



benannt durch/Designated by
 Zentralstelle der Länder
 für Gesundheitsschutz
 bei Arzneimitteln und
 Medizinprodukten
 www.zlg.de
 ZLG-BS-244.10.08



Product Service

ZERTIFIKAT ♦ CERTIFICATE ♦ CERTIFICADO ♦ CERTIFIKAT ♦ СЕРТИФИКАТ ♦ 認證書

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

A4 / 07.17



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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

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ZERTIFIKAT ♦ CERTIFICATE ♦ 認證書 ♦ CERTIFIKAT ♦ CERTIFICADO ♦ CERTIFICAT



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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

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

Declaration of Conformity

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

European Representative: **Prolinx GmbH**

Brehmstr. 56, 40239, Duesseldorf (Germany)

Product Name: Disposable Syringes

UMDNS Code: 13929

Produce No.: FY0601, FY0604

Classification (MDD, Annex IX): IIa, rule 6.

Conformity Assessment Route: Annex V

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the Declaration of Conformity.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC). Amended by DIRECTIVE 2007/47/EC

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany

NB Identification number: 0123

(EC) Certificate(s): G2 093011 0006 Rev.01

Expire date of the Certificate: 2024-05-26

宁波凡友医疗器械有限公司
NINGBO FOYOMED MEDICAL INSTRUMENTS CO., LTD

Place, Date of Issue: Ningbo, 2022-03-10

Signature:



Name: Yingxia Xu

Position: General Manager

Declaration



We, **Ningbo Foyomed Medical Instruments Co., Ltd.** (Add.: Room 805-806, No. 299 of Jiangnan Yipin Garden, Hi-Tech Zone, 315040, Ningbo, People's Republic Of China) hereby declare that our syringes meet with the standard ISO 7886-1 and our needles meet with the standard ISO 7864.

Company Seal

Date: March 14th 2022





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

Certificate

No. Q6 093011 0010 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

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

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



014

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



Intertek



014

A handwritten signature in black ink, appearing to read 'Calin Moldovean'.

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.

