



Product Service

CERTIFICATE

No. Q6 17 11 76830 010

Holder of Certificate: **Changzhou Chuangjia Medical Appliance Co., Ltd.**

Sanhekou Development Zone, Zhenglu Town
213115 Changzhou
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

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, Infusion Sets for Single Use (with Needles), Intravenous Needles for Single Use, Sterile Syringes for Single Use (with Needles), Auto-disable Syringes for Single Use (with Needles), Sterile Needles for Single Use, Sterile Masks, Sterile Gynecological Examination Set, Disposable Irrigation Syringe (Feeding Syringe)

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
DIN EN ISO 13485:2016

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). See also notes overleaf.

Report No.: SH1767407

Valid from: 2018-03-12

Valid until: 2021-01-09

Date, 2018-03-12

S. Preiß

Stefan Preiß



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