证 明 书

CERTIFICATE

中国国际贸易促进委员会

中国国际商会

China Council for the Promotion of International Trade

China Chamber of International Commerce

02132959

中国国际贸易促进委员会
中国国际商会

China Council for the Promotion of International Trade
China Chamber of International Commerce

证明书
CERTIFICATE

241100B0/H00361

号码 No.

兹证明：所附文件的影印件与原件相符。

THIS IS TO CERTIFY THAT: the annexed photostated copy of DOCUMENT is in conformity with the original.

China Council for the Promotion of International Trade

签证员：
Authorized Official: Lyu Cuilian

日期：2024年01月03日
(Date: Jan. 03, 2024)

核查网址 Website for verifying the certificate: http://www.ccpit.com/validate.html

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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 047985 0030 Rev. 00

Manufacturer:

Wenzhou K.L.F. Medical Plastics Co., Ltd
No.29 Gangqiang Road, Airport New Area, Yongxing Street
Longwan District
325000 Wenzhou, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer: CN-MF-000011214

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 and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G21 047985 0030 Rev. 00

Report No.: SH2118501MDR

Valid from: 2022-12-08
Valid until: 2027-12-07

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2022-12-08

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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 047985 0030 Rev. 00

Classification:	I
Device Group:	A030101 - INFUSION CONTROLLERS A060102 - SURGICAL DRAINAGE CONNECTION MEDICAL TUBES A070103 - INFUSION LINES ADAPTERS AND CONNECTORS A070501 - CAPS OR OBTURATORS, NON-PERFORABLE A070502 - CAPS OR OBTURATORS, PERFORABLE
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
The validity of this certificate depends on conditions and/or is limited to the following:	./.

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO

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附加证明书
APOSTILLE

(1961年10月5日海牙公约)
(Convention de La Haye du 5 octobre 1961)

1. 文书出具国：
Country:
中华人民共和国
People's Republic of China

本公文书 This public document

2. 签署人
has been signed by
吕岸连
Lyu Cullen

3. 签署人身份
acting in the capacity of
签证员
Authorized Official

4. 印鉴名称
bears the seal/stamp of
中国国际贸易促进委员会
China Council for the Promotion of International Trade

证明 Certified

5. 签发地
at
北京
Beijing

6. 签发日期
the
2024年01月11日
January 11,2024

7. 签发人
by
徐静媛，一等秘书/ Xu Jingyuan, First Secretary
外交部领事司
Department of Consular Affairs of the Ministry of Foreign Affairs

8. 附加证明书编号
No
U.字第240000012731号

9. 签发机关印鉴：
Seal/Stamp:

10. 签名：
Signature: