



Product Service

Certificate

No. Q6 086097 0012 Rev. 04

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 Devices**
(for detail 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). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q6 086097 0012 Rev. 04](http://www.tuvsud.com/ps-cert?q=cert:Q6_086097_0012_Rev._04)

Report No.: SH2478601
Valid from: 2025-05-14
Valid until: 2026-12-27

Date, 2025-05-14

Christoph Dicks
Head of Certification/Notified Body



Product Service

Certificate

No. Q6 086097 0012 Rev. 04

Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

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

See Scope of Certificate

Zhongshan Gotestmed Co., Ltd.
Area B, Floor 3, Building 2, No.11 Qianyang 1st Road, Yongmo
Village, 528463 Sanxiang Town, Zhongshan City, PEOPLE'S
REPUBLIC OF CHINA

See Scope of Certificate

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

Production and distribution of sterile latex foley catheter, sterile silicone foley catheter, sterile mucus extractor, sterile and non-sterile aerosol mask, sterile suction connecting tube (with and without yankauer handle), sterile breathing circuit, sterile tracheostomy tube, sterile laryngeal mask airway, sterile reinforced endotracheal tube, sterile endotracheal tube, non-sterile digital thermometers, sterile blood lancets, sterile disposable surgical blades (with and without handle), sterile syringes for single use, sterile transfusion sets, sterile dental needles for single use, sterile scalp vein set for single use, sterile infusion sets for single use, sterile I.V. flow regulator for single use, sterile feeding tube, sterile stomach tube, sterile heparin caps for single use, sterile and non-sterile oxygen mask, sterile and non-sterile nasal cannula, sterile three way stopcock and extension tube, sterile suction tube, sterile oropharyngeal airway, sterile infant urine collection bag, sterile urine bag, sterile vaginal speculum, sterile male external catheter, sterile and non-sterile first aid kits, sterile male external catheter (silicone)/silicone condom catheter, sterile hypodermic needles for single use, sterile and non-sterile cotton ball, sterile and non-sterile gauze swab, sterile and non-sterile cotton tipped applicators, sterile and non-sterile plastic forceps, sterile and non-sterile wooden tongue depressors, sterile male swab, sterile female swab, sterile disposable dressing kits, sterile disposable medical brushes, sterile disposable gynecological sets, sterile surgical gowns, sterile and non-sterile non-woven overalls, sterile and non-sterile non-woven isolation gowns, sterile and non-sterile non-woven protective disposables (sleeves, shoe-covers, caps), sterile and non-sterile saliva ejector, sterile rectal tube, non-sterile and sterile negative pressure suction liner, sterile yankauer suction tip, sterile burette set for single use, sterile insulin needles for single use, sterile blood collecting needles for single use, sterile self- destruction safety syringes for single use, sterile safety insulin needle for single use, sterile hypodermic syringes for single use (with needles), sterile infusion sets for single use (with needles), sterile intravenous needles for single use, sterile autodisable syringes for single use, sterile insulin syringes for single use, sterile silicone suction reservoir and flat drain (round drain), sterile and non-sterile ostomy bag, sterile disposable amniotic membrane perforators, sterile disposable gynecologic samplers, sterile disposable endometrial suction cannulas, sterile disposable oral cavity kits, non-sterile disposable nasal speculums, non-sterile disposable ear checker, sterile silicone/sebs/pvc manual resuscitators (mask, positive and expiratory pressure valve, oxygen tube, reservoir), sterile resuscitation mask, sterile continuous positive airway



Product Service

Certificate

No. Q6 086097 0012 Rev. 04

pressure mask/non-invasive ventilation mask, sterile and non-sterile air splint, non-sterile extrication collar, sterile irrigate kits, sterile and non-sterile humidifier jar (bubble humidifier jar), sterile infusion pump, sterile and non-sterile anesthesia mask, sterile heat and moisture exchanger, sterile and non-sterile medical nebulizers, non-sterile cpr masks, non-active wheel chairs, non-sterile hospital beds, non-sterile walking aids, sterile venous blood collection needles, sterile and non-sterile single-use containers for human, sterile and non-sterile capillary blood specimen collection, non-sterile disposable ecg electrode, non-sterile physiotherapy adhesive electrodes and disposable neutral electrode, sterile needle free connectors, sterile combi stoppers, sterile screw caps, sterile pad (alcohol pads) used for disinfection of the medical device, sterile and non-sterile gauze bandage, sterile non-woven swab, sterile and non-sterile gauze ball, sterile first aid blanket, sterile Lap sponge, sterile and non-sterile face masks, non-sterile stethoscope, non-sterile disposable underpads, sterile and non-sterile medical bandages, sterile wound dressings, sterile wound plasters, sterile and non-sterile medical adhesive tapes, sterile intubating stylets, sterile endotracheal tube introducers (bougie), sterile disposable suction canister, sterile oropharyngeal airways, sterile nasopharyngeal airways, sterile disposable irrigation connecting tube, sterile I.V. cannula for single use, sterile and non-sterile examination gloves, in vitro diagnostic consumables (sampling collection and sample transport), sterile nelaton tube, sterile all silicone stomach tube, sterile closed suction catheters, sterile umbilical cord clamp, sterile irrigation set, non-sterile spacer for aerosol, peak flow meter, electronic peak flow meter, sterile adhesive eye pad , sterile and non-sterile oxygen tube, sterile and non-sterile venturi mask, sterile and non-sterile non-rebreathe mask, sterile and non-sterile nebulizing set with mouth piece, sterile and non-sterile tracheostomy mask, sterile pen needle, sterile butterfly needle, sterile tuberculin syringes, non-sterile CPAP mask.



