

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)

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

2018-04-20 Date,

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

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