber tightness control; - Operational check of transducers of the system control and registration system; - Temperature probe operation check - Alarm resolution control and communication. - Generator pressure control
54	Graphic display:	On the non-sterile side: large **15"** color Super TFT (IPS) LCD Graphic display, interactive touch-screen. The display is located on the main control panel. The main display provides the following information and displays: **General data**: Machine identifier (model, factory number, number of doors, type of power supply, manufacturer); time/date; cycle progressive number; language; operator and maintenance password; state of the doors; operating mode; manual/automatic status; scheduled maintenance; chamber temperature/pressure values; Jacket temperature values; generator pressure values; access to sub-menus; technical functions; synoptic of the machine system. **Cycle data:** List of sterilization cycles and tests; menu for displaying and modifying the parameters, phases and sterilization cycles; modifiable parameters of the cycles; set parameters; cycle parameters in real time both in graphical and alphanumeric form; name of the cycle in progress; name and time of the phase in progress with residual execution time; pressure-temperature graph in real time during the cycle; process stage indicators; pressure/temperature in the sterilization chamber; jacket temperature; outcome of the cycle terminated in a regular/irregular manner; cycle stop and manual advance button (equipped with interlock), F0; % saturated vapor. **Technical data:** Status of all inputs and outputs of the control system; offset for tool adjustment; parameters for machine regulation; alarm indicators (visual and audible); text and sound indication of alarms; display of the alarm in progress; display of communication with the controller in progress; indication of maintenance intervals; self-diagnosis status. On the sterile side (double door autoclaves only): **5"** TFT color LCD graphic display, interactive touch-screen. The secondary display provides the following information and displays: **General data:** Machine identifier (model, factory number, manufacturer); state of the doors. **Cycle data:** Name of the current cycle; name and time of the phase in progress with residual execution time; outcome of the finished cycle. **Technical data:** Visual alarm indicators.
55	Pc:	The PC is equipped with a Windows operating system and can be connected to external computer systems via

		RJ45 ethernet output for detailed analysis of operation, history and data export. Through the connection it is possible to have the **remote printing** of the cycle reports and **REMOTE ASSISTANCE** (included in the first year of warranty period), allowing the remote analysis of the possible causes of malfunction and the status of maintenance. In this way, targeted repair interventions by the technical staff and an optimized management of scheduled maintenance are possible. The system is able, via a **voice synthesizer**, to notify the type of alarm, the end of the regular/not regular cycle and the door opening warning.
56	Network connection interface for process logging and material traceability:	The equipment is set up for connection to the computer network via an Ethernet port, for process recording and material traceability using commercially available traceability software, which will have to interface with the text format files (or other if necessary) produced by the system during each sterilization cycle. Mediqua can supply the **Mediqua iCanTrace** management and traceability software as OPTIONAL.
57	Control system:	Advanced control system: includes n.3 independent electronic controllers with their own software and non-volatile memory (a management PC, a control board and a verification board) Each board manages its own temperature probe and its own pressure probe, sending the data to the PC which transmits them both on the displays and via the printer.
58	Self-diagnosis:	While the equipment is switched on, the control system checks the status of the inputs and outputs in real time, regulates the pressure in the generator, receives commands from the operator and manages the phases of the cycle in progress. The control system is able to identify and manage a series of operating anomalies (fault conditions) linked to the safety aspects of the equipment and to the efficacy aspects of the sterilization cycle. Any anomaly is detected and communicated to the operator both via an acoustic signal and via an indication on the display (acronym and anomaly description are displayed); if the cycle is in progress, it is also printed on paper (including date/time and alarm description). Upon identification of the anomaly, the equipment automatically goes into a safe condition and automatically resolves the anomaly; during the resolution, the equipment performs a series of phases which bring the machine to a state equivalent to that of the first start-up to avoid residual dangers. Any cycle in progress is in any case invalidated. At the end of the alarm phase, the operator must reset it (as foreseen in the use and maintenance manual).
59	Coding system for operator identification:	Possibility of memorizing **up to 1000 Operators**, complete with user name and password for accessing programs and work menus. Furthermore, the identification of the operator who selected and started the cycle is present on the receipt of the printer.

