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

Digitally signed by Iarovoi Petru
Date: 2020.11.18 16:59:57 EET
Reason: MoldSign Signature
Location: Moldova

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

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D-ZM-11321-01-00

Product Service

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

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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

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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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

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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Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 073403 0018 Rev. 02

Manufacturer

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

Product Category(ies):

Connecting Tube,
Disposable Infusion Connection Tube,
Disposable Suction Drainage Bag.

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: BJ1973707

Valid from: 2019-10-23
Valid until: 2024-05-26

Date, 2019-10-23

Stefan Preiß
Head of Certification/Notified Body

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Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 073403 0018 Rev. 02

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.
Mancun Industrial Zone, Changyuan County, 453400 Henan,
PEOPLE'S REPUBLIC OF CHINA

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