Sterilmed ®

TIBBİ CİHAZLAR

STEAM STERILIZER
WASHER AND DISINFECTOR
LOW TEMPERATURE STERILIZER

Sterilmed Medical

ElektrikElektronikOtom.İnş.GıdaSan.veDışTic.Ltd.Şti.

About us

Sterilmed Medical was established in 2009 in Ankara to proved services in the medical device sector. It has aimed advancement since the day of its establishment by also taking growth and compliance with the contemporary technologies and protecting the environmental conditions.

Our Firm is following the innovations in its sector and in abroad through its research and development unit and its application staff with a strong infrastructure of engineers, and is continuing to produce devices it had developed in computer environment based on such innovations with high technology and to contribute their development so as to be most beneficial for the Turkish medicine.

With this purpose, our Firm is strictly following the "Quality Management" principles and rules from design of the products to the after sale servicing.

Our Firm has been currently certificated for compliance with ISO 9001 quality management system, ISO 13485 medical device quality management system certificate and ISO 14001 environment management system certificate and with product certificates under MDD 93/42/EEC Medical Devices Directive and PED 97/23/EEC Pressurized Equipment certificate. Furthermore, our steam sterilizers and washing disinfection devices have been certificated by the UK accredited body.

Our Firm is successfully implementing several projects supported by National organizations.

Sterilmed Medical has been awarded with the following:
Our Firm possesses the following certificates;

CE Certificates under the following directives:
ISO 9001,
ISO 13485,
ISO 14001 Quality Management System,
MDD 93/42/EEC Medical Devices Directive,
PED 97/23/EEC Pressure Equipment Directive

Our Vision

To make the Serilmed brand a global brand to make our Firm remembered first in the sector.

Our Mission

Our main task is to create designs with competition power in the global sense by taking the priorities of the sector into consideration and being respectful to the environment and people and giving the first priority to the wishes and expectations of customers, and also to produce innovative technological medical products by meeting all the national and international legal requirements.

Our Basic Values

We are bound up with the Medical Ethical Rules,
We are people-oriented,
We respect environment,
We are creative,
We are customer-oriented,
We are innovative,
We are pro-active,
We believe in the team spirit.

Steam Sterilizers

Sterilmed Medical SMA and SMB series steam sterilizers are able to sterilize all materials that are heat and moisture resistant, packaged and unpatterned, which can be sterilized by pressurized saturated steam.

General Features

Materials :Sterilization chamber, jacket, jenaratorAISI 316 L chamber 6mm.
Jacket and generator Min. 3mm.
Doors :AISI 304 L or 316L 10 mm.
Inner surface chamber cleanning against collosion danger; Glass shered sandblasting or elektropolisaj method.
Outer covering:AISI 304 or 316 L
Gasket channel monoblock groove and cover hinge-pin bracket, minimum thickness 50 mm AISI 304 or 316L stainless steel.

Usage areas:

- Operating theaters and laboratories of hospitals,
- Universities are required to attend faculties of science,
- Veterinary medicine, agriculture, dentistry and pharmacy,
- Medical waste treatment plants,
- Microbiology and research laboratories of industrial establishments
- Food, medicine, cosmetics etc.

Cover and Safety System

Implemented Quality
Management System,
Standards and Directives:

- ISO 9001: 2008
- ISO 13485:2003
- EN ISO 14971:2012
- MDD 93/42AT
- EN 61010-1
- EN 285+A2
- EN 61010-2-040
- 2014/68/EU
- EN 62366

Steam Generator

Door and Safety System

The door is resistant to extreme pressure.

Heat insulation materials needed for heat losses are covered.

The movement of the door is a vertical axis (down-up) and it works extremely quietly with the pneumatic system.

When the door is closed, there is a safety system that prevents any cistern squeeze and allows the door to move in the opposite direction. Pressure and vacuum sealing of the door is provided by silicon based seal which is resistant to the temperature of the device and door sealing is provided by applying vapor pressure to the gasket channel.

The door sealing gasket can be easily replaced without having to remove any part of the device and the gasket is a maintenance-free type. The door seal's replacement time is automatically displayed on the 7 "video graphic touch screen LCD. In addition, the sterilization room can not open the door without the pressure of the press.

Easy loading and unloading operations are carried out with the door which leaves the whole of the sterilization chamber of rectangular shape prism open. In addition, with the safety system preventing sudden opening of the door, the door is prevented from operating without closing the door.

Control Panel

Full automatic, micropocessor controlled with PLC

Preasure measurement: : -1.0...+5 Bar (+ 0.001 bar)

Heat measurement : 0 ºC .... 150ºC (+ 0.1 ºC)

Visual, written and audio warning system monitoring

Preasure error (vacum), steam error (heat)

Power cut (audio and visula warning)

UPS or Batery System

✻ Programme name and number
✻ Sterilizaiton phase
✻ Cell, jacket, jenerator and seal preasures
✻ Cell, jacket, jenerator and seal heats
✻ Total sterilization time and remaining time
✻ Sterilization preasure and heat measurements
✻ Sterilization counter
✻ Sterilization steps
✻ Errors and cause of error
✻ Full automatic, PLC control
✻ Optional remote access via ethernet
✻ USB port RS 232 RS485 ETHERNET module

PLC Micro computer

Touch Panel

Programme Phases
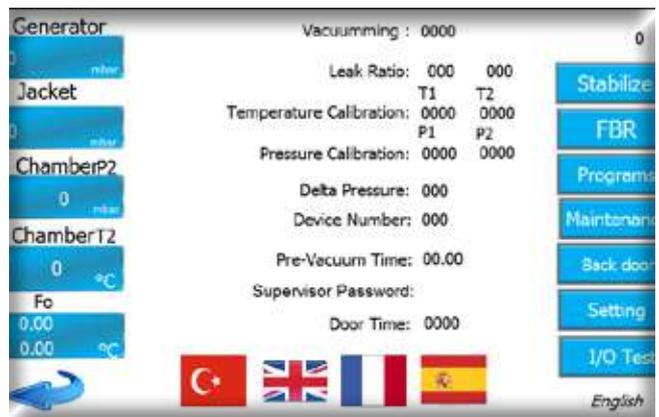
Touch Panel USB and Ethernet

The device can be started manually after the password is entered
Manual Vaccum, Steam, Air etc..

All pressure and temperature values can be seen from touch panel

Touch Panel and Software

❊ Date-time
❊ The name and the name of the program being run
❊ Pre-vacuum time and phase number
❊ Preheating temperature
❊ Sterilization cell temperature
❊ Sterilization cell pressure
❊ Sterilization time
❊ Drying time
❊ Error messages that may occur in the system
❊ Date, time and total time information at the end of the sterilization process
❊ User signature repository at the end of the process.

Settings are selected from the main menu.

Touch Panel Save Programme Data

Touch Panel Sterilization Graph
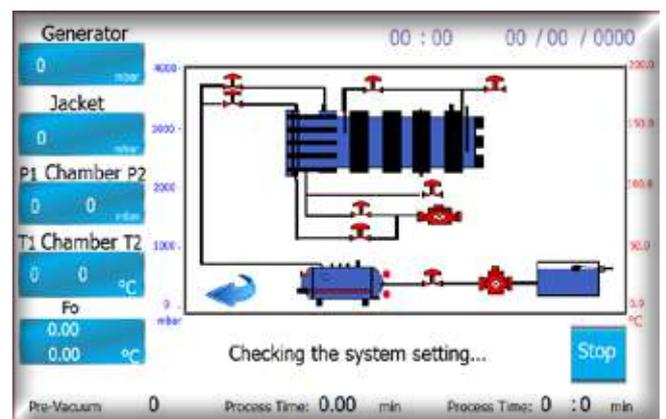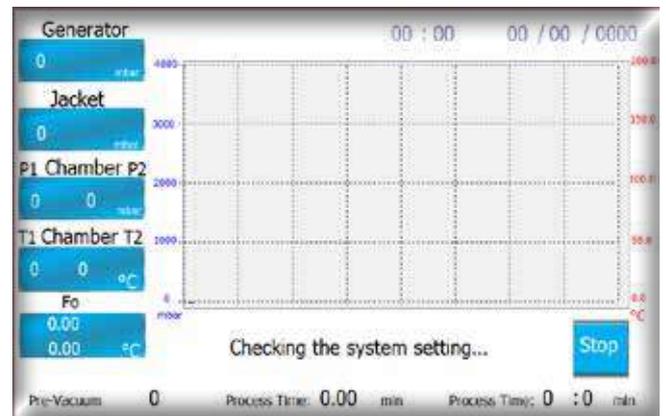
Time date settings can be made Password is entered from the password menu.
(password for manual use)

Generator	Condenser	2.PT100	2.Pressure	Gasket
0	OFF	OFF	OFF	OFF
Jacket	Drain valve	Ligued PT100	GRAVITY	
0	OFF	ON	OFF	
P1 ChamberP2	Door Oto. Manual	Door Double Single	Gen Dry Man. Oto.	
0 0	OFF	OFF	OFF	
T1 ChamberT2	Gen. Jacket	F0	Test	
0 0	OFF	ON	OFF	
Fo 0.00 0.00	Password	Eco Mode	Door Opening	
	ON	ON	OFF	

|					
P1		0	000	00.00	00.00
P2		0	000	00.00	00.00
P3		0	000	00.00	00.00
P4		0	000	00.00	00.00
P5		0	000	00.00	00.00
P6		0	000	00.00	00.00
P7		0	000	00.00	00.00
P8		0	000	00.00	00.00

Technical Details

Preasure measurement :
-1.0...+5 Bar (+ 0.001 bar)
Heat measurement :
0 ºC .... 150ºC (+ 0.1 ºC)
Visual, written and audio
warning system monitoring
Preasure error (vacum), steam error
(heat)
Power cut (audio and visula warning)
Ability to watch the programme
phases on computer
Data recording of work done.
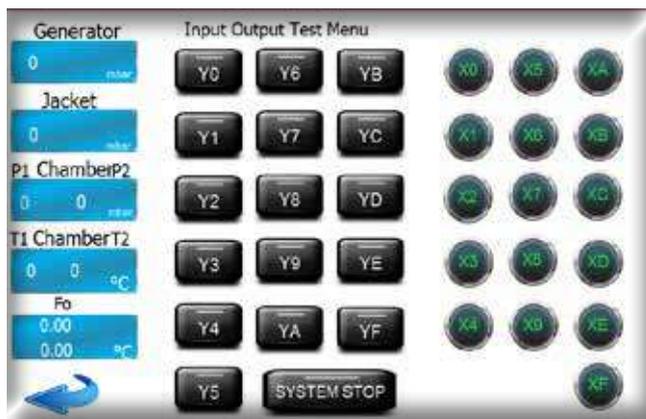
121 ºC rubber,
121 ºC liquid,
134 ºC solid,
134 ºC textile,
Bowie & Dick Test,
Leakage test,
Optional programming,
Ability to add user programme,
Ability to see all preasure and
heat sensors on
Programme and calibration,
Sleep mode and power saving mode,
Automatic start upon user preference.

Pressure Sensor

Temperature Sensor

Thermal Printer

The thermal type printer located in the control unit is supplied with the following values as the cast:

Technical Details

Water pump : Imported 0.75 hp pipe part 304 or 316 stainless steel

Steam installment pipes : 304 or 316 stainless steel

Water installment pipes : 304 or 316 stainless steel

Air installment pipes : 304 or 316 stainless steel

Vacuum pomp : Imported flow speed 2900 cycle/minute

The discharge of the device is by the heat exchanger system.

Optional materials : Stainless steel trolley

Stainless steel loading trolley

Software controlled water saving system

Water Pump
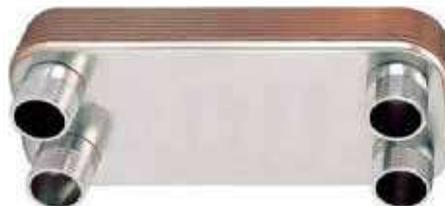
Heat Exchanger

Vacuum Pump
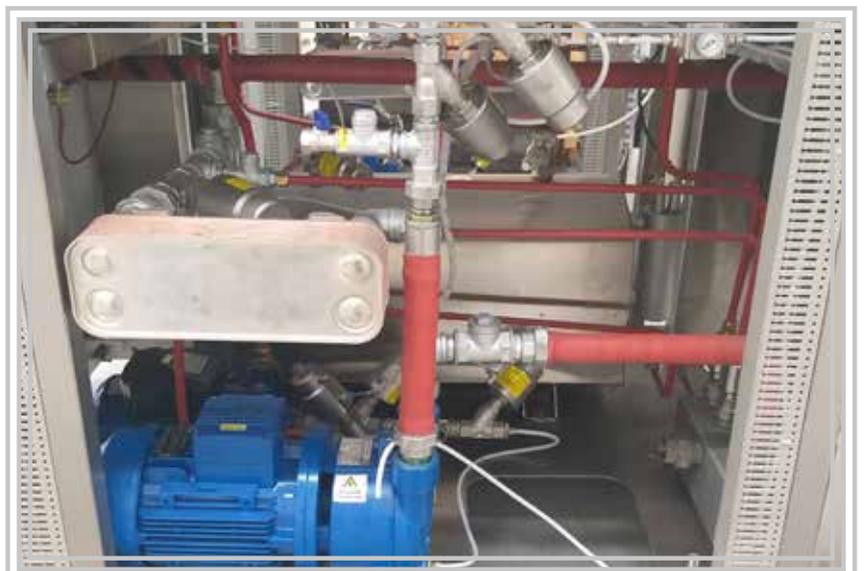
Steam installation view

All Components Of Steam Installment Are 304 or 316 L Stainless Steel

Steam Trap

Hepa Filter

Pneumatic solenoid valve : Imported 304 or 316 stainless steel
Steam trap : Imported 304 Or 316 stainless steel
Safety valve : Sterilizaiton chamber, jacket, jenerator 304 or 316 stainless steel
Hepa filter : 0.01 μm %99.999
Check Valve : 304 or 316 stainless steel

Safety Valve

Check Valve

Pneumatic Valve

CHAMBER JACKET GENERATOR

(0 / +4 Bar) (0 / +6 Bar) (0 / +6 Bar) (0 / +4 Bar) (-1 / +5 Bar)
Manometer

P P P KP35 M

11 — (Y9) — Closing Front Door
12 — (YA) — Opening Front Door
13 — (YD) — Closing Back Door
14 — (YE) — Opening Back Door

(-1 / +5 Bar) (-1 / +5 Bar)
Manometer Manometer

M M

Check Valve Pneumatic Valve Hepa Filter

H

2

Safety Valve Check Valve

Pneumatic Valve

3

Pressure Switch

P

Safety Valve

(-1 / +5 Bar) (-1 / +5 Bar)
Manometer Manometer

M M

1 — (Y1) — Vacuum Water
2 — (Y2) — Chamber Air
3 — (Y3) — Chamber Steam
4 — (Y4) — Jacket Steam
5 — (Y5) — Generator Water
6 — (Y6) — Heat Exch. Water / Chamber Discharge
7 — (Y7) — Chamber Vacuum
8 — (Y8) — Gasket Vacuum
9 — (YB) — Gasket Swelling
10 — (YF) — Generator Discharge

