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 Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

No. G11 066729 0008 Rev. 00

Manufacturer:

Jiangsu Suyun Medical Materials Co., Ltd.
No.18 Jin Qiao Road
Dapu Industrial Park
222002 Lianyungang, Jiangsu Province
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer - CN-MF-000021132

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 IX Chapter I and III 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 management 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:G11 066729 0008 Rev. 00

Report No.: BJ23088502

Valid from: 2025-01-20
Valid until: 2028-03-08

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2025-01-20

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. G11 066729 0008 Rev. 00

Classification:	Class I
Device Group:	A02 - SYRINGES
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization

Classification:	Class I
Device Group:	A03 - TUBULAR DEVICES
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization

Classification:	Class I
Device Group:	A06 - DRAINAGE AND FLUIDS COLLECTION DEVICES
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization

Classification:	Class I
Device Group:	A10 - ABDOMINAL OSTOMY DEVICES
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization

Classification:	Class I
Device Group:	A11 - SAMPLE COLLECTION SWABS
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization

Classification:	Class I
Device Group:	G02 - GASTROINTESTINAL TUBES AND SETS
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization

Classification:	Class I
Device Group:	Q03 - ENT DEVICES
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization

Classification:	Class I
Device Group:	U08 - GYNAECOLOGICAL DEVICES
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization

Classification:	Class I
Device Group:	U10 - OBSTETRICS DEVICES
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization

Classification:	Class I
Device Group:	V02 - NEONATOLOGY AND PAEDIATRIC DEVICES
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization

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No. G11 066729 0008 Rev. 00

Classification:	Class I
Device Group:	V90 - VARIOUS DEVICES NOT INCLUDED IN OTHER CLASSES
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	2025-01-20	BJ23088502	Initial issuance

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