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Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
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www.zlg.de  
ZLG-BS-244.10.08



Product Service

# EC Certificate

Production Quality Assurance System  
Directive 93/42/EEC on Medical Devices (MDD), Annex V  
(Devices in Class IIa, IIb or III)

**No. G2 093011 0006 Rev. 01**

**Manufacturer: 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

**Product Category(ies): Sterile Nonactive Medical Devices and Active Medical Devices**  
(for detailed information see following pages)

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

**Report No.:** SH19994EXT01

**Valid from:** 2019-11-26

**Valid until:** 2024-05-26

**Date,** 2019-11-26

Christoph Dicks  
Head of Certification/Notified Body

TÜV SÜD  
 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFICAT

A4 / 07.17





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

Endotracheal Tube, Reinforced Endotracheal Tube, Latex Foley Catheter, Urethral Catheters(PVC), Nelaton Catheters(latex), Laryngeal Mask 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 Syringes, Disposable Hypodermic Needles, Safety Disable Syringe, Sterile Infusion Sets for Single Use, Sterile Transfusion Sets for Single Use, Sterile Scalp Vein Type Needles for Single Use, 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 Balls, Non-woven Balls(with X-ray), Lap Sponges, Oropharyngeal Airway, Resuscitation Mask, Silicone/SEBS/PVC Manual Resuscitators, Wound Drainage Reservoir, Sterile Latex Surgical Gloves, Digital Thermometers, Digital Blood Pressure Monitors, Electronic Sphygmomanometers, Disposable Irrigating and Feeding Syringes, Disposable Cervical Brushes

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