ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

TÜV SÜD 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.

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Valid from:	2017-08-24
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Date, 2017-08-24

Stefan Preiß

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

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(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

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