Chamber

Air Inlet

Jacket

PT100

Heat Exchanger

Drain

Regulator R

Steam Trap

Safety Valve

Drain

9 Pneumatic Valve

Check Valve

Pneumatic Valve 7

Check Valve Steam Trap

Pneumatic Valve 4

Ball Valve

Pneumatic Valve

8

Drain

Check Valve

Check Valve Drain

Check Valve

V

Generator

Check Valve

Ball Valve

Ball Valve 10 - Optional Pneumatic Valve

1 Pneumatic Valve

Drain

Pneumatic Valve 6

Pneumatic Valve

Water İnlet

W

5

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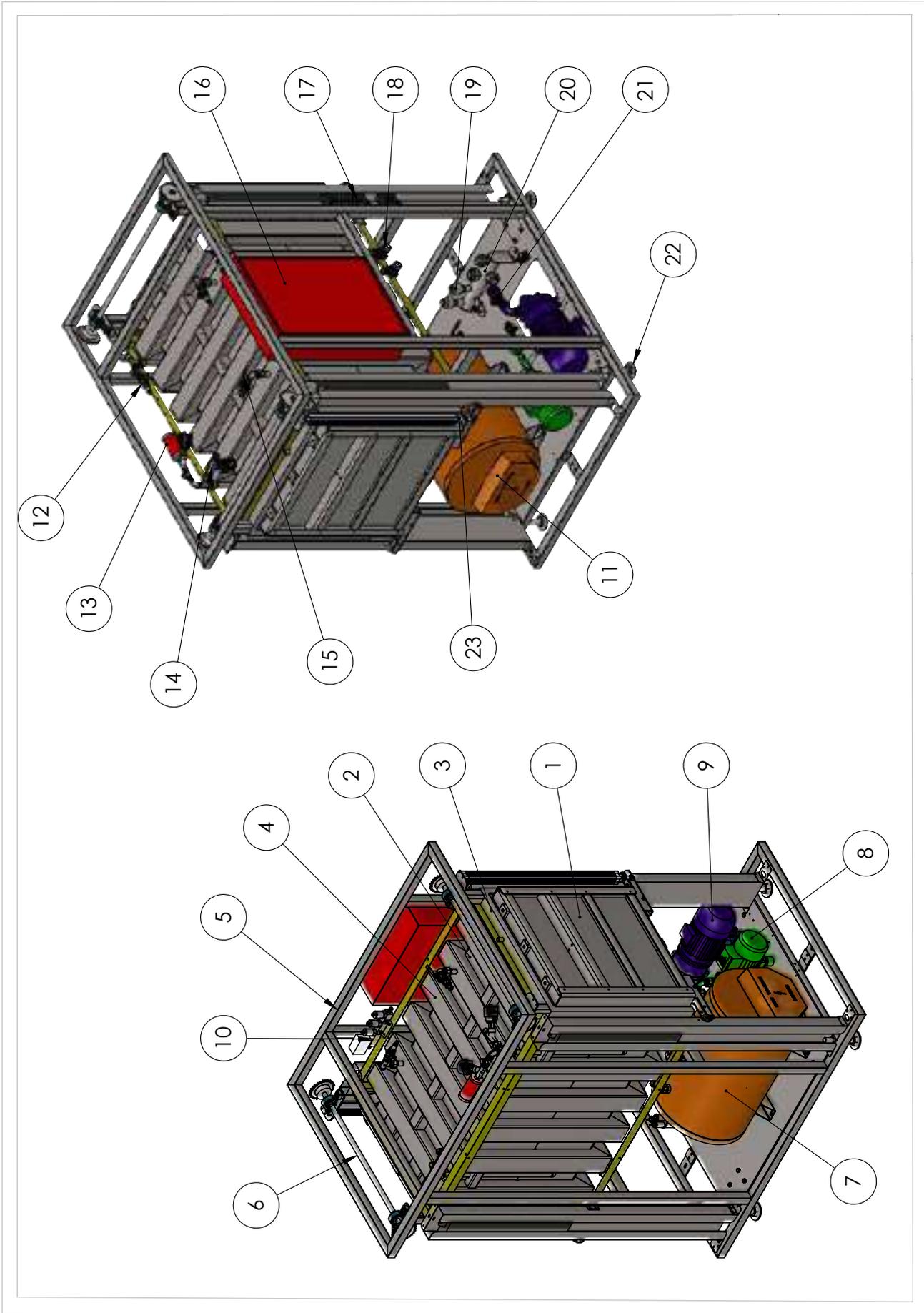
Sterilmed SMB Steam Sterilizer Specifications

DSD: DOUBLE SLIDING DOORS   SSD : SINGLE SLIDING DOOR

| | MODELS | STU | LITER | CHAMBER DIMENSION | | | DEVICE DIMENSION | | | GENERATOR | | REQUIREMENTS FOR INSTALLATION | | | |
				WIDTH	HEIGHT	DEEP	WIDTH	HEIGHT	DEEP	LITER	POWER KW	ELECTRIC KW	WATER	DRAIN	AIR
DOUBLE DOORS	SMB-DSD-160	1	160	400	400	1000	870	1650	1350	50	20	380 VAC	a	b	c
	SMB-DSD-200	1	200	500	500	800	970	1750	1150	50	30	380 VAC	a	b	c
	SMB-DSD-250	1	250	500	500	1000	970	1750	1350	50	30	380 VAC	a	b	c
	SMB-DSD-300A	2	300	500	500	1200	970	1750	1550	50	30	380 VAC	a	b	c
	SMB-DSD-300	4	360	670	670	800	1140	1900	1050	50	30	380 VAC	a	b	c
	SMB-DSD-450	6	450	670	670	1000	1140	1900	1400	50	40	380 VAC	a	b	c
	SMB-DSD-540	8	540	670	670	1250	1140	1900	1600	79	40	380 VAC	a	b	c
	SMB-DSD-675	10	675	670	670	1550	1140	1900	1900	79	50	380 VAC	a	b	c
	SMB-DSD-810	12	810	670	670	1850	1140	1900	2200	89	50	380 VAC	a	b	c
	SMB-DSD-945	14	945	670	670	2150	1140	1900	2500	89	60	380 VAC	a	b	c
SINGLE DOOR	SMB-VD-75	1	96	400	400	600	870	1650	950	50	20	380 VAC	a	b	c
	SMB-SSD-160	1	160	400	400	1000	870	1650	1350	50	20	380 VAC	a	b	c
	SMB-SSD-200	1	200	500	500	800	970	1750	1150	50	30	380 VAC	a	b	c
	SMB-SSD-250	1	250	500	500	1000	970	1750	1350	50	30	380 VAC	a	b	c
	SMB-SSD-300A	2	300	500	500	1200	970	1750	1550	50	30	380 VAC	a	b	c
	SMB-SSD-300	4	360	670	670	800	1140	1900	1050	50	30	380 VAC	a	b	c
	SMB-SSD-450	6	450	670	670	1000	1140	1900	1400	50	40	380 VAC	a	b	c
	SMB-SSD-540	8	540	670	670	1250	1140	1900	1600	79	40	380 VAC	a	b	c
	SMB-SSD-675	10	675	670	670	1550	1140	1900	1900	79	50	380 VAC	a	b	c
	SMB-SSD-810	12	810	670	670	1850	1140	1900	2200	89	50	380 VAC	a	b	c
	SMB-SSD-945	14	945	670	670	2150	1140	1900	2500	89	60	380 VAC	a	b	c

a:the device necessary for water (the reverse osmosis system at least 3 bar pressure 3/4 ")

b:the expense of the device connection (at least 2" pipe or galvanized pipe resistant to 150 degrees)

c: the air necessary for the device (1/2" minimum 6 bar, dry air)

GENERAL FUTURES			
		Standart	Opsiyonel
General Futures	Chamber	6 mm 316 L Stainless Steel	6 mm 316 Ti Stainless Steel
	Jacket	3 mm 304 L Stainless Steel	3 mm 316 L Stainless Steel
	Generator	3 mm 304 L Stainless Steel	3 mm 316 L Stainless Steel
	Cover	10 mm 304 Stainless Steel	10 mm 316 L Stainless Steel
	Chassıs	3 mm 304 L Stainless Steel	3 mm 316 L Stainless Steel
	Gasket Channel and Cover Bearings	50 mm 304 Stainless Steel Monolithic System	50 mm 316L Stainless Steel Monolithic System
	External Material	1 mm 304 L Stainless Steel	1 mm 316 L Stainless Steel
	Troyler	304 L Stainless Steel	316 L Stainless Steel
Control Systems And Programme	Control System	PLC Microprocessor	PLC Microprocessor
	Display	7" Colourful Touch Screen	5", 6" or 10" Colourful Touch Screen
	Printer	40 Column Thermal Printers	40, 60 or 80 Column Thermal and Cartridge Printer
	No of Preset Programs	8	20
	No of Test Programs	2	2
	No of Free Programs	10	50
	Minimum Vacuum Level	70 mm bar	70 mm bar
	Remote Control	No	have remote control via ethernet
	Port	Usb Ethernet Rs232 And Rs 485	Usb Ethernet Rs232 And Rs 485
Mechanical Installation	Hepa Filter	0.01 µm %99.999	0.01 µm %99.999
	Vaccum Pomp	2,2 Kw 2900 cycle/minute	Stainless Steel pump 2,2 Kw 2900 cycle/minute
	Safet Valve	1/2" Brass Stainless Steel adjustable	1/2" Stainless Steel adjustable
	Control Valve	1/2" And 1 " 304 L Stainless Steel	1/2" And 1 " 316 L Stainless Steel
	Check Valve	1/2" And 1 " Brass Stainless Steel	1/2" And 1 " 304 L Stainless Steel
	Exchanger System	-	With Exchanger
	Water Level Control	With Stainless Prob	With Magnetic Sensor Or Flap

Washer Disinfector

Our product has been designed to be used for washing and disinfection of heat-resistant and reusable medical devices tools. It is used in the following:

· Hospitals,

· Outpatient clinics,

· Rehabilitation centers,

· It is used in laboratories.

