ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q6 002901 0001 Rev. 01

Holder of Certificate: **JIANGSU JIANZHIYUAN MEDICAL INSTRUMENTS TECHNOLOGY CO., LTD.**
Floor 2, Building102
No.198, East Wuzhou Road
Development Zone
225000 Yangzhou
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

tuvsud.com/ps-cert

Scope of Certificate: **Production and Distribution of Chest Drainage Catheter for Single Use, Closed Wound Drainage Catheter for Single Use, Three Cavities Stomach Tube for Single Use, Nasal Biliary Drainage Catheter for Single Use, Irrigation and Suction Catheter in Endoscopic Surgery for Single Use, Nasal Feeding Tube for Single Use, Urethra Single J and Double J Catheter for Single Use, Medical Laparoscopic Instrument Trocar Suite for Single Use, Negative Pressure Drainager, Mouth Gag, Medical Enemator, Negative Pressure Drainage (Suction) Connection Tube, Medical Vaginal Irrigator**

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 002901 0001 Rev. 01

Report No.: SH22123201
Valid from: 2022-11-24
Valid until: 2025-10-20

Date, 2022-11-24

Christoph Dicks
Head of Certification/Notified Body

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

Digitally signed by Morozov Maria
Date: 2023.09.08 10:51:32 EEST
Reason: MoldSign Signature
Location: Moldova

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TÜV SÜD
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Applied Standard(s):

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

Facility(ies):

JIANGSU JIANZHIYUAN MEDICAL INSTRUMENTS TECHNOLOGY CO., LTD.
Floor 2, Building102, No.198, East Wuzhou Road, Development Zone, 225000 Yangzhou, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate

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