



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 18 03 03804 003

Manufacturer:

**Suzhou Acmed
Import & Export Co., Ltd**

2-10016,436 Changjiang Road

215011 Suzhou

PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

MedPath GmbH

Mies-van-der-Rohe-Strasse 8

80807 München

GERMANY

Product

Category(ies):

Lap Sponges with X-ray Detectable Thread,
Suction Catheters, Stomach Tubes,
Feeding Tubes, Silicone Foley Catheter,
Sterile Blood Lancets, Disposable Surgical
Blades(with and without Handle),
Scalp Vein Set for Single Use,
I.V. Cannula for Single Use,
Sterile Three-way Stopcock for Single Use,
Sterile Heparin Cap for Single Use,
Three-way Stopcock and Extension Tube,
Infusion Set for Single Use, Transfusion Set,
Sterile Syringes for Single Use(with Needle),
Sterile Hypodermic Needles for Single Use,
Latex Foley Catheter, Sterile Surgical Gloves,
Digital Thermometer, Infra-red Ear Thermometer,
Digital Blood Pressure Monitor
(Digital Sphygmomanometer), Suction Connecting
Tube with Yankauer Handle,
Endotracheal tube, Oxygen Masks,
Sterile and non-sterile Nebulizers



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.:

SH18111601

Valid from:

2018-07-12

Valid until:

2023-07-11

Date, 2018-07-12

Stefan Preiß

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

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Facility(ies):

Suzhou Acmed Import & Export Co., Ltd
2-10016, 436 Changjiang Road, 215011 Suzhou,
PEOPLE'S REPUBLIC OF CHINA

Suzhou Acmed Import & Export Co., Ltd.

Sterile Surgical Gloves CE TF

Declaration Of Conformity

Manufacturer: Name: Suzhou Acmed Import & Export Co., Ltd.
Add: 2-10016,436 Changjiang Road, 215011 Suzhou, P. R.China

European Representative: Name: MedPath GmbH
Add: Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany

Product Name Sterile Surgical Gloves

Object of the declaration: Sizes: 6, 6.5, 7, 7.5, 8, 8.5
Lot No.: Pending
Number of products: Pending

UMDNS Code: 11-883

Classification (MDD, Annex IX): IIa, rule 7

Conformity Assessment Route: Annex V.3

We herewith declare in sole responsibility that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the declaration of conformity.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr. 65,
80339, München, Germany

Identification number: 0123

(EC) Certificate(s): G218 03 03804 003

Expire date of the Certificate: 2023-07-11

Start of CE Marking: 2018-07-12

Place of Issue: Suzhou, CHINA

Date of Issue: 2018-07-12

Signature:

Name: Mark Ho
Position: General Manager

