



Certificate

No. Q6 079078 0013 Rev. 05

Holder of Certificate:

Hangzhou Formed

Medical Devices Co., Ltd.

Building 3, No. 292 Gonghe North Road, Xindeng Town

Fuyang District

311404 Hangzhou

PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate:

Production and Distribution of

Medical Devices (for detail information see Page 2)

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 079078 0013 Rev. 05

Report No.:

SH26104101

Valid from:

2026-07-02

Valid until:

2028-08-04

Date,

2026-07-02

Christoph Dicks

Head of Certification/Notified Body



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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 Formed Medical Devices Co., Ltd.
Building 3, No. 292 Gonghe North Road, Xindeng Town, Fuyang
District, 311404 Hangzhou, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate

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

Production and Distribution of Sterile Laryngeal Mask, Sterile Tracheal Tube Introducer, Sterile Catheter Mount, Sterile Endotracheal Tube, Sterile Naso-Pharyngeal Airway, Oral-Pharyngeal Airway, Sterile Feeding Tube, Non-sterile Oxygen Mask with Reservoir Bag, Non-sterile Nasal Cannula, Non-sterile Oxygen Mask, Non-sterile Nebulizer kit, Non-sterile Silicone Mask, Sterile Nasogastric Tube, Sterile Suction Tubing with Yankauer Handle, Sterile Intubating Stylet, Non-sterile Venturi Mask, Non-sterile Anaesthetic Mask, Sterile Gastric Calibration Tube, Sterile Nelaton Catheter, Sterile Hydrophilic Urinary Catheter, Sterile Catheterization Kit, Sterile Suction Catheter, Sterile Urine Bag, Sterile Foley Catheter, Sterile Breathing System Filter, Sterile Disposable Breathing Circuit, Sterile Suction Reservoir, Sterile Drainage Tube, Sterile Wound Drainage System, Sterile Stomach Tube, Sterile Heat and Moisture Exchanger, Sterile Drainage Bag, Sterile Hydrophilic Urinary Catheter Kit, Sterile Insufflation Tube, Sterile Gastrostomy Tube, Sterile Double Lumen Endobronchial Tube, Sterile Tracheostomy Tube, Sterile Closed Suction Catheter, Non-sterile Manual Resuscitator, Non-sterile Continuous Positive Airway Pressure Mask, Sterile Catheter Fixation Device, Sterile Reservoir Bag, Non-sterile CO₂/O₂ Nasal Cannula, Non-sterile Gas Sampling Line, Non-sterile Gas Tube, Non-sterile CO₂ Sampling Cannula and Tube, Sterile Oxygen Catheter, Sterile Smoke Evacuation Filter, Sterile Male External Catheter.