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 038500 0029 Rev. 00

Manufacturer:

Shaoxing Gangfeng Hospital Products Co., Ltd.
Gaobu Industrial Zone, Gaobu
312035 Shaoxing
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer - CN-MF-000008133

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 038500 0029 Rev. 00

Report No.: SH2302602

Valid from: 2025-01-17
Valid until: 2030-01-16

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2025-01-17

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 038500 0029 Rev. 00

Classification:	Class IIa
Device Group:	M020102 - COTTON GAUZES, FOLDED M020103 - LAPAROTOMY COTTON GAUZES M020202 - NON-WOVEN LAPAROTOMY GAUZES
The validity of this certificate depends on conditions and/or is limited to the following:	na

Revision History:

Rev.	Dated	Report	Description
00	2025-01-17	SH2302602	Initial issuance

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