



# Certificate

No. Q6 093011 0010 Rev. 00

**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 and certification regulation of 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. 00](http://www.tuvsud.com/ps-cert?q=cert:Q6 093011 0010 Rev. 00)

**Report No.:** SH2199401

**Valid from:** 2022-07-06

**Valid until:** 2025-01-26

**Date,** 2022-07-06

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):

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

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, Disposable I.D. Bracelets,  
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 Syringe,  
Disposable Hypodermic Needles, 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,  
Three-way Stopcocks (with Extension Tube), Heparin Caps, I.V. Cannula for Single Use,  
Insulin Needles for Single Use, Disposable Scalpel with Plastic Handle, Blood Lancet,  
Sterile Surgical Blade, Gauze Rolls, Gauze Bandages, Gauze Sponges, Alcohol Pad,  
CPR Mask, 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, Resuscitation Mask,  
Silicone/SEBS/PVC Manual Resuscitators, Wound Drainage Reservoir, Urine Bag,  
Swab, Disposable Cervical Brushes, Sterile Examination Gloves,  
Sterile Latex Surgical Gloves, Surgical Gowns, Digital Thermometers,  
Digital Blood Pressure Monitors, Electronic Sphygmomanometers, Medical Bandages,  
Adhesive Dressing Series, Non-woven Gowns, Non-woven Face Mask,  
Non-woven Caps, Non-woven Shoe Cover, PE Aprons, Stethoscope, ECG Electrode,  
TENS Electrode, Wheel Chairs, Walking Aids, Operating Tables, Operating Lamps,  
Oxygen Concentrators, Vaginal Speculum, Disposable Surgical Drape, Adult Diaper,  
Silicone Condom Catheter, Wooden Tongue Depressors, Frozen Ice Pack, Mattresses,  
Ear/Ulcer Syringe, Single-use Medical Packing for Sterilized Medical Devices