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Zentralstelle der Länder
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bei Arzneimitteln und
Medizinprodukten
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ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 003076 0003 Rev. 02

Manufacturer:

Shinva Medical Instrument Co., Ltd.

Xinhua Medical Scientific Zone

Zibo New & Hi-Tech Industrial Development Zone

255086 Zibo

PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): Ethylene Oxide Sterilizer, Pulse Vacuum Sterilizer, Radiotherapy Simulator, Medical Electron Linear Accelerator, Dental Unit.

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.:

BJ19501033

Valid from:

2019-12-09

Valid until:

2024-05-26

Date,

2019-12-09

Christoph Dicks

Head of Certification/Notified Body

ZERTIFIKAT • CERTIFICATE • CERTIFICADO • CERTIFIKAT • 認證證書



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Facility(ies):

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

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

Shinva Medical Instrument Co., Ltd.
No. 2009 Xinhua Ave, Zhoucun, 255300 Zibo, PEOPLE'S
REPUBLIC OF CHINA

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.



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-Disinfector, 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?q=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

Certificate

No. Q5 003076 0004 Rev. 02

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.

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Development Zone, 255086 Zibo, Shandong, PEOPLE'S
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Design and Development, Production and Distribution of
Autoclave, Dental Unit, Dental Zirconia Ceramic.