60	Methods for recording the data collected, devices used, documentation issued for each cycle and archiving:	Alphanumeric printer on the front panel of the machine, which allows the permanent recording, archivable and independent from the control system of the following data (documentation issued for each cycle): - Hospital/ward ID/no. Autoclave - Model/serial number of the appliance; - Identification of the sterilization or test program; - Progressive number of the cycle; - Operator identifier; - Cycle start/end; - Date/time; - Phase name; - Temperature, pressure, time; - F0, % saturated steam, basic sterilization parameters; - Final outcome of the regular/non-regular cycles; - Operator signature; - Pressure and temperature diagram; - Identification of operating anomalies; Immediate reading system and printing at the end of the cycle (printing after each phase of the cycle on request). Manual digital export system of the reports of the cycles performed on auxiliary storage (USB memory via **USB port** on the panel, remote disk). Storage of up to **100,000 Cycles** performed and alarms occurred during operation.
61	Sterilization programs with automatic execution:	The automatically executed programs have been validated according to the reference standards (UNI EN 285), are programmed in the factory and are available to the user (by anyone authorized to use the autoclave). The execution of the cycles takes place directly from the control panel, on the touch-screen. **The standard cycles cannot be modified.** The phases of the cycles are described below: - Pulsation and heating phase: This is the phase in which vacuum/steam pulsations are performed to bring the autoclave into optimal conditions for starting the sterilization phase. - Sterilization phase: This phase will start counting the predefined sterilization time for each cycle only when the autoclave is in optimal conditions, i.e. when the predefined temperature and pressure values are reached for each cycle. The temperature is uniform throughout the

		chamber and the temperature difference between the probes is less than 0.8°C. - Drying phase: This phase is carried out by means of a vacuum pump. A vacuum is created inside the sterilization chamber for a predefined time, at the end of the vacuum phase the atmospheric pressure of the chamber is re-established through a vacuum breaker filter. The intended use (as described in point 13) of the Mediqua steam sterilizer is limited to the execution of sterilization processes of reusable MD (medical devices) according to the provisions of the MD manufacturer. • **Warmup cycle:** Program for heating the machine to 134°C • **Textiles cycle:** Program for porous materials and fabrics at 134°C; It is used to sterilize hollow and solid instruments packed with drapes, porous materials in general and for any solid and porous load resistant to temperatures of 134°C. • **Gloves cycle:** Program for thermolabile materials at 121°C; It is used to sterilize packaged hollow and solid instruments, gloves, catheters and other plastic or rubber materials or any other thermosensitive solid or porous material that is resistant to 121°C. • **Instruments cycle:** Program for packaged instruments at 134°C and with fractionated drying. Specific for packaged surgical instruments, solid loads and any type of solid and porous material resistant to temperatures of 134°C that require fractionated vacuum drying. • **Instruments heavy load cycle:** Program for packaged instruments at 134°C with fractionated and reinforced drying. Used for instruments packaged at 134°C with fractionated and prolonged drying. Specific for packaged surgical instruments, solid loads and for any type of solid and porous material resistant to temperatures of 134°C which requires fractionated vacuum drying and a prolonged time. • **Flash cycle:** Sterilization program at 134°C. The Flash cycle is used for packaged and unpacked surgical instruments and has been validated with a load that can vary from 1 surgical instrument up to a maximum equal to half the kg envisaged by the reference standard for the machine's sterilization units. • **Prion cycle (Creutzfeldt-Jakob disease):** Sterilization program for Prions at 134°C. It is used to treat porous loads and solids suspected of Creutzfeldt-Jakob contamination. The purpose of this cycle is to ensure sufficient steam penetration on the material which is presumed to be Prion contaminated.

