





Certificate

No. Q6 073684 0019 Rev. 00

Holder of Certificate: Suzhou TexNet Co., Ltd.

RM1103-1104, 11/F, Block A

Xin Tian Xiang Bldg., 388 Suya Road, SIP

215021 Suzhou

PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Production and Distribution of Medical Device Scope of Certificate: (For detailed information see attachment)

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH1862009

Valid from: 2018-10-29 Valid until: 2019-07-28

1. Pumil Stefan Preiß Date, 2018-10-29





Certificate

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EN ISO 13485:2016 Applied Standard(s):

Medical devices - Quality management systems -

Requirements for regulatory purposes

(ISO 13485:2016) DIN EN ISO 13485:2016

Suzhou TexNet Co., Ltd. Facility(ies):

RM1103-1104, 11/F, Block A, Xin Tian Xiang Bldg., 388 Suya Road, SIP, 215021 Suzhou, PEOPLE'S REPUBLIC OF CHINA

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

Production and Distribution of

Absorbent Cotton Products, Medical Adhesive Tape, Medical Bandages (Elastic Bandages, Tubular Bandages, Cohesive Bandages, P.O.P Bandages), Absorbent Gauze Products, Non-woven Products, First Aid Products, Disposable Medical Device for Infusion and Transfusion, Medical Gloves, Medical Tubes/Catheters, Medical Needles, Oxygen Masks, Plastic Medical Products (Medicine Cups, Urine Cups, Tubing Clamps, Tweezers, Medical Trays, Plastic Pouches, Urine Bottles, Bedpans, Identification Bracelets), Surgical Instruments, Disposable Sterile Drapes, Zinc Oxide Adhesive Plasters, Wound Plasters, Wound Plasters (Plaster Strips, Adhesive Wound Dressing), Disposable Medical Pads, Sterile Non-Adhesive Dressing, Basic Dressing Pack, Laryngeal Masks, Alcohol Swabs/Pads and Disposable Urinary Catheterization Kits(Foley), Cotton Applicator, Tongue Depressor, Single-used Sterilization Packaging and Disposable Underpads, Light Handle Covers, Dental Bib, Irrigate Kits, Adult Diapers



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 17 07 73684 017

Manufacturer:

Suzhou TexNet Co., Ltd.

RM1103-1104, 11/F, Block A

Xin Tian Xiang Bldg., 388 Suya Road, SIP

215021 Suzhou

PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Shanghai International Holding

Corp. GmbH (Europe)

Eiffestraße 80 20537 Hamburg GERMANY

Product Category(ies):

Sterile Lap Sponges without X-ray, Gauze Balls, Disposable Sterile Drape, Sterile Gauze Swabs, Sterile Non-Woven Swabs, Disposable Sterile Gown, Sterile Wound Plasters (Sterile Plaster Strips, Sterile Adhesive Wound Dressing), Sterile Non-Adherent Dressing, Basic Dressing Packs, First Aid Kits, Sterile Eye Pads, Urine Meter, Absorbent Cotton Pads, Bandages, Disposable Rectal Tubes, Disposable Urine Bag, Umbilical Cord Clamps, Vaginal Speculum, Male External Catheters,

Examination Gloves with Paper, Light Handle Covers

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.:

SH1762008

Valid from:

2017-12-18

Valid until:

2020-07-29

Date, 2017-12-18

Stefan Preiß



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

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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 17 07 73684 017

Facility(ies):

Suzhou TexNet Co., Ltd.

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