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Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
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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



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**No. G1 003076 0003 Rev. 02**

## 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

# XG1.U Steam Sterilizer

## Product introduction

It can be widely used in department of stomatology and ophthalmology, operating room and other medical institutions. It is suitable for all wrapped or unwrapped solid instruments, A-class cavity instrument (dental hand-pieces and endoscopes), implantable instruments, dressing fabric and rubber tubes, etc.

## Product features

- Equipped with professional and systematized sterilizing programs of fabric, instrument, rubber, liquid, cavity, testing and auxiliary programs of BD, PCD and leakage.
- Temperature, pressure, time, running status, failure warning liquid-crystal display.
- Intelligentized drying system to guarantee the residual humidity of instrument and dressing no more than 0.2% and 1% respectively.
- Build-in efficient steam generator, microcomputer temperature control, time and energy saving.
- Equipped with printer to print date, time and process parameters.
- Over-heat auto protection device, dual door safety lock device, overpressure relief valve, short-circuit protection, and overpressure protection.
- Perfect four-level authority management system to avoid misoperation.



## Technical parameters

Design pressure: -0.1/0.25MPa      Accuracy of temperature display: 0.1℃  
Maximum working pressure: 0.23MPa      Accuracy of pressure display: 1KPa  
Vacuum limit: -0.080MPa      Chamber material: 304 stainless steel  
Sterilization working temperature: 115~138℃

## Configuration Selections Table

### • XG1.U Basic configuration

No.	Order code	Volume (L)	Chamber size (φ×L) mm	Overall size (L×W×H) mm	Net weight (kg)	Input power (kVA)
1	XG1.UCD-100D	100	400×850	1250×730×1660	260	10
2	XG1.UCD-100S	100	400×780	1264×730×1660	300	10
3	XG1.UCD-135D	135	500×710	1110×750×1742	400	11.5
4	XG1.UCD-135S	135	500×620	1140×750×1742	450	11.5
5	XG1.UCD-185D	185	500×950	1350×750×1742	460	11.5
6	XG1.UCD-185S	185	500×860	1365×750×1742	500	11.5
7	XG1.UCD-300D	300	632×1000	1415×890×1780	750	18
8	XG1.UCD-300S	300	632×890	1438×890×1780	800	18

### • Number of Door(s)

- ☐ D-Single door
- ☐ S-Double door

### • Material of Chamber + Jacket

- ☐ SUS304+SUS304 ☆
- ☐ SUS316L+SUS316L

### • Material of Built-in steam generator

- ☐ SUS304 ☆
- ☐ SUS316L

### • Loading mode

- ☐ Shelf loading

### • Voltage

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

### • Frequency

- ☐ 50Hz ☆    ☐ 60Hz

### • Standard accessories

- ☐ Loading shelves×2

# XG1.C Steam Sterilizer

## Product introduction

It is applicable for the sterilization of unpacked solid instrument in department of stomatology, ophthalmology, operation room and CSSD.

## Product features

- Touch screen display of temperature, pressure, time, running status and failure warning.
- Equipped with professional and systematized sterilizing programs of fabric, instrument, rubber and liquid.
- The positive pressure air-discharging system will effectively discharge the cold air from chamber to improve steam saturability.
- Build-in efficient steam generator, microcomputer temperature control, time and energy saving.
- Equipped with post-drying function which makes the residual humidity of sterilized articles less than 3%.
- Equipped with printer to print date, time and process parameters.
- Over-heat auto protection device, dual door safety lock device, overpressure relief valve, short-circuit protection and overpressure protection.
- Perfect four-level authority management system to avoid misoperation.



## Technical parameters

Design pressure: 0 / 0.25MPa      Chamber material: 304 stainless steel  
Maximum working pressure: 0.23MPa      Accuracy of temperature display: 0.1℃  
Sterilization working temperature: 115~138℃      Accuracy of pressure display: 1KPa

## Configuration Selections Table

### XG1.C Basic configuration

No.	Order code	Volume (L)	Chamber size (φ×L) mm	Overall size (L×W×H)mm	Net weight (kg)	Input power (kVA)
1	XG1.CD-100D	100	400×850	1250×730×1660	260	10
2	XG1.CD-100S	100	400×780	1264×730×1660	300	10
3	XG1.CD-135D	135	500×710	1110×750×1742	400	11
4	XG1.CD-135S	135	500×620	1140×750×1742	450	11
5	XG1.CD-185D	185	500×950	1350×750×1742	460	11
6	XG1.CD-185S	185	500×860	1365×750×1742	500	11
7	XG1.CD-300D	300	632×1000	1415×890×1780	750	17
8	XG1.CD-300S	300	632×890	1438×890×1780	800	17

### • Number of Door(s)

- ☐ D-Single door
- ☐ S-Double door

### • Material of Chamber + Jacket

- ☐ SUS304+SUS304 ☆
- ☐ SUS316L+SUS316L

### • Material of Built-in steam generator

- ☐ SUS304 ☆
- ☐ SUS316L

### • Loading mode

- ☐ Shelf loading

### • Voltage

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

### • Frequency

- ☐ 50Hz ☆    ☐ 60Hz

### • Standard accessories

- ☐ Loading shelves×2





# 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](http://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.

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.