



# Certificate

No. Q5 003076 0004 Rev. 01

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

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

**Certification Mark:**



**Scope of Certificate:**

**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), X-ray Diagnostic Unit, X-ray Radiographic Unit, Digital Medical X-ray Radiography System, C-arm X-ray machine for Medical Purpose, Mobile Digit X-ray Unit, Digital X-ray Fluoroscope Radiography System, Digital Medical X-ray photography system, Vehicle-mounted Digital Medical X-ray Radiography System, Moist heat disinfection and sterilization equipment, Dry heat disinfection and sterilization equipment, Chemical sterilization equipment, Washer and disinfection equipment, Digital Operation Room Equipment (Electric Operating Table, Operation Surgical Lamp, LED Surgical Lamp, Manual Operating Table, Multi-functional Medical Bed, Patient Transport Vehicle, Orthopedic Extension Device, Electric Multi-Purpose Obstetric Table, Electro-hydraulic Operating Table), Dental Equipment and Instrument (Dental**

ZERTIFIKAT • CERTIFICATE • 認證證書 • CERTIFICADO • CERTIFICAT

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**Units, Cassette Steam Sterilizer, Dental Electric Oil Free AIR Compressor, Dental Electric Suction System), Medical center gas supply System (Molecular Sieve Oxygen Generator for Medical Use, Central Oxygen Supply System for Medical Use, Central Attract System for Medical Use), Clinical Laboratory Analysis Instrument (Fluorescence Analyzer), Autoclave, Rapid Automatic Washer-Disinfector, H2O2 Low Temperature Plasma Sterilizer, Ethylene Oxide Sterilizer, Pulse Vacuum Sterilizer, Radiotherapy Simulator, Co-60 Therapy Unit, Dental Unit, Dental Zirconia Ceramic, Medical Ceiling Pendant and X-ray Equipment for Computed Tomography.**

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). See also notes overleaf.

Report No.: BJ19501033

**Valid from:** 2019-12-09  
**Valid until:** 2021-03-18

**Date,** 2019-12-09

C.D.H

**Christoph Dicks**  
Head of Certification/Notified Body

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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.  
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REPUBLIC OF CHINA

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