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

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

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 086097 0013 Rev. 00

Manufacturer:

Hangzhou Rollmed Co., Ltd.
Room 913, Yuanmao Mansion
No.5 Wen Er West Road
Xihu District
310012 Hangzhou City
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

MedNet GmbH
Borkstrasse 10, 48163 Muenster, GERMANY

Product Category(ies):

Latex Foley Catheter, Silicone Foley Catheter, Mucus Extractor, Aerosol Mask, Endotracheal Tube, Suction Connecting Tube(with and without Yankauer Handle), Reinforced Endotracheal Tube, Breathing circuit, Laryngeal Mask Airway, Sterile Blood Lancets, Disposable Surgical Blades(with and without handle), Sterile Hypodermic Needles for Single Use, Sterile Syringes for Single Use, Transfusion Sets, Sterile Dental Needles for Single Use, Tracheostomy Tube, Scalp Vein Set for Single Use, Stomach Tube, I.V. Cannula for Single Use, Suction Tube, Sterile Infusion Sets for Single Use, Nasal Cannula, I.V. Flow Regulator for Single Use, Oxygen Mask, Sterile Heparin Caps for Single Use, Feeding Tube, Three Way Stopcock and Extension Tube, Digital Thermometers, Intubating Stylets

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

Report No.: SH1878606

Valid from: 2019-05-28
Valid until: 2024-01-27

Date, 2019-05-28

Stefan Preiß

Head of Certification/Notified Body

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

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

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Facility(ies):

Hangzhou Rollmed Co., Ltd.
Room 913, Yuanmao Mansion, No.5 Wen Er West Road, Xihu District, 310012 Hangzhou City, PEOPLE'S REPUBLIC OF CHINA

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