Product Service

Certificate

No. Q6 086097 0012 Rev. 04

Hangzhou Rollmed Co., Ltd.

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

Production and distribution of sterile latex foley catheter, sterile silicone foley catheter, sterile mucus extractor, sterile and non-sterile aerosol mask, sterile suction connecting tube (with and without yankauer handle), sterile breathing circuit, sterile tracheostomy tube, sterile laryngeal mask airway, sterile reinforced endotracheal tube, sterile endotracheal tube, non-sterile digital thermometers, sterile blood lancets, sterile disposable surgical blades (with and without handle), sterile syringes for single use, sterile transfusion sets, sterile dental needles for single use, sterile scalp vein set for single use, sterile infusion sets for single use, sterile I.V. flow regulator for single use, sterile feeding tube, sterile stomach tube, sterile heparin caps for single use, sterile and non-sterile oxygen mask, sterile and non-sterile nasal cannula, sterile three way stopcock and extension tube, sterile suction tube, sterile oropharyngeal airway, sterile infant urine collection bag, sterile urine bag, sterile vaginal speculum, sterile male external catheter, sterile and non-sterile first aid kits, sterile male external catheter (silicone)/silicone condom catheter, sterile hypodermic needles for single use, sterile and non-sterile cotton ball, sterile and non-sterile gauze swab, sterile and non-sterile cotton tipped applicators, sterile and non-sterile plastic forceps, sterile and non-sterile wooden tongue depressors, sterile male swab, sterile female swab, sterile disposable dressing kits, sterile disposable medical brushes, sterile disposable gynecological sets, sterile surgical gowns, sterile and non-sterile non-woven overalls, sterile and non-sterile non-woven isolation gowns, sterile and non-sterile non-woven protective disposables (sleeves, shoe-covers, caps), sterile and non-sterile saliva ejector, sterile rectal tube, non-sterile and sterile negative pressure suction liner, sterile yankauer suction tip, sterile burette set for single use, sterile insulin needles for single use, sterile blood collecting needles for single use, sterile self- destruction safety syringes for single use, sterile safety insulin needle for single use, sterile hypodermic syringes for single use (with needles), sterile infusion sets for single use (with needles), sterile intravenous needles for single use, sterile autodisable syringes for single use, sterile insulin syringes for single use, sterile silicone suction reservoir and flat drain (round drain), sterile and non-sterile ostomy bag, sterile disposable amniotic membrane perforators, sterile disposable gynecologic samplers, sterile disposable endometrial suction cannulas, sterile disposable oral cavity kits, non-sterile disposable nasal speculums, non-sterile disposable ear checker, sterile silicone/sebs/pvc manual resuscitators (mask, positive and expiratory pressure valve, oxygen tube, reservoir), sterile resuscitation mask, sterile continuous positive airway pressure mask/non-invasive ventilation mask, sterile and non-sterile air splint, non-sterile extrication collar, sterile irrigate kits, sterile and non-sterile humidifier jar (bubble humidifier jar), sterile infusion pump, sterile and non-sterile anesthesia mask, sterile heat and moisture exchanger, sterile and non-sterile medical nebulizers, non-sterile cpr masks, non-active wheel chairs, non-sterile hospital beds, non-sterile walking aids, sterile venous blood collection needles, sterile and non-sterile single-use containers for human, sterile and non-sterile capillary blood specimen collection, non-sterile disposable ecg electrode, non-sterile physiotherapy adhesive electrodes and disposable neutral electrode, sterile needle free connectors, sterile combi stoppers, sterile screw caps, sterile pad (alcohol pads) used for disinfection of the medical device, sterile and non-sterile gauze bandage, sterile non-woven swab, sterile and non-sterile gauze ball, sterile first aid blanket, sterile Lap sponge, sterile and non-sterile face masks, non-sterile stethoscope, non-sterile disposable underpads, sterile and non-sterile medical bandages, sterile wound dressings, sterile wound plasters, sterile and non-sterile medical adhesive tapes, sterile intubating stylets, sterile endotracheal tube introducers (bougie), sterile disposable suction canister, sterile oropharyngeal airways, sterile nasopharyngeal airways, sterile disposable irrigation connecting tube, sterile I.V. cannula for single use, sterile and non-sterile examination gloves, in vitro diagnostic consumables (sampling collection and sample transport), sterile nelaton tube, sterile all silicone stomach tube, sterile closed suction catheters, sterile umbilical cord clamp, sterile irrigation set, non-sterile spacer for aerosol, peak flow meter, electronic peak flow meter, sterile adhesive eye pad, sterile and non-sterile oxygen tube, sterile and non-sterile venturi mask, sterile and non-sterile non-rebreathe mask, sterile and non-sterile



Product Service

Certificate

No. Q6 086097 0012 Rev. 04

nebulizing set with mouth piece, sterile and non-sterile tracheostomy mask, sterile pen needle, sterile butterfly needle, sterile tuberculin syringes, non-sterile CPAP mask.



