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 IIa Devices)

No. G20 109397 0008 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. The Notified Body confirms that the class IIa devices in question conform to the technical documentation and meet the requirements of this Regulation which apply to them. 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.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality assurance system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. 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:G20 109397 0008 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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(Class IIa Devices)

No. G20 109397 0008 Rev. 00

Classification:	Class IIa
Device Group:	M020101 - COTTON GAUZES, CUT
Classification:	Class IIa
Device Group:	M020102 - COTTON GAUZES, FOLDED
Classification:	Class IIa
Device Group:	M020103 - LAPAROTOMY COTTON GAUZES
Classification:	Class IIa
Device Group:	M020105 - COTTON GAUZE PADS
Classification:	Class IIa
Device Group:	M020107 - COTTON GAUZES IN ROLLS
Classification:	Class IIa
Device Group:	M020199 - COTTON GAUZES - OTHER
Classification:	Class IIa
Device Group:	M020202 - NON-WOVEN LAPAROTOMY GAUZES
Classification:	Class IIa
Device Group:	V0599 - CLINICAL PROCEDURES KITS NOT INCLUDED IN OTHER CLASSES - OTHER

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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