It must be used by the expert technical personnel who have completed the required training for washing and disinfection process.

Packaging and Loading

In washing-disnfection processes no packing must be used. Proper baskets for the instruments must be choosen instead.

Do not stack or put the instruments / materials too tight to each other when placing them into basket. Always use same materials or instruments when placing into basket. Use loading cart or shelves when loading the instruments into the device chamber.

Materials that can be used in Washer-Disinfector Programs and Time Periods

❖ Surgical Instruments
❖ Operating Room Containers
❖ Laboratory Instruments
❖ Glass Containers
❖ Rubber Materials
❖ Plastic Materials

Water Consumption: ~120L/Cycle

NO				PROGRAM	SET TEPRERATURE (°C)	TIME
						SET (SEC)
P3	P2	P1	1	Pre-washing	30	120
			2	Washing	60	600
			3	Drying 1	60	300
			4	Drying 2	60	300
		5		Disinfection	90	600
		6		Drying	95	900

P1: WASHING
P2: WASHING + DISINFECTION
P3 : WASHING +DISINFECTION + DRYING
P4 : DRYING

PROGRAM	SET TEPRERATURE (°C)	TIME
		SET (SEC)
Drying	95	9

P5: SELF-DISINFECTION OF THE DEVICE

PROGRAM	SET TEPRERATURE (°C)	TIME
		SET (SEC)
Disinfection	90	600

General Specification
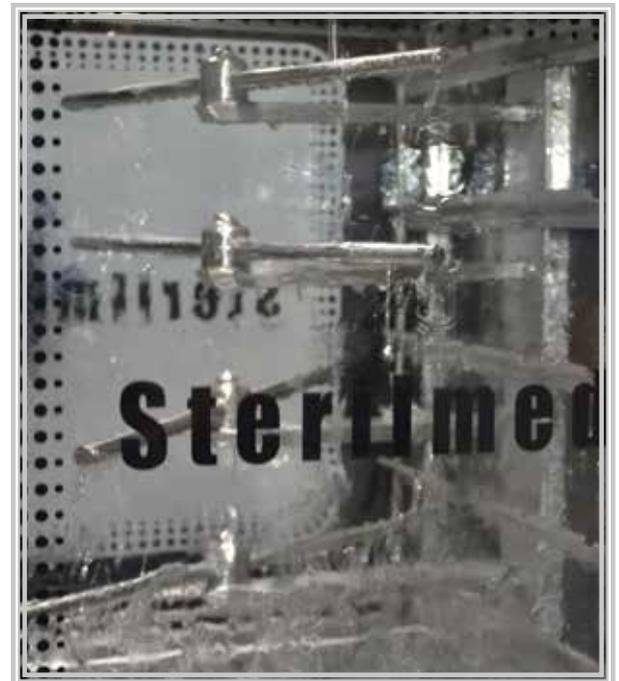
Control System	PLC
Use	Full automatic / button and touch screen
Screen Type	Colour TFT, Touchscreen LCD
Screen Dimension	7"
Keypad	Touchscreen
Printer	40 Characters / Line Thermal Printer
Communication	RS 232 Port / USB , Ethernet
Warning System	Visiual, Audible and Printed
Data Recording	200 PCS Cycle
Monitoring	Touchscreen
Mobility	Easy positioning on 4 swivel castors and hight adjustable legs for uneven floors.

Device Construction

Body	➤	2,5 mm, AISI 304 Stainless Steel
Chamber	➤	1,5 mm, AISI 316L Stainless Steel
Door	➤	Tempered Glass
Outer Panels	➤	1,5 mm, AISI 304 Stainless Steel
Piping	➤	Silicon Hose, 1,5 mm, AISI 304 Stainless Steel
Chamber Polishing	➤	Electropolishing

Installation Requirements

Feeding Water	RO treated deionized water for high performance.
Installation Power 200-250-360 L	~ 25kW, 3 Phase, 380 VAC ±10
150 L	~ 15kW, Mono Phase, 230 VAC ±10
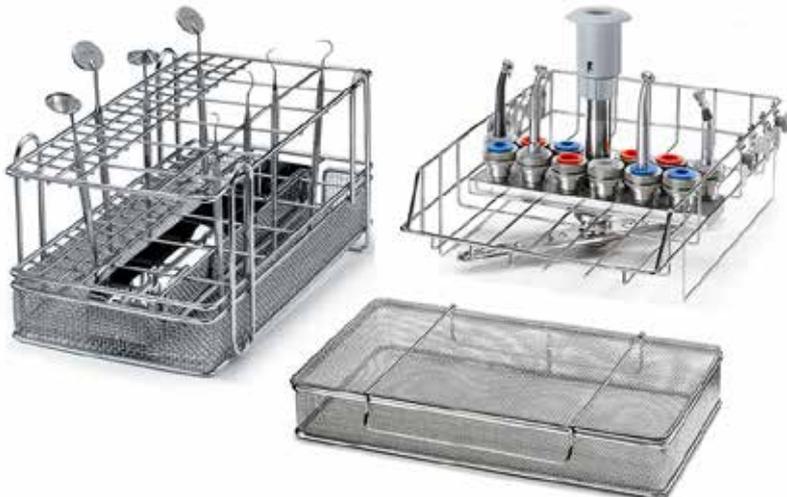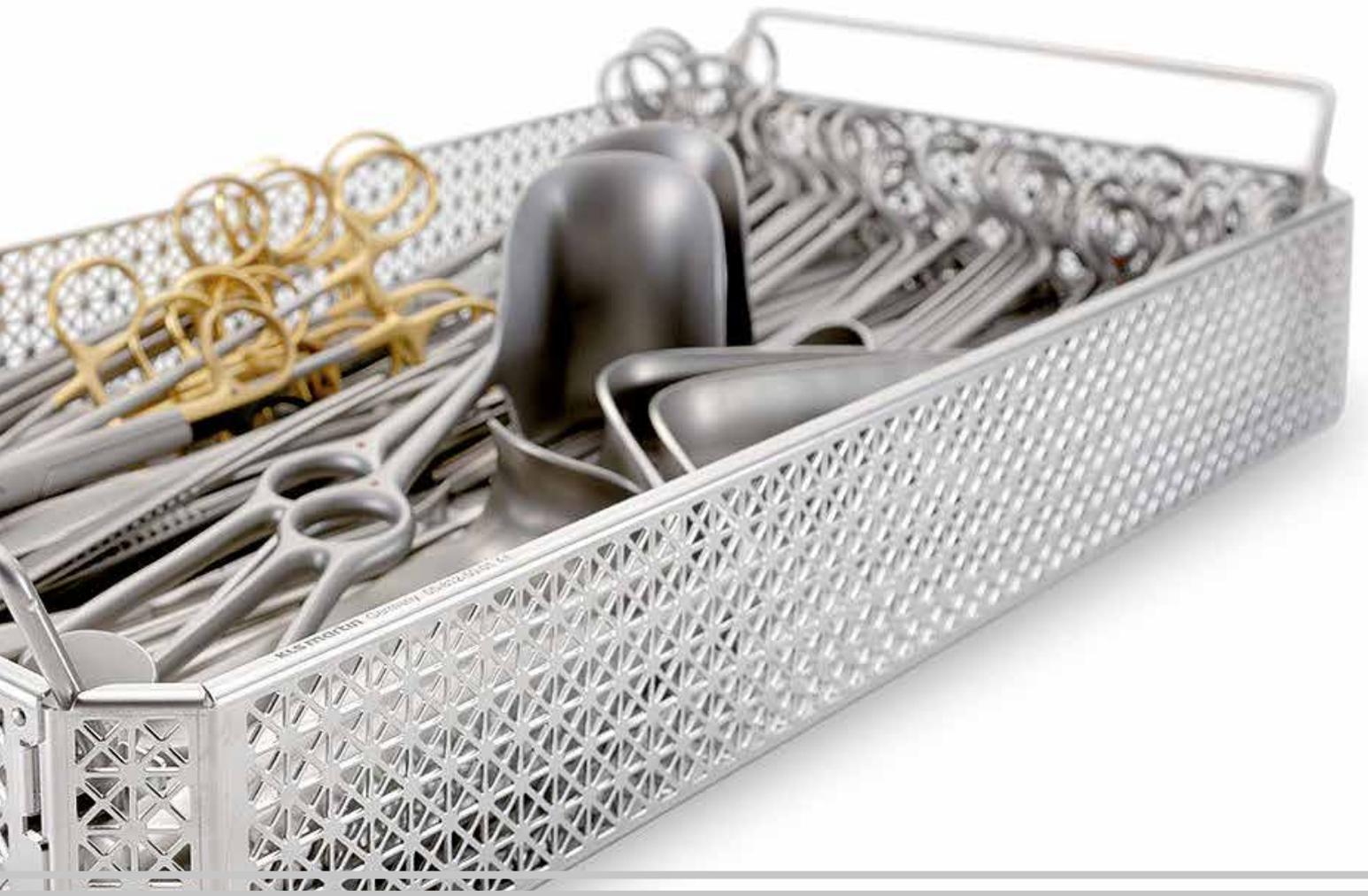
Related Directives And Standards

