ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 003076 0008 Rev. 01

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:

TÜV SÜD EN ISO 13485 tuvsud.com/ps-cert

Digitally signed by Bunic Gheorghe
Date: 2025.04.24 13:47:12 TRT
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Scope of Certificate:

Design and Development, Production and Distribution of Dental Unit, 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, Image-guided radiotherapy system of X-ray-based.

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 0008 Rev. 01

Report No.: BJ23050106
Valid from: 2024-03-19
Valid until: 2027-03-18

Date, 2024-03-18

Christoph Dicks
Head of Certification/Notified Body

EU Quality Management System Certificate CN24/00004750

The management system of

Shinva Medical Instrument Co., Ltd.

Xinhua Medical Scientific Zone, Zibo New & Hi-Tech Industrial Development Zone, 255086, Zibo, Shandong, P.R. China
SRN Number: CN-MF-000009856

has been assessed and certified as meeting the requirements of

MDR (EU) 2017/745 Quality Management System certificate (Annex IX Chapter I and III)

For the following products
The Scope of Registration appears on page 2 of this certificate

This certificate is valid from 17 February 2025 until 29 July 2029 and remains valid subject to satisfactory surveillance audits.
Issue 2. Certified since 29 July 2024

Authorised by
Virginie Siloret
Global Medical Device
Certification Manager
SGS Belgium NV NB1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 - www.sgs.com

EU Quality Management System Certificate CN24/00004750, continued

Shinva Medical Instrument Co., Ltd.

MDR (EU) 2017/745 Quality Management System certificate (Annex IX Chapter I and III)

Class IIa

MDA0311, MDS1009
Dental Unit for oral medical institutions for diagnosis, treatment and operation
(Model name: GRACE-D, GRACE-U)
(Basic UDI-DI: 697061496180002T2)

MDA 0317, MDS1009
Ethylene Oxide Sterilizer
(Basic UDI-DI: 697061496120005R6)

H2O2 Low Temperature Plasma Sterilizer
(Basic UDI-DI: 697061496120004R4)

Pulse Vacuum Sterilizer
(Basic UDI-DI: 697061496120002QY)

Flexible Endoscope Washer-disinfector
(Basic UDI-DI: 697061496120006R8)

Conditions for & limitation to the validity of the certificate:
For placing on the market of Class III or class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors and Annex VIII rule 12 devices) covered by this certificate, a Technical Documentation Assessment Certificate according to Annex IX section 4 and 5 is required.

For Class I devices, audit done by SGS Belgium N.V. is limited to the specific aspect described in Article 52 section 7 of MDR (EU) 2017/745 (sterility, reusability or measurement function).

List of examinations and tests performed, which may include reference to relevant CS and harmonised standards, as per Annex XII, Chapter II, section 10 is available “on request" per email to NB1639@sgs.com.

Limitation: N/A

Certification is based on following reports: - CN/TAO/251495 - ESG 1.5
Authorized representative name and address (if relevant): MedNet EC-REP C IIb GmbH. ; Borkstrasse 10, 48163 Münster, Germany
Previous certificate number: N/A
Change in between this certificate and previous one: Addition of a new device “Flexible Endoscope Washer-disinfector” to the scope.

Shinva Medical Instrument Co., Ltd.

MDR (EU) 2017/745 Quality Management System certificate (Annex IX Chapter I and III)

Sites

Shinva Medical Instrument Co., Ltd.
Xinhua Medical Scientific Zone, Zibo New & Hi-Tech Industrial Development Zone, 255086, Zibo, Shandong, P.R. China

Shinva Medical Instrument Co., Ltd.
No. 2009 Xinhua Ave, Zhoucun, 255300 Zibo City, Shandong, P.R. China

DECLARATION OF CONFORMITY

MANUFACTURER:	SHINVA MEDICAL INSTRUMENT CO., LTD XINHUA MEDICAL SCIENTIFIC ZONE, ZIBO NEW & HI-TECH INDUSTRIAL DEVELOPMENT ZONE, 255086, ZIBO, SHANDONG, PEOPLE'S REPUBLIC OF CHINA
MEDICAL DEVICE: **MODELS:**	PULSE VACUUM STERILIZER XG1.DM,XG1.DW,XG1.H,XG1.U,MAST-A,MAST-H,MAST-C,MAST-V, CLEAN VS
INTENDED USE	SUITABLE FOR STEAM STERILIZATION OF MEDICAL ITEMS WHICH CAN BE STEAM STERILIZED BETWEEN 121 °C AND 135 °C, SUCH AS SURGICAL INSTRUMENTS, FABRICS AND TOWELS, RIGID ENDOSCOPES, CONTAINERS AND PLASTICS.
CLASSIFICATION	IIa RULE 16 ANNEX VIII OF MDR
EMDN CODE	Z120113
CONFORMITY ASSESSMENT ROUTE:	ANNEX IX OF MDR
WE, SHINVA MEDICAL INSTRUMENT CO., LTD. HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF MDR EU 2017/745; ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURE; WE ARE EXCLUSIVELY RESPONSIBLE FOR THE DOC.	
NOTIFIED BODY:	SGS BELGIUM NV NOORDERLAAN 87 BE-2030 ANTWERPEN,BELGIUM
IDENTIFICATION NUMBER:	CE 1639
(EC) CERTIFICATE(S):	CN24/00004750
EC REP **EUROPEAN REPRESENTATIVE:**	MEDNET EC-REP C IIB GMBH BORKSTRASSE 10, 48163 MÜNSTER, GERMANY SRN NUMBER: DE-AR-000011194
START OF CE-MARKING:	2024/08/01
SRN:	CN-MF-000009856
BASIC UDI-DI:	697061496120002QY
PLACE, DATE OF DECLARATION:	2024/08/01, ZIBO
SIGNATURE:	Liu Heng,PRRC