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
BS-MDR-099

Product Service

EU Production Quality Assurance Certificate

Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A

Certificate No. G26 095972 0019 Rev. 00

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 quality management system has been evaluated in accordance with Regulation (EU) 2017/745, Annex XI Part A with a positive result.

Details on devices covered by the quality management system are described on the following page(s). The report referenced below summarises the results of the assessment and includes reference to relevant CS, harmonised standards and test reports.
The certified quality management system is subject to periodical surveillance.

If class I devices in sterile conditions, with measuring function, or reusable surgical instruments are covered by this certificate, the audit was limited to the respective 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.

If class IIa devices are covered by this certificate, the quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis. The devices conform to the technical documentation. The periodical surveillance includes further assessment of the technical documentation on the basis of representative samples.
If class IIb or class III (excluding custom-made implantable devices) devices are covered by this certificate, the quality management system ensures that devices conform to the type that has undergone a type examination. An EU Type-Examination Certificate in accordance with Annex X is required before placing them on the market.

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:G26 095972 0019 Rev. 00

Report No.:	SH25007105
Preceding Certificate No.:	G20 095972 0016 Rev. 00 G21 095972 0015 Rev. 01
Valid from:	2026-01-29
Valid until:	2031-01-28

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2025-12-16

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Certificate No. G26 095972 0019 Rev. 00

Classification:	Class IIa
Device Group:	MDN 1204 - Non-active non-implantable devices for wound and skin care
Classification:	Class I
Device Group:	A10 - ABDOMINAL OSTOMY DEVICES H90 - SUTURE DEVICES - VARIOUS M03 - BANDAGES M04 - SPECIAL DRESSINGS T02 - PROTECTIVE CLOTHING AND DRAPES (EXCLUDING PERSONAL PROTECTIVE EQUIPMENT - PPE) V05 - CLINICAL PROCEDURES KITS NOT INCLUDED IN OTHER CLASSES M01 - COTTON AND SYNTHETIC WADDING M02 - GAUZES
Device Properties:	MDS 1005 - Devices in sterile condition
The validity of this certificate depends on conditions and/or is limited to the following:	-none-

Revision History:

Rev.	Dated	Report	Description
00	2026-01-29	SH25007105	- Renewal of certificate Administrative merge / transfer to new Certificate Type

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