



证明书

CERTIFICATE



中国国际贸易促进委员会
中国国际贸易商会

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

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证明书

CERTIFICATE



24110080/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.



签证员:

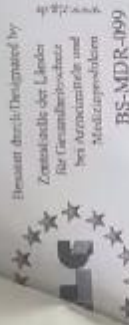
Authorized
Official:

Lyu Cuilian

日期: 2024年01月03日

(Date: Jan. 03, 2024)

验证网址: Website for verifying the certificate: <http://www.cccpintl.com/validate.html>



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,
- re-use 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

Issue date: 2022-12-08

Christoph Dicks

Head of Certification/Notified Body

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:
Device Group:

I
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
MDS 1005.1 - Ethylene Oxide sterilization

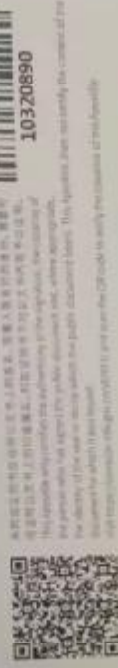
Device Properties:

The validity of this certificate
depends on conditions and/or
is limited to the following:

1.

ZERTIFIKAT ♦ CERTIFICATE ♦ 證書發給





10320890



附加证明书
APOSTILLE

(1961年《海牙公约》认证)
(Certified for Use Under the 1961 Convention)

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

吕理廷
Lyu Lintian

3. 签署人身份
acting in the
capacity of

签证员
Authorized Official

4. 印章名称
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 2024年01月11日
the 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.

证字第2400000012731号

9. 签发机关印章:
Seal/Stamp

10. 签名:
Signature

徐静媛