Medical Devices Directive	MDD 93/42/EEC - 2007/47/EC
Medical Devices Class	Class IIb, acc. to EC MDD 93/42/EEC 2007/47/EC (Annex IX)
Low Voltage Directives	2006/95/EC, EN 60601-1
Electromagnetic Compatibility Directives	2004/108/EC, EN 60601-1-2
Washer and Disinfector Devices	EN 15883-1 Series Standard
Quality Management System Requirements	ISO 9001
Medical Devices Regulatory Requirements	ISO 13485
Enviroment Management System	ISO 14001

Accessories
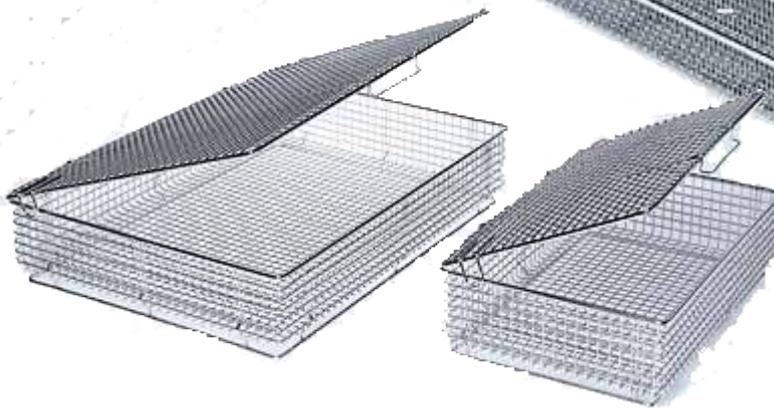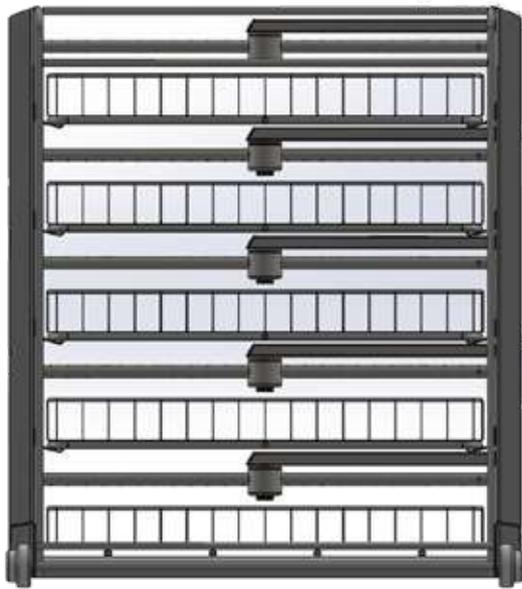
**Racks
&
Trays**

⚠ **INSTALLATION CONDITION :** At least 60 cm. space is needed on both lateral sides of the device to provide an effective technical service. Exhaust fan or ventilation funnel needs to be placed above the device for an effective evacuation of heat !
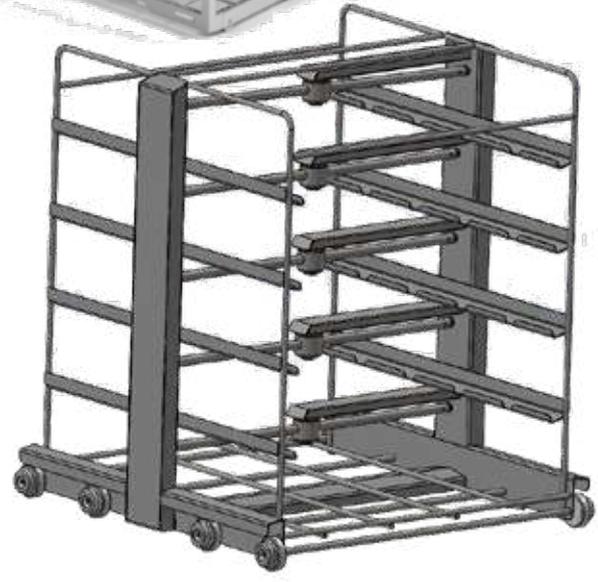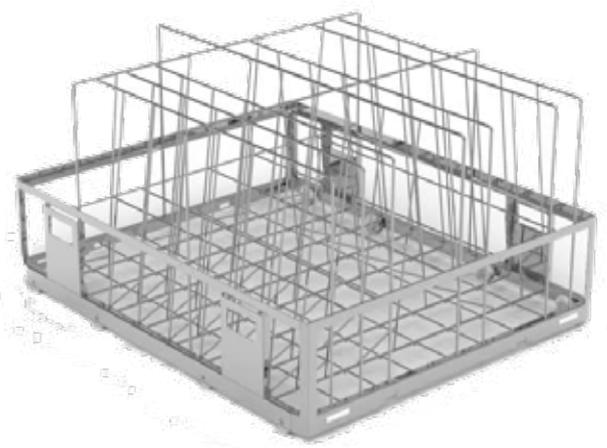
Safety And Quality

Protection against current leaks.

Short Circuit Protection

Includes Safety Valve Protection

Clean Air hepa filter is used

Password protection is available.

Protection against opening of two doors at the same time in double door models

Emergency Stop Button.
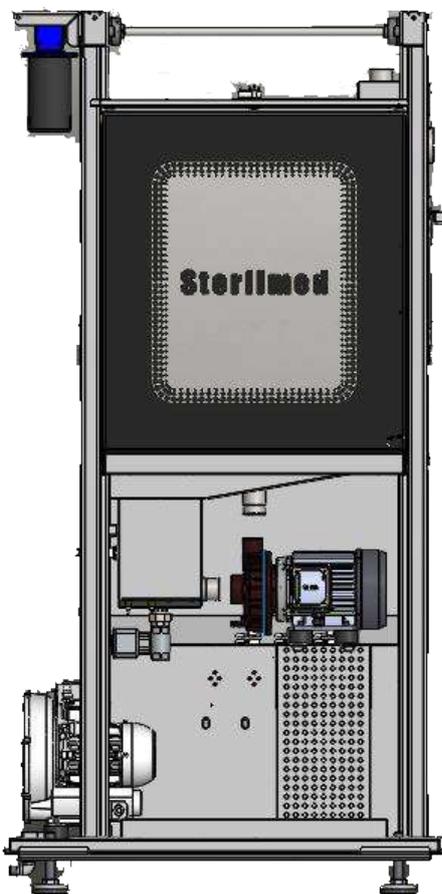
Temperature

Working Range	15°C – 95°C
Measuring	3xPT100 (DIN A Class) Sensor
Sensor Location	Cabinet 2, Water 1

