AGENȚIA MEDICAMENTULUI ȘI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Tip	Denumire
I.3. Certificatul CE	Certificat CE
I.2. Declarația de conformitate CE	Declaratie de conformitate CE

Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data	Cod vamal
			Xg1.U			shinva				
DM000397637	AUTOCLAV	SHINVA	XG1.U		China	SHINVA MEDICAL INSTRUMENT CO., LTD.	SOFRAGRUP S.R.L.	Rg04-000307	27-12-2022	

Содержит([Producatorul], 'shinva') И Содержит([Model], 'Xg1.U') Очистить

Digitally signed by Bunic Gheorghe
Date: 2024.07.24 17:11:37 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
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

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
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(Devices in Class IIa, IIb or III)

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

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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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 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:

TÜV SÜD EN ISO 13485 tuv-sud.com/ps-cert

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

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

TÜV SÜD Product Service

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.

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DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES

	Shinva Medical Instrument Co.,Ltd. Xinhua Medical Scientific Zone Zibo New & Hi-Tech Industrial Development Zone 255086 Zibo PEOPLE'S REPUBLIC OF CHINA
MEDICAL DEVICE:	**Pulse Vacuum Sterilizer**
MODELS:	**XG1.DM,XG1.DW,XG1.H,XG1.U,MAST-A,MAST-H,MAST-C,MAST-V**
CLASSIFICATION	IIB
GMDN CODE:	38671
CONFORMITY ASSESSMENT ROUTE:	ANNEX II EXCL. SECTION 4 OF MDD 93/42/EEC

WE, Shinva Medical Instrument Co., Ltd. HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES. MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES;
INCLUDING, AT 21 MARCH 2010, THE AMENDMENTS BY COUNCIL DIRECTIVE 2007/47/EEC
ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURE.
WE IS EXCLUSIVELY RESPONSIBLE FOR THE DOC.

STANDARDS APPLIED: (HARMONISED - EN) STANDARDS FOR WHICH DOCUMENTED EVIDENCE OF COMPLIANCE CAN BE PROVIDED.
EN 285:2015; EN 12347:1998; ISO 17665-1:2006; IEC 61010-1:2010+AMD1:2016;
IEC 61010-2-40:2015; EN 61326-1:2013;EN ISO 15223-1:2012;EN 1041:2008;ISO 13485:2003;
EN ISO 14971:2012;IEC 60204-1:2009;EN 10204:2004;EN ISO 9606:2017;EN ISO 9712:2012;
EN ISO 15614-1:2017;ISO 14732:2013;MDD/93/42EEC; 2007/47/EC;2006/42/EC ;
EN 62304:2006+AC:2008;EN 62366:2008

NOTIFIED BODY:	TÜV SÜD PRODUCT SERVICE GMBH RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY
IDENTIFICATION NUMBER:	CE 0123
(EC) CERTIFICATE(S):	G1 003076 0003 Rev.02
EC REP **EUROPEAN REPRESENTATIVE:**	MEDNET GMBH BORKSTRASSE 10, 48163 MÜNSTER, GERMANY

START OF CE-MARKING: 09TH December, 2019 (Date or Lot or serial number)

PLACE, DATE OF DECLARATION:	ZIBO, 09TH December, 2019
SIGNATURE:	President