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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 IIa, IIb or III)

No. G2 086389 0013 Rev. 00

Digitally signed by Bolea Petru
Date: 2022.09.14 07:55:45 EEST
Reason: MoldSign Signature
Location: Moldova

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

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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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 IIa, IIb or III)

No. G2 086389 0013 Rev. 00

Facility(ies):

**Yangzhou Super Union Import & Export Co., Ltd.
No.120 Xishan South Road, Chenji Town, 211408
Yizheng City, Jiangsu Province, PEOPLE'S
REPUBLIC OF CHINA**

**Yangzhou Super Union Import & Export Co., Ltd.
Room 2003-2004, Huacheng Building, No. C456
Wenchang West Road, 225009 Yangzhou City,
Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA**

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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 086389 0014 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 Medical Latex Examination Gloves, Sterile Wound Plaster /Strips, Sterile Dressing Adhesive, Urine Drainage Bag, Rectal Tube, Vaginal Speculum, Disposable Colostomy Collection Bag, Sterile Eye Pad, Sterile First-aid Dressing Bandage, Sterile Non-adherent Dressing, Disposable Sterile Gown, Disposable Sterile Drape, First Aid Kits, Sterile Gauze Swabs without X-ray, Sterile Lap Sponges without X-ray, Sterile Non-woven Sponges without X-ray, Sterile Gauze Bandages, Umbilical Cord Clamp

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.: 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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