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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

Digitally signed by Dobrea Alexandru
Date: 2020.02.05 10:49:13 EET
Reason: MoldSign Signature
Location: Moldova

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

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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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