

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

C.D.H

Christoph Dicks
Head of Certification/Notified Body

EC Certificate

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

No. G2 093011 0006 Rev. 01

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



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
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

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



Product Service

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

Certificate

No. Q5 093011 0009 Rev. 00

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

Certificate

No. Q5 093011 0009 Rev. 00

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

ZERTIFIKAT ♦ CERTIFICATE ♦ 認證證書 ♦ CERTIFICADO ♦ CERTIFICAT

管理体系认证 注册证书

兹证明，以下组织：

宁波凡友医疗器械 有限公司

中国浙江省宁波市高新区江南一品花园299号<8-5><8-6>

的管理体系，符合以下标准要求并予以注册：

ISO 9001:2015

此管理体系适用于：

医疗器械经营资质许可范围内的医疗器械销售。

统一社会信用代码：

91330201316925819B

证书编号：

112108006

首次认证日期：

2021年09月13日

认证决定日期：

2021年09月13日

签发日期：

2021年09月13日

有效期至：

2024年09月12日



Intertek



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Calin Moldovean

President, Business Assurance

Intertek Certification Limited, 10A Victory
Park, Victory Road, Derby DE24 8ZF, United
Kingdom

Intertek Certification Limited
是 UKAS 认可的认证机构，
注册号为 014



CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Ningbo Foyomed Medical Instruments Co., Ltd

Room 805-806, No. 299 of Jiangnan Yipin Garden, Hi-Tech Zone, Ningbo City,
Zhejiang Province, P. R. China

has been registered by Intertek as conforming to the requirements of:

ISO 9001:2015

The management system is applicable to:

Sales of medical devices within the scope of medical device business
qualification.

Unified Social Credit Identifier:

91330201316925819B

Certificate Number:

112108006

Initial Certification Date:

13 September 2021

Date of Certification Decision:

13 September 2021

Issuing Date:

13 September 2021

Valid Until:

12 September 2024



Calin Moldovean

President, Business Assurance

Intertek Certification Limited, 10A Victory
Park, Victory Road, Derby DE24 8ZF, United
Kingdom

Intertek Certification Limited is a
UKAS accredited body under
schedule of accreditation no. 014.

