



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 15 10 93011 003

**Manufacturer:** Ningbo Foyomed Medical  
Instruments Co., Ltd.

9F, Ningxing Building  
No. 666 Jiangnan Road  
Hi-Tech Zone  
315040 Ningbo  
PEOPLE'S REPUBLIC OF CHINA



**EC-Representative:** KINGSMEAD SERVICE LIMITED

145-157 St John Street  
London  
EC1V 4PY  
UNITED KINGDOM

**Product Category(ies):** for detailed information see attachment

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.:** SH1599401

**Valid from:** 2016-01-27

**Valid until:** 2021-01-26



**Date,** 2016-01-27

Hans-Heiner Junker

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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**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 15 10 93011 003****Facility(ies):**

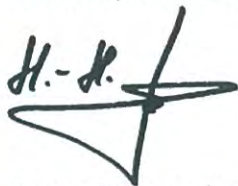
Ningbo Foyomed Medical Instruments Co., Ltd.  
9F, Ningxing Building, No. 666 Jiangnan Road,  
Hi-Tech Zone, 315040 Ningbo, PEOPLE'S  
REPUBLIC OF CHINA

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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

Munich, CRT2, 2016-01-27



Hans-Heiner Junker