



Certificate

No. Q6 076830 0010 Rev. 03

Holder of Certificate: **Changzhou Chuangjia Medical Appliance Co., Ltd.**
Sanhekou Development Zone
Zhenglu Town
213115 Changzhou
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: Production and Distribution of Sterile Nelaton Catheter, Sterile Suction Catheter, Sterile Rectal Tube, Sterile Vaginal Speculum, Sterile Nutritive Cannula(Stomach Tube, Feeding Tube), Sterile Vaginal Irrigator, Sterile Nasal Oxygen Cannula, Sterile Medical Mouthpiece, Sterile Urine Drainage Bag, Sterile Medical Sampler, Sterile Infusion Sets for Single Use(with Needles), Sterile Intravenous Needles for Single Use, Sterile Syringes for Single Use(with or without Needles), Sterile Auto-disable Syringes for Single Use(with Needles), Sterile Needles for Single Use, Sterile Masks, Sterile Gynecological Examination Set, Sterile Disposable Irrigation Syringe(Feeding Syringe), Sterile Disposable Insulin Pen 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 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 076830 0010 Rev. 03

Report No.: SH2367402

Valid from: 2024-01-10

Valid until: 2027-01-09

Date, 2024-01-09

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): **Changzhou Chuangjia Medical Appliance Co., Ltd.**
Sanhekou Development Zone, Zhenglu Town, 213115 Changzhou,
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See Scope of Certificate

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