Pressure

Measuring	1 Pieces Pressure Sensors
Sensor Location	Air 1

Models And Technical Data

Models	WD-6	WD-8	WD-10	WD-12	WD-15	WD-18
	Under-Desk	Big Type				
Cell width (mm)	625	625	625	625	625	625
Cell Height (mm)	450	680	680	680	680	820
Cell depth (mm)	600	600	600	850	850	850
Width of Device (mm)	950	980	980	980	980	980
Height of Device (mm)	840	1930	1930	1930	1930	2070
Depth of Device (mm)	810	820	820	1070	1070	1070
Width of Packaging (mm)	1150	1030	1030	1100	1100	1100
Height of Packaging (mm)	1150	2050	2050	2050	2050	2200
Depth of Packaging (mm)	1010	970	970	1220	1220	1220
Single Door	+	+	+	+	+	+
Double Door	-	+	+	+	+	+
Touch Screen	4.3"	7"	7"	7"	7"	7"
RS232 outlet	+	+	+	+	+	+
Water-heating Resistance (KW)	5	10	10	15	15	15
Drying Resistance (KW)	3	6	6	8	8	8
Drying Motor Fan (m3/h)						
Blowing Flow Rate (m3/h)	100	150	150	150	150	150
Circulation Pump Power (kW)	0,4	1,1	1,1	2,4	2,4	3
Electrical connection characteristics of the circulation pump	230V±10	380V±10	380V±10	380V±10	380V±10	380V±10
Circulation Pump Flow Rate (d/d)	325	650	650	900	900	1200
Detergent Dosage Pump	+	+	+	+	+	+
Neutralizing Agent Dosage Pump	+	+	+	+	+	+
Electric Connection	3L+1N+1PE 50 Hz, 400 V AC					
Water Draining Pipe Diameter (mm)	½"	1"	1"	1"	1"	1"
Number of Racks in the Basket	3	4	5	4	5	6
DIN Basket (piece)	6	8	10	12	15	18
HEPA Filter	H14, Particle Retention Ratio %99,999					

Plasma Sterilizer

❖ Low Temperature Plasma Sterilizer is user-friendly, as the main sterilizing agent is very safe, remaining nontoxic residue (Water and Oxygen).

❖ Fast running cycle increases turnover rate the delicate and state-of-the art medical equipments in the hospital.

❖ This rapid turnover rate lightens the hospitals' financial burden, as they do not need to equip a number of redundant medical devices.

❖ The by-products after sterilization, water and oxygen, contribute Green Environment as well as guarantee user-safety, substituting for other sterilizations which use harmful materials.

❖ Low Temperature Plasma Sterilization is representative of all other kinds of Low Temperature Sterilization such as Ethylene Oxide or Formaldehyde.

❖ The temperature keeps lower than 60 and cycle time is under 1 hour, which prevents heat and moisture damages to sophisticated medical instruments, and prolongs the life expectancies of them.

The STERİLMED Plasma Sterilizer is a sterilization technology based on plasma. Gas plasmas have been referred to as the fourth state of matter (i.e., liquids, solids, gases, and gas plasmas).

The STERİLMED Crystal Sterilizer is a self-contained stand-alone system of hardware and software designed to sterilize medical instruments and devices using a patented hydrogen peroxide gas plasma process.

Hydrogen peroxide vapor is generated by delivering aqueous hydrogen peroxide into the vaporizer where the solution is heated and vaporized. The hydrogen peroxide vapor is then introduced into the sterilization chamber, under sub-ambient pressure, where it is transformed into a gas-plasma by use of electrical energy.

STERİLMED Plasma Sterilizer especially contains independently patented Rapid Warmup and Dry System to boost sterile ability.

General Specification

Sterilization Validation according to ISO 14937.

STERİLMED MEDICAL, Ltd performs sterilization validation followed by ISO 14937.

ISO 14937:2009 specifies general requirements for the characterization of a sterilizing agent and for the development, validation and routine monitoring and control of a sterilization process for medical devices.

The purpose of validation is to demonstrate that the sterilization process established in process definition can be delivered effectively and reproducibly to the sterilization load. Validation consists of a number of identified stages: installation qualification, operational qualification and performance qualification.

❖ Installation qualification is undertaken to demonstrate that the sterilization equipment and any ancillary items have been supplied and installed in accordance with their specification.

❖ Operational qualification is carried out either with unloaded equipment or using appropriate test material to demonstrate the capability of the equipment to deliver the sterilization process that has been defined.

❖ Performance qualification is the stage of validation that uses product to demonstrate that equipment consistently operates in accordance with predetermined criteria and the process produces product that is sterile and meets the specified requirements.

Rapid Warmup & Dry System	PLC
Convenient and Safe Sterilizing Agent	Full automatic / button and touch screen
7" full touch LCD, Easy Monitoring the Cycle Information	Colour TFT, Touchscreen LCD
Plug and Play	7"
USB History Memory	Touchscreen
Automatic PM Alarm System	40 Characters / Line Thermal Printer
Built in Thermal Printer, Printout with Actual Cycle Information	RS 232 Port / USB , Ethernet
Login Function	Visiual, Audible and Printed
Monitoring System	200 PCS Cycle
Auto Interlock & Open System	Touchscreen
Mobility	Easy positioning on 4 swivel castors and hight adjustable legs for uneven floors.

Data logging, interoperability

Sterilization process validation logs may be transferred via SD memory card,
USB connection or by Ethernet TCP / IP connections to any LAN or WAN network such as the Internet.

Installation Requirements

Convenient and Safe Sterilizing Agent

1. "Tank type" sterilant is safe for users to store, to deliver, and to use.

2. The automatic system for changing and installing sterilant tank is convenient and safe for users.

3. STERİLMED Series' tank type sterilant does not need to be replaced often, as it can be used scores of times.

7" full touch LCD, Easy Monitoring the Cycle Information

STERİLMED Series' 7"full touch LCD monitor provides with all functions of the machine using simple letters, pictures, and icons.

User can monitor the actual temperature and pressure from the graph on the monitor.

Plug and Play

STERİLMED Series' warming up time is very rapid (Maximum 15 min) after main power is on, so that standby power consumption is zero during off-duty or overnight.
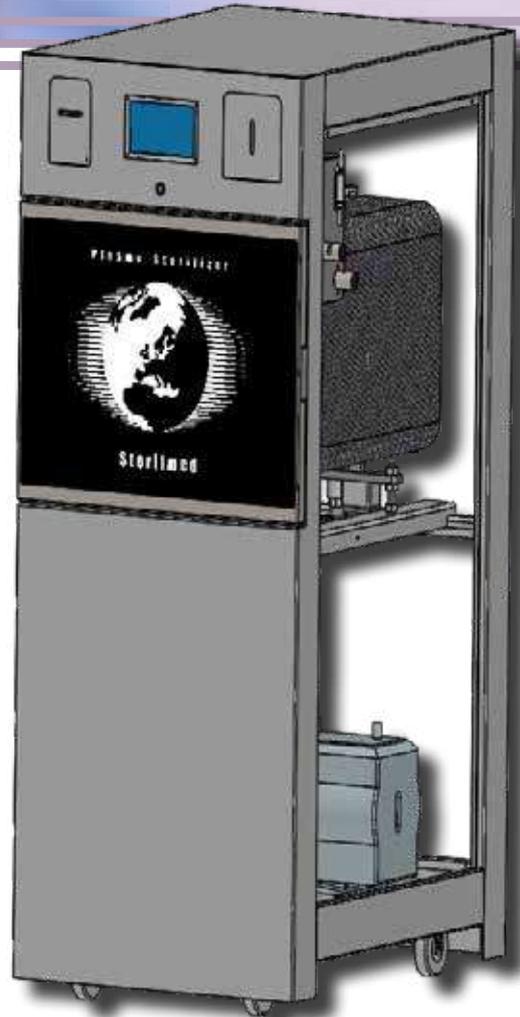
Related Directives, Standards

Medical Devices Directive	MDD 93/42/EEC - 2007/47/EC
Medical Devices Class	Class 2b, acc. to EC MDD 93/42/EEC 2007/47/EC (Annex IX)
Low Voltage Directives	2006/95/EC EN 60601-1
Electromagnetic Compatibility Directives	2004/108/EC EN 60601-1-2
Plasma Sterilizer Devices	EN ISO 14937 Series Standard
Quality Management System Requirements	ISO 9001
Medical Devices Regulatory Requirements	ISO 13485
Enviroment Management System	ISO 14001

USB History Memory

Automatic PM Alarm System

STERİLMED Series provide alarms to prevent from irregular maintenance.
Automatic PM Alarm System is very useful for users and engineers to be noticed.

