



Product Service

Certificate

No. Q5 003076 0004 Rev. 02

Holder of Certificate: **Shinva Medical Instrument Co., Ltd.**

Xinhua Medical Scientific Zone
Zibo New & Hi-Tech Industrial Development Zone
255086 Zibo, Shandong
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate:

Design and Development, Production and Distribution of Dental Unit, Dental Zirconia Ceramic, Medical High-energy Equipment (Medical Electron Linear Accelerator, Multi-leaf Collimator), Blood Irradiator, Remote Control After Loading Machine with Gamma Rays, Medical Laser Instrument Equipment (CTSim), Software (Radiotherapy Information System), Digital Medical X-ray Radiography System, Mobile Digit X-ray Unit, Digital X-ray Fluoroscope Radiography System, Digital Medical X-ray Photography System, Vehiclemounted Digital Medical X-ray Radiography System, Radiotherapy Simulator, Co-60 Therapy Unit, X-ray Equipment for Computed Tomography, Digital Mammography X-ray Equipment, X-ray Blood Irradiator, Digital Operation Room Equipment (Electric Operating Table, Operation Surgical Lamp, LED Surgical Lamp, Patient Transport Vehicle, Orthopedic Extension Device, Electric Multi-Purpose Obstetric Table, Electro-hydraulic Operating Table), Medical Ceiling Pendant, Moist Heat Disinfection and Sterilization Equipment, Dry Heat Disinfection and Sterilization Equipment, Chemical Sterilization Equipment, Washer and Disinfection Equipment, Autoclave, Rapid Automatic Washer-Disinfecter, H2O2 Low Temperature Plasma Sterilizer, Ethylene Oxide Sterilizer, Pulse Vacuum Sterilizer.

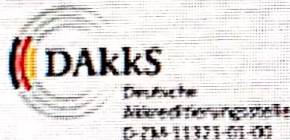
The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see:

www.tuvsud.com/ps-cert?g-cert:Q5_003076_0004_Rev_02

Report No.:	BJ20050106
Valid from:	2021-05-19
Valid until:	2024-03-18

Date, 2021-05-19

Christoph Dicks
Head of Certification/Notified Body



Product Service

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Applied Standard(s): EN ISO 13485:2016
 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
 DIN EN ISO 13485:2016

Facility(ies): Shinva Medical Instrument Co., Ltd.
 No. 2009 Xinhua Ave, Zhoucun, 255300 Zibo, Shandong, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production and Distribution of Moist Heat Disinfection and Sterilization Equipment, Dry Heat Disinfection and Sterilization Equipment, Chemical Sterilization Equipment, Washer and Disinfection Equipment, Autoclave, Rapid Automatic Washer-Disinfector, H₂O₂ Low Temperature Plasma Sterilizer, Ethylene Oxide Sterilizer, Pulse Vacuum Sterilizer.

Shinva Medical Instrument Co., Ltd.
 No. 99 BeiXin Road, Zibo New & Hi-Tech Zone, 255086 Zibo, Shandong, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production and Distribution of Medical High-energy Equipment (Medical Electron Linear Accelerator, Multi-leaf Collimator), Blood Irradiator, Remote Control After Loading Machine with Gamma Rays, Medical Laser Instrument Equipment (CTSim), Software (Radiotherapy Information System), Digital Medical X-ray Radiography System, Mobile Digit X-ray Unit, Digital X-ray Fluoroscope Radiography System, Digital Medical X-ray Photography System, Vehiclemounted Digital Medical X-ray Radiography System, Radiotherapy Simulator, Co-60 Therapy Unit, X-ray Equipment for Computed Tomography, Digital Mammography X-ray Equipment, X-ray Blood Irradiator, Digital Operation Room Equipment (Electric Operating Table, Operation Surgical Lamp, LED Surgical Lamp, Patient Transport Vehicle, Orthopedic Extension Device, Electric Multi-Purpose Obstetric Table, Electro-hydraulic Operating Table), Medical Ceiling Pendant, Dental Zirconia Ceramic.

Shinva Medical Instrument Co., Ltd.
 Xinhua Medical Scientific Zone, Zibo New & Hi-Tech Industrial Development Zone, 255086 Zibo, Shandong, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production and Distribution of Autoclave, Dental Unit, Dental Zirconia Ceramic.

