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

Digitally signed by Granaci Boris
Date: 2023.02.01 11:41:12 EET
Reason: MoldSign Signature
Location: Moldova

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

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(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**

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(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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intertek
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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

intertek
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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

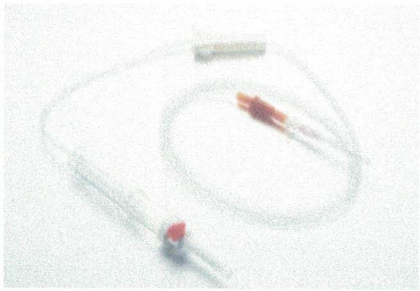
Intertek Certification Limited, 10A Victory Park, Victory Road, Derby DE24 8ZF, United Kingdom

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

Technical specification and component

FY0505

Disposable Blood Transfusion Set



20 drops, Luer slip with needle18G x1 1/2", with plastic needle

With PVC tube, length 150cm, latex free, With air filter, PP regulator, rubber chamber

EO sterilized, latex free.

Packing: 1pc/PE pack

Drip	Adult (20 drops=1±0.1ml)
Tube Material	Medical grade PVC
Tube Length	150cm
Regulator Material	PP
Injection port	Isoamyl rubber
Filter	air filter
Needle Sheath Material	Medical grade Poly Ethylen
Needle Size	18G x1 1/2"
Needle Tube Material	Medical grade SUS304
Class of Medical Device	IIa
Sterilization	EO

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

何国强

宁波凡友医疗器械有限公司
NINGBO FOYOMED MEDICAL INSTRUMENTS CO., LTD.
Add : Room 805-806, No. 299 of Jiangnan Yipin Garden, Hi-Tech Zone, Ningbo, PEOPLE'S REPUBLIC OF CHINA
Tel : 0086-574-81877109 Fax : 0086-574-81877057
Web: http://www.foyomed.com

PRINCIPLE OF OPERATION:

Intravenous therapy is the infusion of liquid substances directly into a vein. Intravenous (IV) means "within vein". Intravenous infusions are commonly referred to as drips. The intravenous route is the fastest way to deliver fluids and medications throughout the body. Intravenous therapy may be used for fluid administration (such as correcting dehydration), to correct electrolyte imbalances, to deliver medications and for blood transfusions.

宁波凡友医疗器械有限公司
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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**