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 Quality Management System certificate (Annex IX QMS)

For the following products

The Scope of Registration appears on page 2 of this certificate

This certificate is valid from 29 July 2024 until 29 July 2029 and remains valid subject to satisfactory surveillance audits.

Issue 1. 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

Digitally signed by Jighili Tatiana
Date: 2024.10.07 17:22:02 EEST
Reason: MoldSign Signature
Location: Moldova
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EU Quality Management System Certificate CN24/00004750, continued

Shinva Medical Instrument Co., Ltd.

MDR EU Quality Management System certificate (Annex IX QMS)

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)

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 - S2A 1.4
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: N/A

Shinva Medical Instrument Co., Ltd.

MDR EU Quality Management System certificate (Annex IX QMS)

Sites

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

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