



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 I in sterile conditions, sterilised systems or procedure packs)

**No. G2S 043337 0044 Rev. 03**

## Manufacturer

**Jiangsu 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 Non-active Medical devices (For  
 detailed information see attachment).**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

**Report No.:** BJ1888504

**Valid from:** 2019-05-27

**Valid until:** 2024-04-13

**Date,** 2019-05-27

Stefan Preiß  
 Head of Certification/Notified Body





TUV SÜD  
ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT



# Certificate

No. Q5 043337 0048 Rev. 01

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



**Scope of Certificate:** **Design and development, production and sales of Sterile /Non-sterile Non-active 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.:** BJ1888504  
**Valid from:** 2019-06-01  
**Valid until:** 2022-05-31

**Date,** 2019-05-27



**Stefan Preiß**  
Head of Certification/Notified Body



TÜV.SÜD  
ZERTIFIKAT ♦ CERTIFICATE ♦ 認證證書 ♦ CERTIFIKAT ♦ CERTIFICADO ♦ CERTIFICAT



**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.18 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).

