



Product Service

质量管理体系认证证书

证书号 : Q5 135233 0001 Rev. 00

证书持有者 :

陕西杏旭康达医疗科技有限公司

中华人民共和国陕西省西安市临潼区新丰工业园108国道南侧
(双科金属结构公司院内一楼西侧) 710600

场所 :

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见证书认证范围

认证标志 :



认证范围 :

一次性使用无菌回缩式自毁注射器的设计开发、生产和分销。

认证标准 :

ISO 13485:2016

(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)

医疗器械 - 质量管理体系 - 用于法规的要求

认证机构TÜV SÜD产品服务有限公司证明上述公司已经建立并运行了满足所列标准要求的质量管理体系。

TÜV 南德集团检测、认证、审定与核查准则所有适用要求也须得到遵守。本证书信息可在<https://cnquery.tuv-sud.cn/cncaquery/cert.html>上查询。

报告号 :

BJ25144301

生效期 :

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有效期 :

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Christoph Dicks

Head of Certification/Notified Body

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TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TUV®



Product Service

Certificate

No. Q5 135233 0001 Rev. 00

Holder of Certificate: Shaanxi Xingxukangda Medical Technology Co., Ltd.
(West side of first floor inside Shuangke Metal Structure Company)
South side of National Highway 108
Xinfeng Industrial Park
Lintong District
710600 Xi'an City, Shaanxi Province
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Shaanxi Xingxukangda Medical Technology Co., Ltd.
(West side of first floor inside, Shuangke Metal Structure Company),
South side of National Highway 108, Xinfeng Industrial Park, Lintong District, 710600 Xi'an City, Shaanxi Province, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate

Certification Mark:



Scope of Certificate: Design and Development, Production and Distribution of Disposable sterile Retractable self-destructing Syringe.

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

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). 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:Q5 135233 0001 Rev. 00

Report No.: BJ25144301
Valid from: 2026-03-19
Valid until: 2029-03-18

Date, 2026-03-19

Christoph Dicks
Head of Certification/Notified Body