



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.**

Welyuan Industrial Zone
Menggang, Changyuan County
453400 Henan
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



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

Certificate

No. Q5 073403 0026 Rev. 01

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



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)

(Devices in Class IIa, IIb or III)

No. G1 073403 0025 Rev. 03

Manufacturer:

Henan Tuoren Medical Device Co., Ltd.

Weiyuan Industrial Zone

Menggang, Changyuan County

453400 Henan

PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): Endotracheal Tube, Tracheotomy Tube, Endobronchial Tube, Infusion Pump, I.V. Cannula, Reinforced Endotracheal Tube, Laryngeal Mask Airway, Foley Catheter Kit, Suction Catheter, Breathing Circuit, Oxygen Mask, Anesthesia Mask, Guedel Airway, Endotracheal Intubation Kit, Nasal Oxygen Tube, Heat and Moisture Exchanger, Suction Handle, Manual Resuscitator, LOR Indicator Syringe, Disposable Pressure Transducer.

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.:

BJ1973704

Valid from:

2019-11-21

Valid until:

2024-05-26

Date,

2019-11-21

Christoph Dicks

Head of Certification/Notified Body



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