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Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
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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

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

A4 / 07.17



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## 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 Vaginal Speculum for Single Use, Sterile Gynaecological Collectors for Single Use, Sterile Rectal Catheter for Single Use, Sterile Nasal Speculum for Single Use, Sterile Urine Drainage Bag for Single Use, Sterile Applicator with Cotton Tip, Sterile Tongue Depressor, Sterile Otolaryngological Set for single use, Sterile Gynecological Kit for Single Use, Transport Swab, Sterile Catheter Tip Syringe for Single Use, Sterile Extension Tube for Single Use, Sterile Laryngological Speculum for Single Use, Sterile Umbilical Cord Clamp for Single Use, Sterile Amniohook for Single Use, Ear funnel, Forceps, Ostomy bags and accessories. Sterile Holder Accessories for Single Use (Fastener, Arm Drape).

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 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFIKAT ◆ CERTIFICATE