Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

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

EU Quality Assurance Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A
(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

No. G21 095972 0015 Rev. 01

Manufacturer:

Zhende Medical Co., Ltd.
Gaobu Town
312035 Shaoxing, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer - CN-MF-000009961

Authorized Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex XI Part A of this regulation with a positive result.
As applicable the involvement of the notified body is limited to the aspects relating to:
- establishing, securing and maintaining sterile conditions,
- conformity of the devices with the metrological requirements,
- reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

The certified quality assurance system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:G21 095972 0015 Rev. 01

Report No.: SH22071MDR01

Preceding Certificate No.: G21 095972 0015 Rev. 00

Valid from: 2024-06-26
Valid until: 2026-01-28
Date of Initial Issuance: 2021-01-29

Issue date: 2024-06-26

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
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EU Quality Assurance Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A
(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

No. G21 095972 0015 Rev. 01

Classification:	Class I
Device Group:	A10 - ABDOMINAL OSTOMY DEVICES
Device Properties:	MDS 1005.2 - Sterilisation by irradiation
Classification:	Class I
Device Group:	H90 - SUTURE DEVICES - VARIOUS
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	Class I
Device Group:	M01 - COTTON AND SYNTHETIC WADDING
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	Class I
Device Group:	M02 - GAUZES
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization MDS 1005.2 - Sterilisation by irradiation MDS 1005.3 - Sterilization by moist heat
Classification:	Class I
Device Group:	M03 - BANDAGES
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization MDS 1005.2 - Sterilisation by irradiation
Classification:	Class I
Device Group:	M04 - SPECIAL DRESSINGS
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization MDS 1005.2 - Sterilisation by irradiation
Classification:	Class I
Device Group:	T02 - PROTECTIVE CLOTHING AND DRAPES (EXCLUDING PERSONAL PROTECTIVE EQUIPMENT - PPE)
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization

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EU Quality Assurance Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A
(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

No. G21 095972 0015 Rev. 01

Classification:	Class I
Device Group:	V05 - CLINICAL PROCEDURES KITS NOT INCLUDED IN OTHER CLASSES
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
The validity of this certificate depends on conditions and/or is limited to the following:	-none-

Revision History:

Rev.	Dated	Report	Description
00	2021-01-29	SH2007101	-
01	2024-06-26	SH22071MDR01	Supplemented: Device(s)/group of device(s) added

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