Product Service

Certificate

No. Q6 086097 0012 Rev. 04

Zhongshan Gotestmed Co., Ltd.

Area B, Floor 3, Building 2, No.11 Qianyang 1st Road, Yongmo Village, 528463 Sanxiang Town, Zhongshan City, PEOPLE'S REPUBLIC OF CHINA

Production and distribution of sterile and non-sterile first aid kits, sterile and non-sterile cotton ball, sterile and non-sterile gauze swab, sterile and non-sterile cotton tipped applicators, sterile female swab, sterile and non-sterile wooden tongue depressors, sterile male swab, sterile disposable dressing kits, sterile and non-sterile plastic forceps, sterile disposable medical brushes, sterile oropharyngeal airway, sterile disposable gynecological sets, sterile infant urine collection bag, sterile urine bag, sterile vaginal speculum, sterile surgical gowns, sterile and non-sterile non-woven overalls, sterile male external catheter, sterile and non-sterile non-woven protective disposables (sleeves, shoe-covers, caps), sterile and non-sterile non-woven isolation gowns, sterile male external catheter (silicone)/silicone condom catheter, sterile and non-sterile saliva ejector, non-sterile and sterile negative pressure suction liner, sterile pad (alcohol pads) used for disinfection of the medical device, sterile oropharyngeal airways, sterile nasopharyngeal airways, sterile disposable irrigation connecting tube, sterile nelaton tube, sterile all silicone stomach tube, sterile latex foley catheter, sterile silicone foley catheter, sterile mucus extractor, sterile and non-sterile aerosol mask, sterile suction connecting tube (with and without yankauer handle), sterile breathing circuit, sterile tracheostomy tube, sterile laryngeal mask airway, sterile reinforced endotracheal tube, sterile endotracheal tube, sterile blood lancets, sterile disposable surgical blades (with and without handle), sterile syringes for single use, sterile transfusion sets, sterile dental needles for single use, sterile scalp vein set for single use, sterile infusion sets for single use, sterile I.V. flow regulator for single use, sterile feeding tube, sterile stomach tube, sterile heparin caps for single use, sterile and non-sterile oxygen mask, sterile and non-sterile nasal cannula, sterile three way stopcock and extension tube, sterile suction tube, sterile hypodermic needles for single use, sterile rectal tube, sterile yankauer suction tip, sterile burette set for single use, sterile insulin needles for single use, sterile blood collecting needles for single use, sterile self- destruction safety syringes for single use, sterile safety insulin needle for single use, sterile hypodermic syringes for single use (with needles), sterile infusion sets for single use (with needles), sterile intravenous needles for single use, sterile autodisable syringes for single use, sterile insulin syringes for single use, sterile silicone suction reservoir and flat drain (round drain), sterile and non-sterile ostomy bag, sterile disposable amniotic membrane perforators, sterile disposable gynecologic samplers, sterile disposable endometrial suction cannulas, sterile disposable oral cavity kits, non-sterile disposable nasal speculums, non-sterile disposable ear checker, sterile silicone/sebs/pvc manual resuscitators (mask, positive and expiratory pressure valve, oxygen tube, reservoir), sterile resuscitation mask, sterile continuous positive airway pressure mask/non-invasive ventilation mask, sterile and non-sterile air splint, non-sterile extrication collar, sterile irrigate kits, sterile and non-sterile humidifier jar (bubble humidifier jar), sterile and non-sterile anesthesia mask, sterile heat and moisture exchanger, sterile and non-sterile medical nebulizers, non-sterile cpr masks, sterile venous blood collection needles, sterile needle free connectors, sterile combi stoppers, sterile screw caps, sterile and non-sterile gauze bandage, sterile non-woven swab, sterile and non-sterile gauze ball, sterile first aid blanket, sterile Lap sponge, sterile and non-sterile face masks, non-sterile disposable underpads, sterile and non-sterile medical bandages, sterile wound dressings, sterile wound plasters, sterile and non-sterile medical adhesive tapes, sterile intubating stylets, sterile endotracheal tube introducers (bougie), sterile disposable suction canister, sterile I.V. cannula for single use, sterile and non-sterile examination gloves, sterile closed suction catheters, sterile umbilical cord clamp, sterile irrigation set, non-sterile spacer for aerosol, sterile adhesive eye pad, sterile and non-sterile oxygen tube, sterile and non-sterile venturi mask, sterile and non-sterile non-rebreathe mask, sterile and non-sterile nebulizing set with mouth piece, sterile and non-sterile tracheostomy mask, sterile pen needle, sterile butterfly needle, sterile tuberculin syringes, non-sterile CPAP mask.