



Product Service

# EC Certificate

## Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)  
(Devices in Class IIa, IIb or III)

**No. G1 17 03 43337 047**

**Manufacturer: Jianguo Suyun Medical Materials Co., Ltd.**

No.1 Medicine Lane, Renmin Rd.  
222002 Lianyungang  
PEOPLE'S REPUBLIC OF CHINA

**EC-Representative: Shanghai International Holding Corp. GmbH (Europe)**

Eiffestraße 80  
20537 Hamburg  
GERMANY



**Product Category(ies):**

Sterile Infusion Sets for Single Use, Sterile Transfusion Sets for Single Use, Sterile Syringe for Single Use, Sterile Urinary Catheter for Single Use (Nelaton Catheter, Foley Catheter and Silicone Catheter), Sterile Arterial Venous Fistula Needle for Single Use, Sterile Scalp Vein Sets for Single Use, Sterile Blood Collection Needle for Single Use, Sterile Feeding Catheter for Single Use, Sterile Nasal Oxygen Cannula for Single Use, Sterile Proctoscope for Single Use, Laryngeal Mask Airway, Sterile Suction Catheter for Single Use, Sterile Endotracheal Tube for Single Use, Sterile Insulin Syringe for Single Use, Sterile Stomach Tube with Guide Wire for Single Use, Sterile Stomach Tube for Single Use (Nasogastric Tube, Levin Tube), Sterile Feeding Tube for Single Use, Sterile Duodenal Tube for Single Use, Disposable Curettes, Heat and Moisture Exchange (Artificial Nose), Sterile Hypodermic Needle for Single Use, Sterile Dental Injection Needles for Single Use, Sterile Intravascular Catheters for Single Use (I.V. Cannula), Suction Catheter Kit, Sterile Incision Retractor for Single Use, Light-resistant Infusion Sets for Single Use.

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

**Report No.:** BJ1688504  
**Valid from:** 2017-08-24  
**Valid until:** 2022-06-13

**Date,** 2017-08-24

Stefan Preiß

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

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No. G1 17 03 43337 047

#### Facility(ies):

Jiangsu Suyun Medical Materials Co., Ltd  
No.18 Jin Qiao Road, Dapu Industrial Park, 222002 Lianyungang,  
Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA

Jiangsu Suyun Medical Materials Co., Ltd.  
No.1 Medicine Lane, Renmin Rd., 222002 Lianyungang,  
PEOPLE'S REPUBLIC OF CHINA





# Certificate

No. Q5 043337 0048 Rev. 01

**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):** Jiangsu Suyun Medical Materials Co., Ltd.  
No.1 Medicine Lane, Renmin Rd., 222002 Lianyungang,  
PEOPLE'S REPUBLIC OF CHINA

Jiangsu Suyun Medical Materials Co., Ltd  
No.18 Jin Qiao Road, Dapu Industrial Park, 222002 Lianyungang,  
Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA

## Attachment:

Sterile Infusion Sets for Single Use, Sterile Transfusion Sets for Single Use, Sterile Syringe for Single Use, Sterile Vaginal Speculum for Single Use, Sterile Urinary Catheter for Single Use (Nelaton Catheter, Foley Catheter and Silicone Catheter), Sterile Gynaecological Collectors for Single Use, Sterile Rectal Catheter for Single Use, Sterile Scalp Vein Sets for Single Use, Sterile Suction Catheter for Single Use, Sterile Blood Collection Needle for Single Use, Sterile Arterial Venous Fistula Needle for Single Use, Sterile Nasal Oxygen Cannula for Single Use, Sterile Proctoscope for Single Use, Laryngeal Mask Airway, Sterile Feeding Catheter for Single Use, Sterile Endotracheal Tube for Single Use, Sterile Insulin Syringe for Single Use, Sterile Stomach Tube with Guide Wire for Single Use, Sterile Stomach Tube for Single Use (Nasogastric Tube, Levin Tube), Sterile Duodenal Tube for Single Use, Sterile Nasal Speculum for Single Use, Sterile Urine Drainage Bag for Single Use, Sterile Feeding Tube for Single Use, Sterile Specimen Container for Single Use, Sterile Applicator with Cotton Tip, Sterile Tongue Depressor, Sterile Otolaryngological Set for Single Use, Trial Lenses Sets, Disposable Curettes, Sterile Gynecological Kit for Single Use, Transport Swab, Heat and Moisture Exchange (Artificial Nose), Sterile Catheter Tip Syringe for Single Use, Intrauterine Insemination Catheter (IUI Cannula), Disposable Uterine Sound (Hysterometers), Sterile Hypodermic Needle for Single Use, Sterile Extension Tube for Single Use, Disposable Bibs, I.D. Bracelet, Sterile Laryngological Speculum for Single use, Sterile Umbilical Cord Clamp for Single Use, Sterile Dental Injection Needles for Single Use, Sterile Amniohook for Single Use, Sterile Intravascular Catheters for Single Use (I.V. Cannula), Suction catheter Kit, Sterile Incision Retractor for Single Use, Light-resistant Infusion Sets for Single Use, Ostomy bags and accessories, Vacuum Blood Collection Tubes, Alcohol Pads, Forceps, Ear funnel, Disposable Circumcision Stapler, Sterile Holder Accessories for Single Use (Fastener, Arm Drape).