



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 17 10 60202 023

Manufacturer:**Shanghai Channelmed Import & Export Co., Ltd. (Channelmed Group)**

Room 1402, No. 707 of Zhangyang Road

200120 Shanghai

PEOPLE'S REPUBLIC OF CHINA

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

Eiffestraße 80

20537 Hamburg

GERMANY

**Product****Category(ies):**

First-Aid-Kit,
Sterile Hemostasis Adhesive Dressing Series
(Sterile Wound Plasters Liquid Transfusion Plaster
and Adhesive Dressing),
Sterile Gauze Swabs without X-ray,
Sterile Lap Sponge without X-ray,
Sterile Non-Woven Sponge without X-ray,
Sterile Gauze Bandage, Disposable Surgical Gowns,
Oropharyngeal Airways,
Sterile Latex Examination Gloves,
Stomach Tubes, Rectal Tubes,
Feeding Tubes, Umbilical Cord Clamp, Urine Bags,
Sterile Vaginal Speculum,
Sterile Wooden Tongue Depressor,
Male External Catheter, Gynecological Sets,
Medical Brushes, Ostomy Bag and Accessories,
Cotton Tipped Applicators, Brush-sponge

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.:

SH1744812

Valid from:

2018-04-20

Valid until:

2022-01-25

Date, 2018-04-20

Stefan Preiß



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

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No. G2S 17 10 60202 023**Facility(ies):**

Shanghai Channelmed Import & Export Co., Ltd. (Channelmed Group)

Room 1402, No. 707 of Zhangyang Road, 200120 Shanghai,
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Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 17 10 60202 021

Manufacturer:

**Shanghai Channelmed Import & Export
Co., Ltd. (Channelmed Group)**

Room 1402, No. 707 of Zhangyang Road
200120 Shanghai
PEOPLE'S REPUBLIC OF CHINA

**EC-Representative:**

**Shanghai International Holding
Corp. GmbH (Europe)**

Eiffestraße 80
20537 Hamburg
GERMANY

**Product
Category(ies):**

**Sterile Gauze Swabs with X-ray,
Sterile Lap Sponge with X-ray,
Sterile Non-Woven Sponge with X-ray
and other devices 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.:

SH1744812

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2018-04-20

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Date, 2018-04-20

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Attachment for Certificate No G2 17 10 60202 021

Supplement 001 dated 2018-04-20



Product Service

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

Sterile Infusion Sets for Single Use,
Sterile Syringes For Single Use,
Sterile Dental Needle for Single Use,
Scalp Vein for Single Use, I.V. Cannula for Single Use,
Hypodermic Needle for Single Use,
Blood Transfusion Sets, Sterile Latex Surgical Gloves,
Urethral Catheter, Tracheal Tubes, Tracheotomy Tube,
Connecting Tube with Yankauer Handle,
Intubating Stylet, All Silicone Foley Catheter,
Laryn-geal Mask Device, Tracheobronchial Tubes,
Reinforced Endotracheal Tubes, Suction Catheter,
Nelaton Catheter, Blood Lancets,
Disposable Surgical Blades(with and without handle),
Nasal Oxygen Cannula, Oxygen Mask,
Tracheotomy Mask, Infusion Set with Burette,
Three-way Stopcocks, Heparin Caps, Syringe for Insulin,
Foley Catheter, Gauze Roll,
Gauze Roll with X Ray Thread,
Wound Drainage Reservoir,
Venous Blood Collection Needles,
Sterile Safety Auto Disable Syringes for Single Use,
Alcohol Pads, Alcohol Swab Sticks,
Sterile Surgical Packs, Nebulizer Mask,
Oxygen Mask with Reservoir Bag, Extension Tube

Munich, CRT2, 2018-04-20

Stefan Preiß

Certification Medical Technology

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No. G2 17 10 60202 021**Facility(ies):**

Shanghai Channelmed Import & Export Co., Ltd.
(Channelmed Group)
Room 1402, No. 707 of Zhangyang Road, 200120
Shanghai, PEOPLE'S REPUBLIC OF CHINA