



Product Service

Certificate

No. Q6 086097 0012 Rev. 01

Holder of Certificate: **Hangzhou Rollmed Co., Ltd.**

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

Certification Mark:



Scope of Certificate: **Production and Distribution of Medical Device(For detailed information see attachment)**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH1978607

Valid from: 2020-02-13

Valid until: 2023-01-27

Date, 2020-02-13

Christoph Dicks
Head of Certification/Notified Body

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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): 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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For the product(s)/product category (ies):
Production and Distribution of Medical Device:

Latex Foley Catheter, Silicone Foley Catheter, Mucus Extractor, Aerosol mask, Suction Connecting Tube (with and without Yankauer Handle), Breathing circuit, Tracheostomy tube, Laryngeal Mask Airway, Reinforced Endotracheal Tube, Endotracheal Tube, Digital Thermometers, Sterile Blood Lancets, Disposable Surgical Blades (with and without handle), Sterile Syringes for Single Use, Transfusion Sets, Sterile Dental Needles for Single Use, Scalp Vein Set for Single Use, Sterile Infusion Sets for Single Use, I.V. Flow Regulator for Single use, Feeding tube, Stomach Tube, Sterile Heparin Caps for Single Use, Oxygen Mask, Nasal Cannula, Three Way Stopcock and Extension Tube, Suction Tube, Oropharyngeal Airway, ID Bracelet, Infant Urine Collection Bag, Urine Bag, Vaginal Speculum, Male External Catheter, First Aid Kits, Male External Catheter (Silicone)/Silicone Condom Catheter, Sterile Hypodermic Needles for Single Use, Cotton Ball, Gauze Swab, Cotton Tipped Applicators, Plastic Forceps, Wooden Tongue Depressors, Male Swab, Female Swab, Disposable Dressing Kits, Disposable Medical Brushes, Disposable Gynecological Sets, Sterile Surgical Gowns, Sterile Non-woven Overalls, Sterile Non-woven Isolation Gowns, Non-woven Protective Disposables (Sleeves, Shoe-covers, Caps), Aneroid Sphygmomanometers, Saliva Ejector, Rectal tube, Negative Pressure Suction Liner, Yankauer Suction Tip, Sterile Burette Set for Single Use, Insulin Needles for Single Use, Sterile Blood Collecting Needles for Single Use, Sterile Self-Destruction Safety Syringes for Single Use, Safety Insulin Needle for Single Use, Sterile Hypodermic Syringes for Single Use (with needles), Infusion Sets For Single Use (With Needles), Intravenous Needles for Single Use, Auto-Disable Syringes for Single Use, Sterile Insulin Syringes for Single Use, Silicone Suction Reservoir and Flat Drain (Round Drain), Disposable Colostomy Collection Bag, Disposable Amniotic Membrane Perforators, Disposable Gynecologic Samples, Disposable Endometrial Suction Cannulas, Disposable Oral Cavity Kits and Implements, Disposable Nasal Speculums, Disposable Ear Checker, Silicone/SEBS/PVC Manual Resuscitators (Mask, Positive And Expiratory Pressure Valve, Oxygen Tube, Reservoir), Resuscitation Mask, Continuous Positive Airway Pressure Mask/Non-Invasive Ventilation mask, Air Splint, Extrication Collar, Irrigate Kits, Humidifier Jar(Bubble Humidifier Jar), Infusion Pump, Anesthesia Mask, Heat and Moisture Exchanger, Medical Nebulizers, CPR Masks, Wheel Chairs, Hospital Beds, Walking Aids, Single-Use Containers For Human Venous Blood Specimen Collection, Venous Blood Collection Needles, Single-Use Containers for Human, Capillary Blood Specimen Collection, Disposable ECG Electrode, Physiotherapy Adhesive Electrodes and Disposable Neutral Electrode, Needle Free Connectors, Combi Stoppers, Screw Caps, Sterile Pad(Alcohol Pads), Gauze Bandage, Non-woven Swab, Gauze Ball, Rescue Blanket, Lap Sponges, Paper-Poly Pouch, Face Masks, Stethoscope, Disposable Underpads, Medical Paper Rolls, Medical Non-woven Rolls, Medical Bandages, Medical Papers, Wound Dressings, Wound Plasters, Medical Adhesive Tapes, Intubating Stylets, Endotracheal Tube Introducers(bougie), Disposable Negative Pressure Drainage Bottle, Oropharyngeal Airways, Nasopharyngeal Airways, Disposable Irrigation Connecting Tube, I.V. Cannula for Single Use.