MAST-V Steam Sterilizer

Product introduction

MAST-V is a fast, compact and versatile sterilizer which is researched and developed according to the latest requirements of medical institution and CSSD. It is designed and manufactured combines high capacity with cost-efficiency, while offering high operating reliability and easy maintenance.

The design of chamber accords with state GB1502011, GB8599-2008, CE, European EN285 standard, ASME and PED.



Product features

- Superb chamber machining and welding process**
 The acid-proof stainless steel chamber and jacket are automatically robot-welded to guarantee long time and trouble-free operation.
- Nice chamber surface**
 Surface Smoothness, Ra≤0.5; No welding part or bolt in the chamber which effectively protects the items to be sterilized. Steam baffle plates are surrounded by silicon rubber protecting the chamber surface.
- Reliable and durable chamber**
 Chamber is designed according to professional analytical method. High-emulation software ANSYS is used for chamber simulation. Design service life: 10 years (or 20000 times sterilization)
- Reasonable sealing structure**
 Compact designed sealing groove, durable circular hollow silicon gasket, sealed by compressed air.
- Vertical sliding door**
 The door is up and down vertical sliding by air cylinder. It is faster and saves space, while offering proven, handles-free convenience.
- Precise pressure detecting and control**
 Intelligent pressure transmitters, Wika (Germany), ensure steam pressure detecting and control both in Chamber and jacket.
- Unique vacuum noise-reduction system**
 LNS low-noise and water-saving vacuum system, effective reduced the noise during running.
- Humanized operation system**
 Colorful touch screen on loading-side, 6 indicating lamps on unloading sides, which are concise, vivid and exactly showing sterilization running status and alarming information.
- Reasonable pipeline layout**
 All the pipes, valves and components are designed and installed in single side, which is more convenience for repair and maintenance. The sterilizers can be installed against the wall and also, two sterilizers can use the same maintenance space to save installation space.

Configuration Selection Table

MAST-V Basic configuration

No.	Volume (L)	Chamber size (W×H×D) mm	Overall size (W×H×D) mm	Net weight (kg)	Input power (kVA)
1	280	535×535×1000	1200×1800×1340	800	2.5/34
2	450	675×675×1000	1307×1900×1340	1000	4/46
3	610	675×675×1350	1307×1900×1690	1200	4/46
4	800	675×675×1750	1307×1900×2090	1300	4/68
5	910	675×675×2006	1307×1900×2346	1450	4/68

Number of Door(s)

- Single door(D)
- Double door(S)

Material of Chamber + Jacket

- SUS316L+SUS316L (M1) ☆
- SUS316Ti+SUS316L (M2)
- SUS316Ti+SUS316Ti (M3)

Side cover

- With side cover ☆
- Without side cover

Steam source

- External steam supply
- Built-in steam generator(D) ☆
 - SUS304 ☆
 - SUS316L
- Built-in steam generator + External steam supply(S)

Loading mode

- Shelf loading(A)
- Loading cart and transfer trolley(B)
- Floor trolley loading(C)

Note:

Machine less than 240L only available for shelf loading.

Floor trolley loading only available for machine more than 1200L.

Voltage

- 380V, 3-Phases ☆
- 220V, 3-Phases
- 240V, 3-Phases
- 400V, 3-Phases
- 415V, 3-Phases

Frequency

- 50Hz ☆
- 60Hz

Optional configuration

- Remote monitoring system
- Air differential seal (Double door only)
- Bio-seal (Double door only)
- Pressure gauges for built-in steam generator
- Safety valve for built-in steam generator
- Auto flush for steam generator
- Compressed air pressure detection
- Vacuum pump water pressure detection

Standard accessories

- Loading cart×1
- Transfer trolley×1(For single door model)
- Transfer trolley×2(For double door model)

Extra optional accessories

- Loading cart×□
- Transfer trolley×□
- Loading basket
 - SHINVA Standard (535Lx380Wx195Hmm)×□
 - SHINVA Standard (535Lx380Wx100Hmm)×□
 - ISO Standard(585Lx395Wx200Hmm)×□
 - Loading rack for paper-plastic pouch(465Lx330Wx90Hmm)×□
- Installation kits
 - Steam inlet kits (For machine with external steam supply)×□
 - Compressed air inlet kits
 - Water inlet kits
 - Vacuum pump and cooling water inlet kits×□
 - Built-in steam generator water inlet kits×□
 - Water drainage kits×□
- External air compressor
 - BZ-60L,60L/min×□
 - WY-120L,120L/min×□
- External water softener
 - Water-S-100,100L/hour×□
 - Water-S-500,500L/hour×□

Note: The items with "☆" are standard configuration.

