



Product Service

Certificate

No. Q6 051736 0013 Rev. 00

Holder of Certificate: **Unimax Medical Products Co., Ltd.**

Special No. 1 Liansai Road
Changshangkou Town
433024 Xiantao City, Hubei Province
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate:

Production and Distribution of Medical Gauze Products, Medical Bandages, Medical Non-woven Products, Disposable Medical Plastic Products, Medical Cotton Products, Zinc Oxide Plaster, Adhesive Dressing Tapes, ABD Pad, Surgical Drapes, Surgical Gowns, First-aid-kit, Surgical Gloves, Examination Gloves, Sterile Hemostatic Adhesive Dressing (Wound Plaster/Liquid Transfusion Plaster/Adhesive Wound Dressing), Medical Eye Pads, Urethral Catheters, Tracheal Tubes, Suction Catheters, Nelaton Catheters, Feeding Tubes, Stomach Tubes, Tracheostomy Tubes, Urine Bags, Umbilical Cord Clamps for Single Use, Disposable Medical Device of Infusion and Transfusion, Intravascular Catheters, Disposable Surgical Blades, Sterile Scalpel with Plastic Handle, Surgical Instruments, Wheelchairs, Blood Bags, Wooden Tongue Depressors, Alcohol Pads, Non-woven Face Masks

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). See also notes overleaf.

Report No.: SH1812016
Valid from: 2019-05-06
Valid until: 2021-06-30

Date, 2019-05-06

Stefan Preiß

Certificate

No. Q6 051736 0013 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): **Unimax Medical Products Co., Ltd.**
Special No. 1 Liansai Road, Changshangkou Town, 433024
Xiantao City, Hubei Province, PEOPLE'S REPUBLIC OF CHINA

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 051736 0015 Rev. 01

Manufacturer

Unimax

Medical Products Co., Ltd.

Special No. 1 Liansai Road

Changshangkou Town

433024 Xiantao City, Hubei Province

PEOPLE'S REPUBLIC OF CHINA

Product

Category(ies):

Urine Bag, Gauze Sponges, Gauze Balls, Non-woven Sponges, Gauze Bandages, Medical Eye Pad, Sterile Wound Plaster, Liquid Transfusion Plaster, Adhesive Wound Dressings, Surgical Drapes, Surgical Gowns, Sterile Plastic Cover, Non-woven Face Mask

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.:

SH19120CN01

Valid from:

2020-01-20

Valid until:

2023-11-27

Date,

2020-01-20

C.D.H

Christoph Dicks
Head of Certification/Notified Body



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
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 051736 0015 Rev. 01

Facility(ies):

**Unimax Medical Products Co., Ltd.
Special No. 1 Liansai Road, Changshangkou Town,
433024 Xiantao City, Hubei Province, PEOPLE'S
REPUBLIC OF CHINA**



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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 051736 0014 Rev. 01

Manufacturer:

Unimax

Medical Products Co., Ltd.

Special No. 1 Liansai Road
Changshangkou Town
433024 Xiantao City, Hubei Province
PEOPLE'S REPUBLIC OF CHINA

**Product
Category(ies):**

**Infusion Sets, Gauze Sponges (Swabs) with or
without X-ray Detectable, Gauze Balls with X-ray
Detectable, Laparotomy Sponges with or without
X-ray Detectable, Non-woven Sponges (Swabs)
without X-ray Detectable**

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.:

SH19120CN01

Valid from:

2020-01-20

Valid until:

2023-11-27

Date,

2020-01-20

Christoph Dicks
Head of Certification/Notified Body



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 051736 0014 Rev. 01

Facility(ies):

Unimax Medical Products Co., Ltd.

Special No. 1 Liansai Road, Changshangkou Town,
433024 Xiantao City, Hubei Province, PEOPLE'S
REPUBLIC OF CHINA