62	Test programs with automatic execution:	**As required by the UNI EN 285 standard, the autoclave provides for test cycles as listed below:** **• Vacuum Test:** Chamber tightness test. This test is used to verify that there are no leaks (air, steam) in the chamber and therefore the vacuum seal of the autoclave. When starting the vacuum test the chamber must be empty. **• Bowie and Dick Test:** Test for the penetration of steam into the porous load. The purpose of this test is to verify the efficiency of steam penetration and air removal in porous loads. **• Helix Test:** Steam penetration test in hollow bodies. The purpose of this test is to verify the efficiency of steam penetration and the removal of air inside the hollow bodies. This test must be used by all autoclaves that sterilize hollow bodies. The management of the sterilization cycles and test cycles is implemented by a computerized system which, in addition to the control, management and recording of the sterilization programs, has the possibility of transferring the data to an external centralized acquisition and supervision system (traceability of sterilized materials).
63	Custom cycles:	The customized cycles can be programmed according to one's needs via the touch-screen monitor by users enabled by access code. When the program setting is completed, this can be performed automatically by the sterilizer and remains saved in its memory. It is possible to set **up to 1000 new customized cycles**, identifiable by a number and blocked by an access code. To run a customized cycle, simply select the corresponding cycle number and start it. To set up a new customized cycle, it is possible to do so from the modification menu, where the required values can be set, such as pressure, vacuum, temperature, phases and times, ***no lower than those certified by the manufacturer Mediqua and foreseen by UNI EN 285***.
64	Autostart feature:	The autoclave is equipped with an automatic start function, which can be programmed according to need. The date (week day) and the start-up time can be programmed. Once this function has been set and activated, it is possible to automatically start the initial heating cycle, the vacuum test and, if the appliance is equipped with the automatic loading/unloading system (OPTIONAL), it is also possible to automatically start the Bowie and Dick or Helix test.
65	Alarm log storage:	**Storage of up to 100,000 cycles of the alarm history.**
66	Energy saving and standby features:	To reduce energy consumption and optimize machine downtime due to self-heating, the autoclave is equipped with the **standby** function. With this function active, the heating of the autoclave is interrupted after a certain

		period of inactivity of the machine or at the end of the last cycle performed. Possibility of switching on, switching off, automatic and programmable stand-by. Possibility of choosing to set energy saving and stand-by after a period of inactivity of the machine or at the end of the last cycle, also choosing the level of energy saving to be applied.
67	Maintenance:	Presence and programmability, via the operator interface, of a schedule relating to ordinary and preventive maintenance: - Possibility of scheduling maintenance deadlines or other maintenance-related interventions. Warnings on display and on the printed receipt.
68	Power supply: - Tension - Power - Current intensity - Frequency	 - 400 V 3P + N + E - 19 kW - 28 A - 50 Hz
69	Power requirement stabilized within:	+/- 10%
70	Uninterruptible Power Requirement:	No
71	Operating ambient temperature limits:	5÷40°C
72	Operating ambient humidity limits:	35÷85%
73	Vacuum pump cooling water: - flow rate - maximum temperature - pressure - max hardness - consumption	 - 20 l/min - <15 °C - 1,5-3 Bar - 0-10 °f - 35-130 l/cycle - With the water recovery system (optional) on the vacuum pump, it is possible to reduce up to 50% of the consumption of water of the vacuum pump. - With the ECOPUMP system (optional) there is no need of cooling water for the vacuum pump.

74	Generator water: - flow rate - consumption - pressure - conductivity	 - 20 l/min - 5-20 l/cycle - 2-3 Bar - 5-10 mS/cm Ph 5-7
75	Air supply: - flow rate - pressure - consumption	 - 15 Nl/min - 6-8 Bar - 7 Nl/cycle
76	Drain: - flow rate - temperature	- 40 l/min - Material resistant to 140 °C
77	Safety valve discharge:	- Material resistant to 140 °C - Dedicated drain for safety valve **(The discharge of the safety valve must be free from vent obstructions)**
78	Condensate drain (for S and SE models):	NOT APPLICABLE
79	Line steam supply from the thermal plant (only for S and SE models)	NOT APPLICABLE
80	Drain cooling system:	On the drain manifold of the machine, an automatic system can be installed as **OPTIONAL** which allows to lower the drain temperature.
81	kW consumption per cycle:	A display and printing system of the energy consumption (total and realtime during the cycle) in kW can be installed as an **OPTIONAL** in the machine.
82	Generator water consumption of and vacuum pump cooling water consumption:	A system for displaying and printing the total water consumption per cycle of the generator and the vacuum pump/heat exchanger cooling water consumption can be installed in the machine as an **OPTIONAL**.