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

Product Service

Certificate

No. Q5 073403 0026 Rev. 01

Holder of Certificate: **Henan Tuoren Medical Device Co., Ltd.**
Weiyuan Industrial Zone
Menggang, Changyuan County
453400 Henan
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

tuv-sud.com/ps-cert

Scope of Certificate: **Design, Development, Production and Distribution of Infusion Pump, I.V. Cannula, Endotracheal Tube, Reinforced Endotracheal Tube, Tracheotomy Tube, Endobronchial Tube, Laryngeal Mask Airway, Connecting Tube, Foley Catheter Kit, Suction Catheter, Breathing Circuit, Oxygen Mask, Anesthesia Mask, Guedel Airway, Endotracheal Intubation Kit, Disposable central venous catheter kit, Anesthesia Kit and Anesthesia Needle, Manual resuscitator, Disposable Infusion Connection Tube, Suction Drainage Bag, Disposable Suction Drainage Bag, Nasal Oxygen Tube, Suction Handle, Heat and moisture exchanger, Disposable pressure transducer, Electronic infusion pump, LOR Indicator Syringe.**

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.

Report No.: BJ1973704

Valid from: 2019-11-29
Valid until: 2022-11-28

Date, 2019-11-21

Christoph Dicks
Head of Certification/Notified Body

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

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

Henan Tuoren Medical Device Co., Ltd.
Weiyuan Industrial Zone, Menggang, Changyuan County, 453400 Henan, PEOPLE'S REPUBLIC OF CHINA

Henan Tuoren Medical Device Co., Ltd.
Middle of Weft 7 Road, Nanpu District, 453400 Changyuan County, Henan, PEOPLE'S REPUBLIC OF CHINA

Henan Tuoren Medical Device Co., Ltd.
Mancun Industrial Zone, Changyuan County, 453400 Henan, PEOPLE'S REPUBLIC OF CHINA

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