



Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00



Product Service

Certificate

No. Q6 073425 0011 Rev. 03

Holder of Certificate: **Jiangsu Zhengkang Medical Apparatus Co., Ltd.**
Sanhekou, Zhenglu Town
213115 Changzhou City, Jiangsu
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: **Production and Distribution of
Infusion Sets for Single Use (with Needle),
Sterile Hypodermic Syringes for Single Use (with Needle),
Disposable Sterile Hypodermic Needles, Scalp vein Sets,
Sterile Insulin Syringes for Single Use,
Disposable Transfusion Set (with Needle)**

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 073425 0011 Rev. 03

Report No.: SH25061201

Valid from: 2025-09-06

Valid until: 2028-09-05

Date, 2025-07-25

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):

Jiangsu Zhengkang Medical Apparatus Co., Ltd.
Sanhekou, Zhenglu Town, 213115 Changzhou City, Jiangsu,
PEOPLE'S REPUBLIC OF CHINA

See scope of certificate