



Product Service

Certificate

No. Q6 003804 0004 Rev. 00

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

Certification Mark:



Scope of Certificate: Production and Distribution of
Medical Device
(for detail 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). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q6 003804 0004 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:Q6_003804_0004_Rev_00)

Report No.: SH21111601

Valid from: 2021-09-10
Valid until: 2024-07-11

Date, 2021-09-10

Christoph Dicks
Head of Certification/Notified Body

Certificate

No. Q6 003804 0004 Rev. 00

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

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

See Scope of Certificate

For the product(s)/process(es) of the following company/ies:
Production and Distribution of Medical Devices without X-ray
Detectable Thread, Lap Springs with X-ray Detectable Thread,
Surgical Sponges, Sterile Wound Dressings (Self-Adhesive and Non-Adhesive),
Sterile Wound Patches (Self-Adhesive and Non-Adhesive), First-Aid Kits,
Disposable Sterile Drapes, Sterile Surgical Gowns,
Sterile Pad (Alcohol Pad), Endotracheal Tubes, Urine Bags, Vaginal
Syringes, Ostomy Bags, Suction Catheters, Stomach Tubes,
Feeding Tubes, Silicone Foley Catheter, Latex Foley Catheter,
Section Connecting Tube with Venturer Handle, Endotracheal Tube,
Oxygen Masks, Sterile and non-Sterile Nebulizers, 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 Luer-Lock 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, Sterile Surgical Gloves, Digital Thermometer, Infrared Ear
Thermometer, Digital Blood Pressure Monitor (Digital Sphygmomanometer),
Central Venous Catheter Set,
Gauze Roll, Absorbent Cotton Wool, Absorbent Cotton Ball, Medical Bandage,
Medical Support, Medical Tapes, Patient Footwear, Pill Crusher, Medical Gloves,
Face Masks, Disposable Cap, Disposable Shoe Cover, Isolation Gown,
Disposable Coverall, Medical Forceps, Medical Brushes, Disposable I.D.
Probes, Disposable Medical Cup, Face Shields, Medical Goggles, Surgical
Scissors with and without Needle, Disposable ECG Electrode

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

Production and Distribution of Gauze Sponges without X-ray Detectable Thread, Lap Sponges with X-ray Detectable Thread, Non-woven Sponges, Sterile First-aid Dressing Bandage, Sterile Wound Plasters (Sterile Plaster Strips), First-Aid Kits, Disposable Sterile Drapes, Medical Dressing Kits, **Surgical Gown**, Sterile Pad (Alcohol Pad), Rectal Tubes, Urine Bags, Vaginal Speculums, Ostomy Bags, Suction Catheters, Stomach Tubes, Feeding Tubes, Silicone Foley Catheter, Latex Foley Catheter, Suction Connecting Tube with Yankauer Handle, Endotracheal Tube, Oxygen Masks, Sterile and non-Sterile Nebulizers, 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, Sterile Surgical Gloves, Digital Thermometer, Infra-red Ear Thermometer, Digital Blood Pressure Monitor (Digital Sphygmomanometer), Central Venous Catheter Set, Gauze Roll, Absorbent Cotton Wool, Absorbent Cotton Ball, Medical Bandage, Medical Support, Medical Tapes, Patient Footwear, Pill Crusher, Medical Gloves, Face Masks, Disposable Cap, Disposable Shoe Cover, Isolation Gown, Disposable Coverall, Medical Forceps, Medical Brushes, Disposable I. D. Bracelets, Disposable Medical Cup, Face Shields, Medical Clippers, Surgical Suture with or without Needle, Disposable ECG Electrode

Suzhou Acmed Import & Export Co., Ltd.

Medical Glove CE TF

EU DECLARATION OF CONFORMITY

Manufacturer: Suzhou Acmed Import & Export Co., Ltd.
2-10016,436 Changjiang Road,215011 Suzhou,China
SRN: CN-MF-000023317SRN:

European Representative : MedPath GmbH
Mies-van-der-Oohe-Strasse 8, 80807
Munich,Germany
SRN: DE-AR-000000087

Product Name : Medical Glove (Vinyl)

Size: X-small, Small, Medium, Large, X-Large

GMDN Code: 47176 Vinyl examination/treatment glove, non-powdered
47177 Vinyl examination/treatment glove, powdered

Basic UDI-DI: 697279894EG03RF

Classification : Class I, according to Rule 1, Annex VIII, Regulation (EU) 2017/745

Applicable Standard: ISO13584:2016, EN455-1: 2000, EN455-2:2015, EN455-3:2015, EN455-4:2009
EN ISO374-1:2016, EN ISO 374-2:2014, EN 16523-1:2015, EN374-4:2013
EN ISO 374-5:2016, EN 420:2003+A1:2009

We herewith declare in sole responsibility that the above mentioned products meet the provision of the MDR EU_2017/45 and its transposition in national laws. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the declaration of conformity.

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

Notify Body : TUV SUD Product Service GmbH, Zertifizierstelle Ridlerstrabe .
65, 80339 Munichen, Germany

Certificate: Q6 003804 0004 Rev. 00

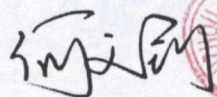
NB Identification number: 0123

Date CE Certificate is Expired: 2024-07-11

Date CE mark was affixed: 2021-09-10

Place:Suzhou JiangSuDate: 2021-09-10

Signature :



Name : Mark Ho

Position : General Manager

Suzhou Acmed Import & Export Co., Ltd.

Medical Glove CE TF

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European Representative : MedPath GmbH
Mies-van-der-Oohe-Strasse 8, 80807
Munich,Germany
SRN: DE-AR-000000087

Product Name : Medical Glove (Latex)

Size: X-small, Small, Medium, Large, X-Large

GMDN Code: 47172 Latex examination/treatment glove, non-powdered
47173 Latex examination/treatment glove, powdered

Basic UDI-DI: 697279894EG01RB

Classification : Class I, according to Rule 1, Annex VIII, Regulation (EU) 2017/745

Applicable Standard: ISO13584:2016, EN455-1: 2000, EN455-2:2015, EN455-3:2015, EN455-4:2009
ISO14971:2019, ISO10993-1:2020, ISO10993-5:2009, ISO10993-10: 2013

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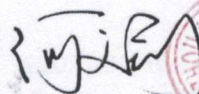
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Name : Mark Ho

Position : General Manager

