



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 IIa, IIb or III)

No. G2 086389 0013 Rev. 00

Manufacturer:

**Yangzhou Super Union
Import & Export Co., Ltd.**

No.120 Xishan South Road
Chenji Town
211408 Yizheng City, Jiangsu Province
PEOPLE'S REPUBLIC OF CHINA

Product
Category(ies):

Disposable Sterilized Latex Surgical Gloves, Disposable
Surgical Blades (with and without Handle), Sterile Blood
Lancets, Sterile Syringes for Single Use, Sterile Infusion Sets
for Single Use, Sterile Transfusion Set for Single Use, Sterile
Scalp Vein Type Needles for Single Use, Sterile Hypodermic
Needles for Single Use, Sterile Insulin Syringes for Single
Use, Disposable Irrigating and Feeding Syringes, Disposable
Medical Three-way Stopcocks, Disposable Connecting
Extension Tubes, Disposable Infusion Enteral Giving Set,
Laryngeal Mask, Endotracheal Tube, Reinforced
Endotracheal Tube, Suction Catheter, Mucus Extractor,
Tracheostomy Tube, Oxygen Mask, Nelaton Tube, Silicone
Foley Catheter, Feeding Tube, Abdominal/Thoracic Drain
Tube, Stomach Tube, Sterile Gauze Swabs with X-ray, Sterile
Lap Sponges with X-ray, Sterile Non-woven Sponges with X-
ray, Blood Collection Needle for Single Use, Sterile Dental
Needles for Single Use, Insulin Needles for Single Use, Sterile
Suction Tube (Yankauer Suction Set)

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.: SH1881506
Valid from: 2019-12-03
Valid until: 2024-04-08
Date, 2019-12-03

Christoph Dicks
Head of Certification/Notified Body



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No. G2 086389 0013 Rev. 00

Facility(ies):

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No.120 Xishan South Road, Chenji Town, 211408
Yizheng City, Jiangsu Province, PEOPLE'S
REPUBLIC OF CHINA**

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Wenchang West Road, 225009 Yangzhou City,
Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA**

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT