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

TÜV SÜD 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 038500 0030 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. 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 038500 0030 Rev. 00

Report No.: SH2302602

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

Issue date: 2025-01-17

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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Classification:	Class I
Device Group:	M020101 - COTTON GAUZES, CUT M020102 - COTTON GAUZES, FOLDED M020201 - NON-WOVEN FOLDED GAUZES M030101 - HYDROPHILIC GAUZE BANDAGES M030301 - ELASTIC FIXING BANDAGES V0501 - CLINICAL EMERGENCY KITS
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
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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