



Product Service

CERTIFICATE

No. Q2N 16 10 86097 005

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

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


Certification Mark:

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

Applied Standard(s):

EN ISO 13485:2012 + AC:2012
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2003 + Cor. 1:2009)
DIN EN ISO 13485:2012

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.: SH1678604

Valid from: 2017-01-28
Valid until: 2020-01-27

Date, 2016-12-15

S. Preiß
Stefan Preiß



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Attachment for Certificate No Q2N.16.10.86097.005

Supplement 001 dated 2016-12-15



Product Service

For the product(s)/product category (ies):

Production and Distribution of
 Latex Foley Catheter, Silicone Foley Catheter,
 Mucus Extractor, Nebulizer Mask, Ultrasonic Nebulizer,
 Suction Connecting Tube (with and without Yankauer Handle),
 Compressor Nebulizer, Breathing circuit, Tracheostomy tube,
 Laryngeal Mask Airway, Reinforced Endotracheal Tube,
 Endotracheal Tube, Infra-red Ear Thermometers,
 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, Umbilical Cord Clamp,
 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, Nelaton Tube,
 I.V. Cannula for Single Use, 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

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Product Service

Saliva Ejector, Rectal tube, Negative Pressure Suction Liner, Yankauer Suction Tip, Sterile Medical Stainless Steel Tube for Single Use, 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), Connection Cannula, Preformed Nasal and Oral Tracheal Tube, Mucus Extractor, Abdominal/Thoracic drain tube, 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 End 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, I.V.Cannula, 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, Gauze Swab, Non-woven swab, Gauze Ball, Non-woven Ball, Cotton Ball, Rescue Blanket, Lap Sponges, Paper-Poly Pouch, Face Masks, Surgical

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Product Service

Sheets, Surgical Drapes, Coveralls, Surgical Kits, Arm Sleeves, Snood
Covers, Beard Covers, Stethoscope, Disposable Underpads, Medical paper
rolls, Medical Non-Woven rolls, Medical Bandages, Medical papers,
Hydrocolloid Dressings, Foam Dressings, Surgical Films, Wound Dressings,
Transparent Dressings, Wound Plasters, Tubing Securement Devices, Medical
Adhesive Tapes, Cooling Pads, Snore Stoppa, Sample Container.

Munich, MHS-CRT, 2016-12-15

Stefan Preiß
Certification Medical Technology

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