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 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 109397 0009 Rev. 00

Manufacturer:

Xuchang Zhende Surgical Dressing Co., Ltd.
Area A, Baihua Road East
South Side of Erji river
Industry Cluster District
Yanling County
461200 Xuchang Henan
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer - CN-MF-000009222

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 109397 0009 Rev. 00

Report No.: SH21495MDR01

Valid from: 2025-04-23
Valid until: 2030-04-22

Issue date: 2025-04-23

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

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No. G21 109397 0009 Rev. 00

Classification:	Class I
Device Group:	M010102 - PURE COTTON
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization MDS 1005.3 - Sterilization by moist heat

Classification:	Class I
Device Group:	M010103 - COTTON PAD
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization MDS 1005.3 - Sterilization by moist heat

Classification:	Class I
Device Group:	M010199 - COTTON WADDING - OTHER
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization MDS 1005.3 - Sterilization by moist heat

Classification:	Class I
Device Group:	M020101 - COTTON GAUZES, CUT
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:	M020102 - COTTON GAUZES, FOLDED
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:	M020105 - COTTON GAUZE PADS
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:	M020107 - COTTON GAUZES IN ROLLS
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:	M020199 - COTTON GAUZES - OTHER
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization

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(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

No. G21 109397 0009 Rev. 00

	MDS 1005.2 - Sterilisation by irradiation MDS 1005.3 - Sterilization by moist heat
Classification:	Class I
Device Group:	M030101 - HYDROPHILIC GAUZE BANDAGES
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	Class I
Device Group:	T020603 - MEDICAL USE FACE MASKS, TYPE I (NOT FOR HEALTHCARE PROFESSIONALS)
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	Class I
Device Group:	T020604 - MEDICAL USE FACE MASKS, TYPE II AND IIR
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	Class I
Device Group:	T020699 - MEDICAL USE FACE MASKS (EXCLUDING PERSONAL PROTECTIVE EQUIPMENT - PPE) - OTHER
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	Class I
Device Group:	V0501 - CLINICAL EMERGENCY KITS
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	Class I
Device Group:	V0599 - CLINICAL PROCEDURES KITS NOT INCLUDED IN OTHER CLASSES - OTHER
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	2025-04-23	SH21495MDR01	Initial issuance

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