

## **SM Model Steam Sterilizer**

# Technical Datasheet

STERILMED's Steam Sterilizer Models are designed and manufactured for fast and efficient sterilization of heat & moisture resistant materials; as textile material, surgical instruments, dressing tools, rubber materials and liquids in a glass container with pre-vacuum configuration.

STERILMED's Steam Sterilizer Models are horizontal loading system which aim to provide the best service in healthcare institutions with its both single-door and double-door automatic pneumatic door system options which open to sterile /non-sterile area.

		CHAMBER				DEVICE DIMENSION				STEAM GENERATOR	
	MODELS	LITER	STU	WIDTH	HEIGHT	DEEP	WIDTH	HEIGHT	DEEP	LITER	POWER KW
SMB-DSD DOUBLE DOORS	SMB-DSD-160	160	1	400	400	1000	870	1650	1350	50	20
	SMB-DSD-200	200	1.5	500	500	800	970	1750	1150	50	30
	SMB-DSD-250	250	1.5	500	500	1000	970	1750	1350	50	30
	SMB-DSD-300A	300	2	500	500	1200	970	1750	1550	50	30
	SMB-DSD-300	360	4	670	670	800	1140	1900	1050	50	30
	SMB-DSD-450	450	6	670	670	1000	1140	1900	1400	50	40
	SMB-DSD-540	560	8	670	670	1250	1140	1900	1600	79	40
	SMB-DSD-675	695	10	670	670	1550	1140	1900	1900	79	50
	SMB-DSD-810	830	12	670	670	1850	1140	1900	2200	89	50
	SMB-DSD-945	965	14	670	670	2150	1140	1900	2500	89	60
SMB-SSD SINGLE DOOR	SMB-VD-75	100	1	400	400	625	870	1650	950	50	20
	SMB-SSD-160	160	1	400	400	1000	870	1650	1350	50	20
	SMB-SSD-200	200	1.5	500	500	800	970	1750	1150	50	30
	SMB-SSD-250	250	1.5	500	500	1000	970	1750	1350	50	30
	SMB-SSD-300A	300	2	500	500	1200	970	1750	1550	50	30
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## Device

Control System Operation Mode

Display Type

Display Sizes Available

**Key Pad** 

Printer

Communication

Warning System

Data Storage Monitoring

Mobility

Steam Control

PLC (Programmable Logic Controller) Fully Automatic / Button Command Color TFT, LCD Touch Screen

7,0"(Optional 10,0")

Touchscreen

40 Character/line, Integrated Thermal Printer

RS232 Port

Visual & Audio & Printed Alarms

1000 cycles

Addition to Touchscreen, analogue gauges for chamber, jacket, generator and air pressure Easy positioning on 4 castors (2 x swivel) and firm fixing on suspension legs 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

### Safety & Quality Features

- V Protects operator from electrical current leaks.
- √ Short circuit protection.
- √ Safety valve.
- V HEPA filter for air filtration.
- V Water level control with electrodes in generator.
- V 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.



Vacuum Leak Test

**Customized Program Capacity** 







~ 25 min











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

Medical Device Directive

Device Classification

Low Voltage Directive

**EMC Directive** 

Pressure Equipment Directive

Sterilization - Steam sterilizers - Large sterilizers

**Quality Management System Requirements** 

Medical Devices – Quality management systems – Requirements for regulatory purposes Environmental Management Systems - Requirements with guidance for use

93/42/FEC as amended by directive 2007/47/FC

: Class IIb. acc. To EC MDD 93/42/EEC 2007/47/EC (Annex II)

: 2006/95/EC - EN 60601-2-040

2004/108/EC EN 60601-1-2

: 2014/68/EU : EN 13445-1, -2, -3, -4, -5 (Pressure Vessels)

· FN285-2016

: EN - ISO 9001:2015

ISO 13485:2016

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**

105°C - 141°C (chamber) (Despite to it, Non-Heating Outer Surface) Normal 1 x PT 100 Sensor (Optional plus 2) Measurement Chamber (1), Optional (1 for chamber and Location

1 for liquid (Validation)),

## **Pressure**

Pressure Transducer (3) Location Chamber (1), Jacket (1), Generator (1)

#### **Vacuum**

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

#### Construction

Electrostatic Powdered Profile Steel, AISI 304-316 L/Ti S.S. Rectangular, 6 mm, AISI 316 L/Ti Stainless Steel Chamber 3 mm, AISI 316 L/Ti Stainless Steel, Full Cover Jacket 10 mm. AISI 304-316 L/Ti Stainless Steel Door Panels Surrounding AISI 304-316 L/Ti Stainless Steel Piping AISI 304-316 L/Ti Stainless Steel **Chamber Polishing** Mechanical/Electro Polishing, Optional

## **Installation Requirement**

3 Phase / 400 VAC ±10 Water RO treated deionized water for high performance

#### **Feeding Water Requirements**

Residue on evaporation Silicate (SiO<sub>2</sub>) ≤ 1 mg/L Iron ≤ 0,2 mg/L Cadmium ≤ 0,005 mg/L Lead ≤ 0,05 mg/L Heavy metals other than iron, cadmium, ie ≤ 0,1mg/L Chloride (CI) ≤ 2 mg/L Phosphate (P<sub>2</sub>O<sub>5</sub>) ≤ 0,5 mg/L Conductivity (at 25°C) ≤ 5 µS/cm pH Value (degree of acidity) 5 to 7.5 Appearance Free of sediment, clear, colorless Asperity (Σ Earth Alkali Ions) ≤ 0.02 mMol/L

\*Water quality should be checked by standard analytical 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**

Inner Trolley (AISI 304 L/Ti Stainless Steel)

Transport (Loading/Unloading) Trolley (Optional Height Adjusting, AISI 304 L/Ti Stainless S.) STU Basket (AISI 304 L/Ti Stainless Steel)









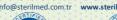
≤ 10 mg/L







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Drainage Inclined metal pipe to be installed onsite at least 2 meters Water of length (diameter: 1") Steam (Condensed) Steam Trap (built-in) Vacuum Motor (built-in)

Chamber Test Pressure 7 Bar/Abs 148 °C Test Temperature Working Temperature 134 °C Working Pressure 3,2 Bar/Abs

## Steam Generator

Water Level Protection CRES\* / AISI 304 steel box 3 Phase, 400 ±10 VAC, 20-60 kW (Depends on the Model) Test Pressure 7 Bar/Abs 159°C Test Temperature Working Temperature 145 °C Working Pressure 4.2 Bar/Abs Construction AISI 316 L/Ti Stainless Steel/ CRES\*

## Consumption

Electricity Average 10 kW/ Per Cycle Average ~80 Lt/ Per Cycle Water (Approximate)

## Steam

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