



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
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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 I in sterile conditions, sterilised systems or procedure packs)

No. G2S 086097 0014 Rev. 01

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

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

Product Category(ies):

**First Aid kits, Cotton Ball, Gauze Swab,
Cotton Tipped Applicators, Female Swab,
Wooden Tongue Depressors, Male Swab,
Disposable Dressing Kits, Plastic Forceps,
Disposable Medical Brushes, Oropharyngeal Airway,
Disposable Gynecological Sets, ID Bracelet,
Infant Urine Collection Bag, Urine Bag,
Vaginal Speculum, Sterile Surgical Gowns,
Sterile Non-woven Overalls, Male External Catheter,
Non-woven Protective Disposable(Sleeves,
Shoe-covers, Caps), Sterile Non-woven Isolation Gowns,
Male External Catheter(Silicone)/Silicone Condom Catheter,
Saliva Ejector, Negative Pressure Suction Liner,
Sterile Pad(Alcohol Pad), Oropharyngeal Airways,
Nasopharyngeal Airways, Disposable Irrigation Connecting
Tube**

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.: SH20786CN01

Valid from: 2020-02-26

Valid until: 2024-01-27

Date, 2020-02-26

Christoph Dicks
Head of Certification/Notified Body

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