



# Certificate

No. Q5 093011 0009 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:** **Design and Development,  
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, which meets the requirements of the listed standard(s). See also notes overleaf.

**Report No.:** SH1899404

**Valid from:** 2019-03-25  
**Valid until:** 2022-01-26

**Date,** 2019-03-25

Stefan Preiß

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# Certificate

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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

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

Design, Development, Production and Distribution of Silicone Urethral  
Catheters, Tracheostomy Tubes for Single Use, Non-absorbable Surgical  
Sutures with/without Needles, Condom

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

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**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**

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