



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 15 01 86389 006

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

EC-Representative: Shanghai International Holding
Corp. GmbH (Europe)

Eiffestraße 80
20537 Hamburg
GERMANY

Product Category(ies): For detailed information see attachment

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.: SH1481502

Valid from: 2015-04-07

Valid until: 2019-04-08



Date, 2015-04-09

Hans-Heiner Junker

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

Page 1 of 3



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(Devices in Class IIa, IIb or III)**No. G2 15 01 86389 006****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**

Attachment for Certificate No G2.15.01.86389.006

Supplement 001 dated 2015-04-07



Product Service

For the product(s)/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,
Umbilical Cord Clamp,
Silicone Suction Reservoir and Flat Drain (Round Drain),
Connection Cannula, Sterile Suction Tube (Yankauer Suction Set),
Laryngeal Mask, Endotracheal Tube,
Preformed Nasal and Oral Tracheal Tube,
Reinforced Endotracheal Tube,
Suction Catheter, Mucus Extractor,
Tracheostomy Tube, Oxygen Mask, Nelaton Tube,
Silicone Foley Catheter, Nasal Oxygen Cannula,
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

Munich, CRT2, 2015-04-09

Hans-Heiner Junker
Certification Medical Technology

Page 3 of 3