



Product Service

# CERTIFICATE

No. Q1N 16 01 43337 043

**Holder of Certificate:** Jiangsu Suyun Medical Materials Co., Ltd.No.1 Medicine Lane, Renmin Rd.  
222002 Lianyungang  
PEOPLE'S REPUBLIC OF CHINA**Facility(ies):**Jiangsu Suyun Medical Materials Co., Ltd.  
No.1 Medicine Lane, Renmin Rd., 222002  
Lianyungang, PEOPLE'S REPUBLIC OF CHINAJiangsu Suyun Medical Materials Co., Ltd.  
No.18 Jin Qiao Road, Dapu Industrial Park,  
222002 Lianyungang, Jiangsu Province,  
PEOPLE'S REPUBLIC OF CHINA**Certification Mark:****Scope of Certificate:** Design, Development, Production and Sales of  
General Medical Devices (detailed as the attachment)**Applied  
Standard(s):**EN ISO 13485:2012 + AC:2012  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2003 + Cor. 1:2009)  
DIN EN ISO 13485:2012

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.:** BJ1588504**Valid from:** 2016-06-01**Valid until:** 2019-05-31**Date,** 2016-05-17  
Stefan Preiß

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DAKKS

Deutsche  
Akkreditierungsstelle  
D-704-11121-01-20

TÜV SÜD Product Service GmbH · Zertifizierstelle · Aidlerstraße 65 · 80339 München · Germany

TUV®





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:

**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 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



*H.-H. Junker*

Hans-Heiner Junker

Date, 2014-06-05

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

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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****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





Product Service

# CERTIFICATE

No. Q1N 17 03 43337 046

**Holder of Certificate:** Jiangsu Suyun Medical Materials Co., Ltd.No.1 Medicine Lane, Renmin Rd.  
222002 Lianyungang  
PEOPLE'S REPUBLIC OF CHINA**Facility(ies):**Jiangsu Suyun Medical Materials Co., Ltd.  
No.1 Medicine Lane, Renmin Rd., 222002  
Lianyungang, PEOPLE'S REPUBLIC OF CHINAJiangsu Suyun Medical Materials Co., Ltd  
No.18 Jin Qiao Road, Dapu Industrial Park,  
222002 Lianyungang, Jiangsu Province,  
PEOPLE'S REPUBLIC OF CHINA**Certification Mark:****Scope of Certificate:** Design, Development, Production and Sales of  
General Medical Devices (detailed as the attachment)**Applied  
Standard(s):**EN ISO 13485:2012 + AC:2012  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2003 + Cor. 1:2009)  
DIN EN ISO 13485:2012

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.:** BJ1688504**Valid from:** 2017-08-24**Valid until:** 2019-05-31**Date,** 2017-08-24

Stefan Preis



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D-ZM-11321-01-00





Product Service

Attachment for Certificate No. Q1N 17 03 43337 046

Dated: 2019-05-31

For the product(s)/product category (ies):

Detail Information Related to Facilities and Product Categories:

## Product Categories

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.

## In Facilities

Jiangsu Suyun Medical Materials Co., Ltd.

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

Jiangsu Suyun Medical Material Co., Ltd.

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

Munich, MHS-CRT 2017-08-24

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D-ZM-11321-01-00



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:

**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 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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*S. Preiß*







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****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

