



Product Service

Certificate

Q6 093011 0010 Rev. 01**Holder of Certificate: Ningbo Foyomed Medical Instruments Co., Ltd.**

Room 805-806
No. 299 of Jiangnan Yipin Garden
Hi-Tech Zone
315040 Ningbo
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:**Scope of Certificate: Production and Distribution of Medical Devices**
(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). 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 093011 0010 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:Q6_093011_0010_Rev.01)

Report No.: SH24099401**Valid from:** 2025-01-27**Valid until:** 2028-01-26**Date,** 2025-01-09

Christoph Dicks

Head of Certification/Notified Body



Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00



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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):

Ningbo Foyomed Medical Instruments Co., Ltd.

Room 805-806, No. 299 of Jiangnan Yipin Garden, Hi-Tech Zone,
315040 Ningbo, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate

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

Production and Distribution of Sterile Medical Device:

Endotracheal Tube, Reinforced Endotracheal Tube, Latex Foley Catheter, Urethral Catheters(PVC), Nelaton Catheters(latex), Sterile Feeding Tubes, Disposable Rectal Tubes, Sterile Suction Catheters, Disposable Stomach Tubes, Disposable Mucus Extractors, Disposable Umbilical Cord Clamps, Laryngeal Masks Airways, Tracheostomy Masks, Oxygen Masks, Nebulizers Masks, Venturi Masks, Oxygen Masks with Reservoir Bag, Connecting Tubes with Yankauer Handle, Oxygen Connection Tubings, Nasal Oxygen Cannula, Safety Syringes, Auto Disable Syringes, Disposable Hypodermic Needles, Blood Lancet, Sterile Surgical Blade, Disposable Scalpel with Plastic Handle, Safety Disable Syringes, Sterile Infusion Sets for Single Use, Sterile Transfusion Sets for Single Use, Sterile Scalp Vein Type Needles for Single Use, Disposable Irrigating and Feeding Syringes, Disposable Syringe, Three-way Stopcocks(with Extension Tube), Heparin Caps, Insulin Needles for Single Use, Gauze Sponges, Gauze Balls, Non-woven Balls(with X-ray), Lap Sponges, Cotton Tipped Applicators, Absorbent Cotton Balls, Medical Dressing Kits, Dressing Eye Pads, Absorbent Cotton Wools, Surgical Brushes, Oropharyngeal Airway, Wound Drainage Reservoir, Swab, Disposable Cervical Brushes, Sterile Latex Surgical Gloves, Surgical Gowns, Urine Bag, Vaginal Speculum, Wooden Tongue Depressors, Disposable Breathing Circuits, Heat and Moisture Exchangers

Non-Sterile Medical Device:

Disposable I.D. Bracelets, Gauze Rolls, Gauze Bandages, Resuscitation Mask, Silicone/SEBS/PVC Manual Resuscitators, Rubber Examination Gloves, Digital Blood Pressure Monitors, Digital Thermometers, Alcohol Pad, CPR Mask, Medical Bandages, Adhesive Dressing Series, Non-woven Gowns, Non-woven Face Mask, Non-woven Caps, Non-woven Shoe Cover, PE Aprons, Stethoscope, ECG Electrode, Wheel Chairs, Walking Aids, Disposable Surgical Drape, Adult Diaper, Silicone Condom Catheter, Frozen Ice Pack, Mattresses, Ear/Ulcer Syringe, Single-use Medical Packing for Sterilized Medical Devices, Spacers for Aerosol, Spirometer, Underpad, Vomit Bag, Sharp Container, Ostomy Bag, Bed Sheet, Oral Swab, Suction Bottle Set, Humidifier Bubble, Non-woven swabs, Peak Meters