REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

CE

Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant
						shinva	
DM000397640	AUTOCLAV	SHINVA	MAST-C		China	SHINVA MEDICAL INSTRUMENT CO., LTD.	SOFRAGRUP S.R.L.
DM000397635	AUTOCLAV	SHINVA	XG1.DW		China	SHINVA MEDICAL INSTRUMENT CO., LTD.	SOFRAGRUP S.R.L.
DM000397637	AUTOCLAV	SHINVA	XG1.U		China	SHINVA MEDICAL INSTRUMENT CO., LTD.	SOFRAGRUP S.R.L.
DM000397634	AUTOCLAV	SHINVA	XG1.DM		China	SHINVA MEDICAL INSTRUMENT CO., LTD.	SOFRAGRUP S.R.L.
DM000397639	AUTOCLAV	SHINVA	MAST-H		China	SHINVA MEDICAL INSTRUMENT CO., LTD.	SOFRAGRUP S.R.L.
DM000397641	AUTOCLAV	SHINVA	MAST-V		China	SHINVA MEDICAL INSTRUMENT CO., LTD.	SOFRAGRUP S.R.L.
DM000397636	AUTOCLAV	SHINVA	XG1.H		China	SHINVA MEDICAL INSTRUMENT CO., LTD.	SOFRAGRUP S.R.L.
DM000397638	AUTOCLAV	SHINVA	MAST-A		China	SHINVA MEDICAL INSTRUMENT CO., LTD.	SOFRAGRUP S.R.L.

Содержит([Producatorul], 'shinva')

Digitally signed by Bunic Gheorghe
Date: 2024.07.21 09:43:49 EEST
Reason: MoldSign Signature
Location: Moldova

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

Product Service

Confirmation Statement on validity of EC Certificate (MDD)

pursuant to Directive 93/42/EEC concerning medical devices

No. GCQ 003076 0009 Rev. 01

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

This Confirmation Statement is only valid in combination with the following EC Certificate (MDD):

G1 003076 0003 Rev. 02

This Confirmation Statement confirms the validity of the aforementioned EC Certificate (MDD).
It considers clarification of scope statements, scope reductions and changes to the manufacturer data initiated 26 May 2021 or later.
The conditions laid down in Article 120 (3) of Regulation (EU) 2017/745 on medical devices for placing devices on the market and putting into service apply. For details and confirmation statement validity see: www.tuvsud.com/ps-cert?q=cert:GCQ 003076 0009 Rev. 01

Report No.: BJ23050106

Valid until: 2024-05-26

Issue Date: 2024-03-18

Christoph Dicks
Head of Certification/Notified Body

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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

2024/05/20

Confirmation Letter Reference: CLNB1639 - CN/TAO/251495

To whom it may concern,

Confirmation of receipt of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that, SGS Belgium NV, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1639 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following 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
SRN Number: CN-MF-000009856

Authorized representative:
MedNet EC-REP C IIb GmbH
Borkstrasse 10, 48163 Münster, Germany
SRN Number: DE-AR-000011194

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that:

- The manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry;
- The certificates expired after 26th May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3 of MDR (as amended by EU 2023/607), are shown below:

- 26th May 2026 for Class III custom-made implantable devices
- 31st December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31st December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31st December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body SGS Belgium NV NB1639,

Pp[Sean Kelly]
Virginie SILORET
Global Medical Device Certification Manager
Email: Virginie.siloret@sgs.com
Phone: +41 22 739 98 58

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive**:**

Device name or Basic UDI-DI	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	**MDD Device name** (please indicate if correlation with MDR denomination is not obvious)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	**MDD/AIMDD Certificate Reference(s)** of the devices under MDR application, and the NB Identification
Dental Unit Basic UDI-DI: 697061496180002T2	Class IIa	Dental Unit	N/A	Certificate No. G1 003076 0003 Rev. 02 NB0123
Ethylene Oxide sterilizer Basic UDI-DI: 697061496120005R6	Class IIa	Ethylene Oxide sterilizer	N/A	Certificate No. G1 003076 0003 Rev. 02 NB0123
H2O2 Low Temperature Plasma Sterilizer Basic UDI-DI: 697061496120004R4	Class IIa	H2O2 Low Temperature Plasma Sterilizer	N/A	Certificate No. G1 003076 0006 Rev. 01 NB0123
Pulse Vacuum Sterilizer Basic UDI-DI: 697061496120002QY	Class IIa	Pulse Vacuum Sterilizer	N/A	Certificate No. G1 003076 0003 Rev. 02 NB0123

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	**MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)**	**If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device**	**MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification**
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/05/20	Version 1	Initial issue