



Product Service

Certificate

No. Q6 094558 0006 Rev. 04

Holder of Certificate: **Jiangyin Fanmei Medical Device Co., Ltd.**
No.19 Yishan Rd, Lingang Street
214400 Jiangyin
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Production and Distribution of Auto-disable Syringe, Syringe for Insulin, Sterile Hypodermic Needle for Single Use, Sterile Syringe for Single Use (with Needle), Sterile Syringe for Single Use (without Needle), Sterile Irrigation syringe for single use**

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, 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:Q6_094558_0006_Rev_04

Report No.: SH25100501

Valid from: 2025-04-11
Valid until: 2028-04-10

Date, 2025-03-24

Christoph Dicks
Head of Certification/Notified Body



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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): **Jiangyin Fanmei Medical Device Co., Ltd.**
No.19 Yishan Rd, Lingang Street, 214400 Jiangyin, PEOPLE'S
REPUBLIC OF CHINA

See Scope of Certificate