STERİLMED Series' sterilization history can be downloaded to your USB memory stick, and maintained at your convenience. Furthermore, it can be remote-controlled by its own out-of-state network system.

Rapid Warmup & Dry System

1. The world's first patented "Rapid Warmup and Dry System" allows to overcome the humidity-related problem.

2. STERİLMED Series automatically removes residual moisture through the enhanced drying performance for medical devices in warm up phase.

3. Rapid Warmup and Dry System" gets rid of Cold Points and maintains same temperature inside chamber, which is very effective for sterilizing the complicated medical devices with its strong penetration power.

STERİLMED Series provide User ID and PSW, so that hospital can manage users who access the sterilizer.

Safety And Quality

Built in Thermal Printer, Printout with Actual Cycle Information

Built-in thermal printer uses 60mm (Ø) Roll paper. Users do not need to replace it often.

The printout from this printer provides temperature, pressure with the cycle graph on the paper.

Login Function

Monitoring System

1. Cycle temperature, pressure, and sterilization cycle status can be remotely monitored.

2. Thanks to the monitoring system, STERİLMED Series can be maintained and upgraded easily.

Auto Interlock & Open System

One gentle push makes the chamber door locked, and the chamber door can be opened automatically when the door sensor detects finger movement. STERİLMED Series' extraordinary user friendly functions provide convenient and safe environment.

Reactor chamber

Pressure gauge

STERILIZING GAS

Gas tank

Gas flow

To application

Control valve

Mass Flow Controller
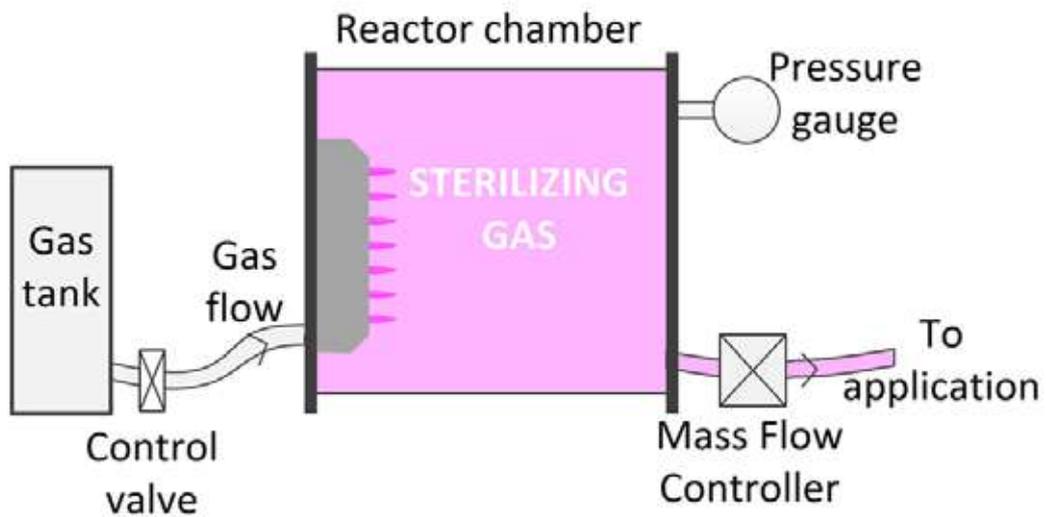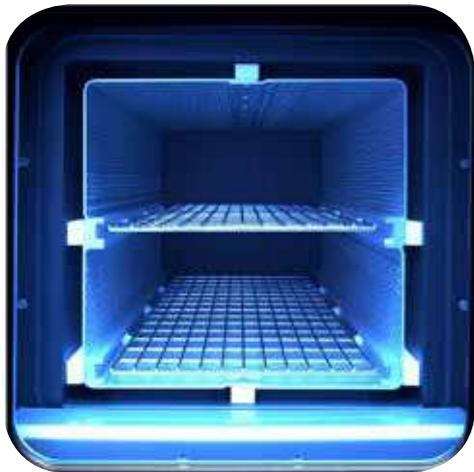
Models & Specifications

Item / Description		SM PL80	SM PL100	SM PL125	SM PL150
Sterilizing Agent		Hydrogen Peroxide	Hydrogen Peroxide	Hydrogen Peroxide	Hydrogen Peroxide
		25 Cycles / Bottle	20 Cycles / Bottle	15 Cycles / Bottle	10 Cycles / Bottle
Total Cycle Time	Quick	25+5 Min	30+5 Min	40+5 Min	40+5 Min
	Standard	35+5 Min	40+5 Min	50+5 Min	50+5 Min
	Special	45+5 Min	50+5 Min	60+5 Min	60+5 Min
Cycle Temperature		50±5	50±5	50±5	50±5
SAL (Sterility Assurance Level)		10^{-6}	10^{-6}	10^{-6}	10^{-6}
By-Products		Oxygen And Vapor Water Only			
Lumen Claims		Rigid Lumen & Flexible Lumen, Endoscopes			
Chamber	Type	Rectangular			
	Material	Stainless Steel(SUS)			
Dimensions	Overall	680mm(W) x 1600mm(H) x 930mm(D)	680mm(W) x 1600mm(H) x 980mm(D)	680mm(W) x 1600mm(H) x 1030mm(D)	680mm(W) x 1600mm(H) x 1030mm(D)
	Chamber	400mm(W) x 400mm(H) x 520mm(D)	400mm(W) x 400mm(H) x 640mm(D)	400mm(W) x 400mm(H) x 8000mm(D)	400mm(W) x 400mm(H) x 940mm(D)
Volume		Total : 80 Liter	Total : 100 Liter	Total : 125 Liter	Total : 150 Liter
Weight		280kg	300kg	330kg	350kg
Control		Microprocessor & Windows CE Embedded			
Cycle Information		Screen, Printer, USB, 100/10Mbps Ethernet(Option)			
PM Cycle		Automatic Alarm & Setup			
Electrical		110V/220V, 50/60Hz, 1Phase, 3000W			
Installation Requirements		Front, Rear : 100cm Left Side, Right Side: 10cm Placement : Built-in Wheels Provide Mobility			
Room Conditions		5 ~ 40 , 0 ~ 95%RH(Non-Condensing)			
Printer		Built-in Thermal Printer(60Ø Roll Paper) Cycle Parameters (Temp, Pressure, Time, Daily&Total Cycle, Etc) Alarm & Error Display			
Others		Emergency Stop(Front), Operator ID Login, Self-Diagnosis, Multi-Language, RFID Coding System			

INSTALLATION CONDITION : At least 60 cm. space is needed on both lateral sides of the device to provide an effective technical service. Exhaust fan or ventilation funnel needs to be placed above the device for an effective evacuation of heat !

Quality Certificates

Sterilmed
TIBBİ CİHAZLAR

Başkent Organize Sanayi Bölgesi 18. Cadde
No:43 Malıköy, Sincan, Ankara, Türkiye
Tel: +90 312 375 81 00 Faks: +90 312 375 92 92

info@sterilmed.com.tr
www.sterilmed.com.tr

SM Model Steam Sterilizer
Technical Datasheet

Sterilmed ® TIBBİ CİHAZLAR

STERILMED's steam sterilizer is offered in a prevacuum configuration and is designed and manufactured for fast and efficient sterilization of textile material, surgical instruments, dressing tools, rubber materials and liquids in a glass container in healthcare facilities.

