



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 14 04 43337 044

**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 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.

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.:** BJ1388507-1

**Valid from:** 2014-04-14

**Valid until:** 2019-04-13



**Date,** 2014-06-05

Hans-Heiner Junker

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

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**No. G2S 14 04 43337 044**

**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