Authorization Letter

We, Shinva Medical Instrument Co., Ltd., based in Xinhua Medical Scientific Zone, Zibo New & Hi-Tech Industrial Development Zone, Shandong Province, P. R. China., **assign** Sofragrup SRL, based in 65/3-56, Nicolae Costin str. Chisinau, Republic of Moldova as **authorized representative** in correspondence with the conditions of directive 93/42/EEC, 98/79/EEC or 90/385/EEC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova, and to perform Essential Duties required by Law No. 102 09.06.2017 regarding medical devices.

Place: Zibo, China

Date: Jan 20, 2019

Signed: 张本开

山东新华医疗器械股份有限公司
SHINVA MEDICAL INSTRUMENT CO., LTD.

SHINVA



ENGINEER TRAINING CERTIFICATE

THIS CERTIFICATE
IS PROUDLY PRESENTED TO

Corneliu BUNIC

We declare that Corneliu BUNIC, an engineer from
Sofragrup SRL in Republic of Moldova, joined our engineer
training regarding Sterilizers products from
Sep. 08, 2019 to Sep. 13, 2019. After theoretical and practice test,
he/she has proved to be qualified to do maintenance and service for
the mentioned products. Hereby we certify this certificate to award.

Best regards,

International Business Department
Shinva Medical Instrument Co., Ltd.

山东新华医疗器械股份有限公司
SHINVA MEDICAL INSTRUMENT CO., LTD.

Sep. 15, 2019

DATE



Tong Yongxu

SIGNATURE

To:	Sofragrup SRL
Product:	Steam sterilizer MAST-V series
Date:	2021-07-08
Author:	Kevin Chen

Quotation List

No.	Name and model	Order code	Quantity
1	Steam Sterilizer MAST-V	MAST-V-800SD-B-M1	1 Unit
2	Accessories	Door gasket 4 pcs. HEPA filter 2 pcs. Printer paper 30 pcs.	
3	RO Water Treatment system	Waters-1500	

Specification Description	Reference Photos
<p>MAST-V-800SD-B-M1 Double door With built-in steam generator Chamber Volume: 800L Chamber Design: Horizontal and rectangle Door Design: Automatic vertical sliding door Chamber Dimension(W×H×D): 675×675×1750mm Overall Dimension(W×H×D): 1307×1900×2090mm Material: Chamber: 316L S.S. Jacket: 316L S.S. Door plate: 316L S.S. Pipeline: 304 S.S. Steam generator: 316L S.S with separate pressure sensor Chamber insulation cover: Embossed aluminum sheet Net Weight: 1300Kg Power: Three Phase 380V 50Hz Input Power: 68KVA Cycle time: 45-60minutes/Cycle Designed Pressure:-0.1/0.3MPa Working pressure: -0.1/0.25MPa Designed Temperature: 144℃ Maximum Working Temperature: 139℃ Vacuum Limit: -0.080MPa Control: PLC Display and operation: 8.4" Colorful Touch Screen Data Record: Built-in printer Built-in Programs: 1-WARM-UP 2-B&D TEST 3-FABRIC 4-INSTRUMENT 5-THERMO 6-FLASH 7-ORTHOPEDECS 8-LEAK TEST 9-PRION 10-LUMEN 11-HEAVY ITEM 12-SMALL ITEM 13-EXPOSED LIQUID 14-GRAVITY 15-POSI.PULSE 16-DRY 17-PCD TEST 18-A/D TEST 19~32-USER01~14 Accessories: Loading cart x 2, 304S.S. Transfer trolley x 2, 304S.S. Air compressor x 1, 60L/h</p>	