



Notified and designated by  
 Germanische der Länder  
 für Gesundheitsschutz  
 bei Arzneimitteln und  
 Medizinprodukten  
 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. 01**

**Manufacturer:**

**Hangzhou Rollmed Co., Ltd.**

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

**Facility(ies):**

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

**Product  
 Category(ies):**

Latex Foley Catheter, Silicons 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.

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**Valid from:** 2020-02-26

**Valid until:** 2024-01-27

**Date:** 2020-02-26

Christoph Dicka  
 Head of Certification/Notified Body

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

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