



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

证明书

CERTIFICATE

号码 No.

241100B0/H00362

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)

证明书验证: 请通过验证该证明书的中心: <http://www.ccpit.com/validate.html>

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AKKS

Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Certificate

No. Q6 047985 0026 Rev. 03



Product Service

Holder of Certificate:

**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

Certification Mark:



Scope of Certificate:

Production and Distribution of
Sterile hypodermic syringes for single use,
Sterile infusion sets for single use,
Sterile transfusion sets for single use,
Sterile burette infusion sets for single use,
Sterile connecting tubes for single use,
Sterile injection caps for single use,
Sterile irrigation sets for single use,
Sterile luer lock caps for single use,
Sterile transfer sets for single use,
Sterile 3-way stopcocks for single use,
Sterile extension sets for single use,
Sterile infusion sets for single use with pressure infusion
apparatus, Sterile yankauer handles for single use
The provision of ETO sterilization services for medical devices

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). 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-Q6-047985-0026-Rev_03

Report No.:

SH2318501

Valid from:

2024-01-01

Valid until:

2026-12-31

Date,

2023-12-29

Christoph Dicks
Head of Certification/Notified Body



Certificate

No. Q6 047985 0026 Rev. 03

Applied Standard(s):

ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

Facility(ies):

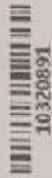
Wenzhou K.L.F. Medical Plastics Co., Ltd
No.29 Gangqiang Road, Airport New Area, Yongxing Street,
Longwan District, 325000 Wenzhou, Zhejiang, PEOPLE'S
REPUBLIC OF CHINA

See Scope of Certificate





本附加证明书是根据《中华人民共和国护照法》和《中华人民共和国出入境管理法》的有关规定，由中华人民共和国外交部授权的机构签发的。该附加证明书是证明公文书真实性的唯一有效文件。其效力与公文书本身具有同等效力。The public document signed in this public document was signed and issued according to the authority of the state of China, which has public document status. This document does not certify the content of the document or other facts.



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附加证明书
APOSTILLE

1961 (H. 106) 1961 (H. 106)
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

吕岩连
Lyu Yanlian

3. 签署人身份
acting in the
capacity of

签证官
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
the

2024年01月11日
January 11, 2024

7. 签发人
by

徐静媛 / Xu Jingyuan, First Secretary
Department of Consular Affairs of the Ministry of Foreign Affairs

8. 附加证明书编号
No

证字第240000012732号

9. 签发机关印章:
Seal/Stamp

10. 签名:
Signature

徐静媛

