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

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

Product Service

Certificate

No. Q5 078455 0017 Rev. 01

Holder of Certificate: **Zhanjiang Star Enterprise Co., Ltd.**
No. 1, West Jinhua Road
Mazhang District
524094 Zhanjiang
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate:

**Design and Development,
Production and Distribution of
Foley Catheters, Nelaton Catheters,
Endotracheal Tubes, Drainage Bags,
Urethral Catheterization Sets,
Male External Catheters,
Latex Stomach Tubes,
T-Tube and Basic Dressing Sets,
Suction Catheters for Single Use
in the Respiratory Tract,
Tracheostomy Tubes for Single Use,
Urethral Catheters (Silicone),
Urethral Catheters (PVC),
Stomach Tubes (PVC),
Reinforced Endotracheal Tubes,
Anesthesia Kits, Mouth Gags (Mouth Opener),
Endotracheal Tube Holders,
Male External Catheters (Silicone)
/Silicone Condom Catheters,
Nebulizers and Laryngeal Masks**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Digitally signed by Potînga Stela
Date: 2021.08.19 14:43:21 EEST
Reason: MoldSign Signature
Location: Moldova

Report No.: SH1909019
Valid from: 2019-09-03
Valid until: 2022-08-31

Date, 2019-09-03

Stefan Preiß
Head of Certification/Notified Body

A4 / 07.17

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

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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):

Zhanjiang Star Enterprise Co., Ltd.
No. 49 Jinchuan Road, 524094 Zhanjiang,
PEOPLE'S REPUBLIC OF CHINA

Zhanjiang Star Enterprise Co., Ltd.
No. 1, West Jinhua Road, Mazhang District, 524094
Zhanjiang, PEOPLE'S REPUBLIC OF CHINA

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