



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
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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 I in sterile conditions, sterilised systems or procedure packs)

No. G2S 073684 0017 Rev. 01

Manufacturer

Suzhou TexNet Co., Ltd.

RM1103-1104, 11/F, Block A

Xin Tian Xiang Bldg., 388 Suyu Road, SIP

215021 Suzhou

PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Suzhou TexNet Co., Ltd.

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

Product Category(ies):

Sterile Lap Sponges without X-ray Detectable Material,
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.:

SH19620EXT01

Valid from:

2019-09-26

Valid until:

2024-05-26

Date,

2019-09-26

Stefan Preiß

Head of Certification/Notified Body

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

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