DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

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:**

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

**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

Digitally signed by Granaci Boris
Date: 2022.09.21 12:20:00 EEST
Reason: MoldSign Signature
Location: Moldova

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

A4 / 07.17


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D-ZM-11321-01-00

TÜV SÜD
Product Service

# 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**


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D-ZM-11321-01-00

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Product Service

# 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




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# 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

ISO 9001:2015 CERTIFICATION
Intertek
UKAS MANAGEMENT SYSTEMS 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

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# 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

ISO 9001:2015 CERTIFICATION Intertek

UKAS MANAGEMENT SYSTEMS 014

**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.

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

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

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Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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ZLG-BS-244.10.08

TÜV SÜD 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**

**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**


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

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ZLG-BS-244.10.08

TÜV SÜD 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**


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# FY0604 Insulin Syringe

## Specifications:

| | |
|---|---|
| **Volume** | 0.3ml, 0.5ml, 1ml |
| **Parts** | Three parts |
| **Syringe Body Material** | Medical grade polypropylene |
| **Syringe Plunger Material** | Medical grade polypropylene |
| **Syringe Piston Material** | Medical grade natural rubber or isoprene rubber |
| **Protection Cap Material** | Medical grade polypropylene |
| **Fixed Needle Sheath Material** | Medical grade polypropylene |
| **Fixed Needle Size** | 27-31G |
| **Fixed Needle Tube Material** | Medical grade SUS304 |
| **Sterilization** | EO |
| **Class of Medical Device** | IIa |

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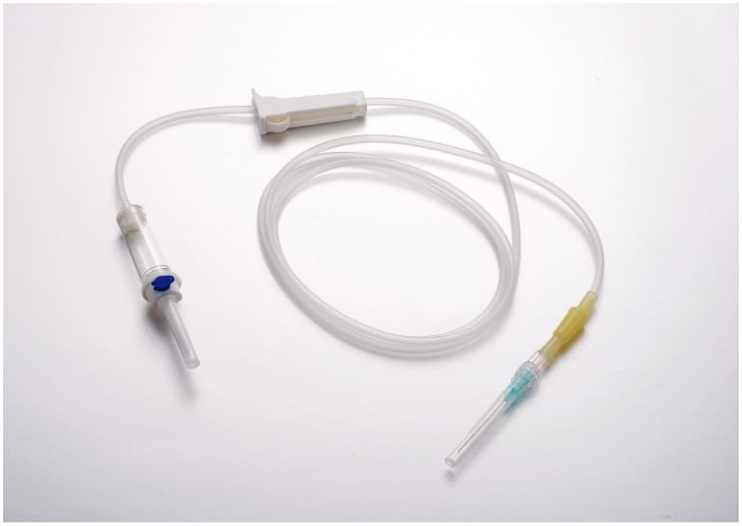
何国强



# FY0501　Disposable Infusion Set

## Specifications:

| | |
|---|---|
| **Drip** | Adult (20 drops=1±0.1ml)/Child(60drops=1±0.1ml) |
| **Tube Material** | Medical grade PVC,　high elastic Medical grade PVC or others |
| **Tube Length** | 120cm, 150cm or others |
| **Regulator Material** | PE, PP, or ABS |
| **Injection port** | Latex tube |
| **Filter** | Drug filter, air filter for optional |
| **Luer** | Luer lock/Luer slip |
| **Needle Sheath Material** | Medical grade polypropylene |
| **Needle Size** | 18-30G |
| **Needle Tube Material** | Medical grade SUS304 |
| **Sterilization** | EO |
| **Class of Medical Device** | IIa |

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NINGBO FOYOMED MEDICAL INSTRUMENTS CO.,LTD
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# FY0505　Disposable Blood Transfusion Set

## Specifications:

| | |
|---|---|
| **Drip** | 20 drops=1±0.1ml |
| **Tube Material** | Medical grade PVC,　high elastic medical grade PVC or others |
| **Tube Length** | 120cm, 150cm or others |
| **Regulator Material** | PE, PP, or ABS |
| **Injection port** | Latex tube |
| **Filter** | Drug filter, air filter for optional |
| **Luer** | Luer lock/Luer slip |
| **Puncture Device Material** | ABS |
| **Needle Sheath Material** | Medical grade polypropylene |
| **Needle Size** | 18-30G |
| **Needle Tube Material** | Medical grade SUS304 |
| **Sterilization** | EO |
| **Class of Medical Device** | IIa |

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

# 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: Sterile Infusion Sets for Single Use
UMDNS Code: 13217

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

Start of CE Marking: 2016.3

Place, Date of Issue: Ningbo, 2022-06-10
宁波凡友医疗器械有限公司
NINGBO FOYOMED MEDICAL INSTRUMENTS CO.,LTD
Signature:
Name: **Yingxia XU**
Position: **General Manager**

# 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: Sterile Transfusion Sets for Single Use
UMDNS Code: 14126

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, 2022-06-10**
Signature:
Name: **Yingxia Xu**
Position: **General Manager**

# 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