	MODELS	STU	CHAMBER WIDTH	CHAMBER HEIGHT	CHAMBER DEEP	DEVICE DIMENSION WIDTH	DEVICE DIMENSION HEIGHT	DEVICE DIMENSION DEEP	STEAM GENERATOR LITER	STEAM GENERATOR POWER KW
SMB-DSD DOUBLE DOORS	SMB-DSD-160	1	400	400	1000	870	1650	1350	50	20
	SMB-DSD-200	1	500	500	800	970	1750	1150	50	30
	SMB-DSD-250	1	500	500	1000	970	1750	1350	50	30
	SMB-DSD-300A	2	500	500	1200	970	1750	1550	50	30
	SMB-DSD-300	4	670	670	800	1140	1900	1050	50	30
	SMB-DSD-450	6	670	670	1000	1140	1900	1400	50	40
	SMB-DSD-540	8	670	670	1250	1140	1900	1600	79	40
	SMB-DSD-675	10	670	670	1550	1140	1900	1900	79	50
	SMB-DSD-810	12	670	670	1850	1140	1900	2200	89	50
	SMB-DSD-945	14	670	670	2150	1140	1900	2500	89	60
SMB-SSD SINGLE DOOR	SMB-VD-75	1	400	400	600	870	1650	950	50	20
	SMB-SSD-160	1	400	400	1000	870	1650	1350	50	20
	SMB-SSD-200	1	500	500	800	970	1750	1150	50	30
	SMB-SSD-250	1	500	500	1000	970	1750	1350	50	30
	SMB-SSD-300A	2	500	500	1200	970	1750	1550	50	30
	SMB-SSD-300	4	670	670	800	1140	1900	1050	50	30
	SMB-SSD-450	6	670	670	1000	1140	1900	1400	50	40
	SMB-SSD-540	8	670	670	1250	1140	1900	1600	79	40
	SMB-SSD-675	10	670	670	1550	1140	1900	1900	79	50
	SMB-SSD-810	12	670	670	1850	1140	1900	2200	89	50
	SMB-SSD-945	14	670	670	2150	1140	1900	2500	89	60

Device

Control System	PLC (Programmable Logic Controller)
Operation Mode	Fully Automatic / Button Command
Display Type	Color TFT, LCD Touch Screen
Display Sizes Available	7,0"
Key Pad	Touchscreen
Printer	40 Character/line, integrated thermal printer
Communication	RS232 Port
Warning System	Visual & Audio & Printed
Data Storage	1000 cycles
Monitoring	Addition to Touchscreen, analogue gauges for chamber, jacket, generator and air pressure
Mobility	Easy positioning on 4 castors (2 x swivel) and firm fixing on suspension legs
Steam Control	Through pneumatic and electric valves

Standard Programs

Medical & Surgical Instruments (134°C)	~ 60 min
Textile Materials (134°C)	~ 60 min
Rubber Articles (121°C)	~ 80 min
Liquids in Glass Container (121°C)	~ 60 min
Silicone Implants (134°C)	~ 80 min
Flash (134°C)	~ 20 min
Prion (134°C)	~ 90 min
Bowie & Dick Test (134°C)	~ 45 min
Vacuum Leak Test	~ 25 min
Customized Program Capacity	20

Safety & Quality Features

√ Protects operator from electrical current leaks.
√ Short circuit protection.
√ Safety valve.
√ Hepa filter for air filtration.
√ Water level control with electrodes in generator.
√ Water level buoy (at water tank).
√ Steam traps for precise exhausting.
√ Leak test.
√ Password protection.
√ Sensors against obstructions on the doors pathway.
√ Doors locks under pressure.
√ Unable to open both doors at once in Septic-Aseptic models.
√ Emergency stop button.

Process times are load-dependent and approximate. They refer to full process including drying with an average load.

TSE · DEKRA · CE · HYGCEN GERMANY · UDEM TS 18001 : 2007 · ISO 9001:2015 CERTIFIED COMPANY · ISO 13485:2016 · HPi VS

SM Model Steam Sterilizer
Technical Datasheet

Sterilmed
TIBBİ CİHAZLAR

Medical Device Directive	: 93/42/EEC as amended by directive 2007/47/EC
Device Classification	: Class IIb, acc. To EC MDD 93/42/EEC 2007/47/EC (Annex II)
Low Voltage Directive	: 2006/95/EC - EN 60601-2-040
EMC Directive	: 2004/108/EC EN 60601-1-2
Pressure Equipment Directive	: 2014/68/EU : EN 13445-1, -2, -3, -4, -5 (Pressure Vessels)
Sterilization – Steam sterilizers – Large sterilizers	: EN285:2016
Quality Management System Requirements	: EN - ISO 9001:2015
Medical Devices – Quality management systems – Requirements for regulatory purposes	: ISO 13485:2016
Environmental Management Systems – Requirements with guidance for use	: ISO 14001:2015

"Type" tests of STERILMED steam sterilizers are performed and certified according to the directives of EN 285 and TS EN 17665-1-2 by The German accreditation company HYGCEN GmbH.

Temperature

Range	110ºC - 141ºC (chamber)
Measurement	3 x PT 100 Sensors
Location	Chamber (2), Generator (1)

Pressure

Measurement	Pressure Transducer (4)
Location	Chamber (2), Jacket (1), Generator (1)

Vacuum

Source	Pump, liquid ring (2.2KW)
Capacity	60 mbar
Pre-Vacuum	Yes

Construction

Body	Electrostatic powdered profile steel/AISI 304 stainless
Chamber	6.0 mm, AISI 316 L/Ti stainless steel
Jacket	~2.5-3 mm, AISI stainless steel, full cover
Door	12 mm, AISI 304 stainless steel
Panels Surrounding	AISI 304 stainless steel
Piping	brass, AISI 304 stainless steel
Chamber Polishing	Electro polishing, Optional

Installation Requirement

Power	30 kW, 3 Phase / 400 VAC ±10
Water	RO treated deionized water for high performance

Feeding Water Requirements

Residue on evaporation	$\leq$ 10 mg/L
Silicate (SiO_2)	$\leq$ 1 mg/L
Iron	$\leq$ 0,2 mg/L
Cadmium	$\leq$ 0,005 mg/L
Lead	$\leq$ 0,05 mg/L
Heavy metals other than iron, cadmium, ie	$\leq$ 0,1mg/L
Chloride (Cl)	$\leq$ 2 mg/L
Phosphate (P_2O_5)	$\leq$ 0,5 mg/L
Conductivity (at 25°C)	$\leq$ 5 µS/cm
pH Value (degree of acidity)	5 to 7,5
Appearance	Free of sediment, clear, colorless
Asperity (Σ Earth Alkali Ions)	$\leq$ 0,02 mMol/L

*Water quality should be checked by standard analitycal test methods by the institution which utilizes the sterilizer.

Installation Conditions

At least 60 cm. space is needed on both lateral sides of the device to provide an effective technical service. Exhaust fan or ventilation funnel needs to be placed above the device for an effective evacuation of heat.

Optional Accessories

2 Shelves including chamber rails
Cart Set (Transport + Loading) with adjustable height option
Single Transport Trolley (Optional Height Adjusting)
Single Loading Cart (AISI 304 Stainless)
STU Basket (AISI 304 Stainless)

Drainage

Water	Inclined metal pipe to be installed onsite at least 2 meters of length (diameter: 2" - 3")with
Steam (Condensed)	Steam Trap (built in)
Air	Vacuum Motor (built in)

Chamber

Test Pressure	7 Bar/Abs
Test Temperature	148 ºC
Working Temperature	134 ºC
Working Pressure	3,2 Bar/Abs

Steam Generator

Capacity	50 L
Water Level Protection	CRES* / AISI 304 steel box
Power	(3 Phase, 400 ±10 VAC) 30 KW
Test Pressure	7 Bar/Abs
Test Temperature	159 ºC
Working Temperature	145 ºC
Working Pressure	4,2 Bar/Abs

* CRES : Corrosion Resistant Stainless Steel

Consumption

Electricity	10 kW/cycle
Water (Approximate)	~80 Lt/cycle

Steam

Type	97% Saturated Steam at 4.2 Bar Abs. Pressure
Source	Built in Steam Generator or Central Steam System
Side of Applied Steam	Lateral

STERİLMED MEDİCAL
ELEKTRİK ELEKTRONİK OTOM. İNŞ. GIDA SAN. VE DIŞ TİC. LTD. ŞTİ.
Başkent Organize Sanayi Bolgesi 18. cadde No: 43 Malıkoy, Sincan / ANKARA / TURKEY   Tel:+90 312 375 81 00 * Fax:+90 312 375 92 92
info@sterilmed.com.tr
www.sterilmed.com.tr