



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 077536 0012 Rev. 00**

## Manufacturer

**Changzhou Major**

**Medical Products Co., Ltd.**

No.1 Beiyang Road, Hexi Village, Zouqu Town

213144 Changzhou City, Jiangsu Province

PEOPLE'S REPUBLIC OF CHINA

## Product Category(ies):

**Wound Plasters,  
Liquid Transfusion Plasters,  
Adhesive Wound Dressings**

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.:**

SH19706EXT01

**Valid from:**

2020-03-03

**Valid until:**

2024-05-26

**Date,**

2020-03-03

Christoph Dicks

Head of Certification/Notified Body



# Certificate

No. Q5 077536 0011 Rev. 01

**Holder of Certificate:**

**Changzhou Major  
Medical Products Co., Ltd.**  
No.1 Beiyang Road, Hexi Village, Zouqu Town  
213144 Changzhou City, Jiangsu Province  
PEOPLE'S REPUBLIC OF CHINA

**Facility(ies):**

Changzhou Major Medical Products Co., Ltd.  
No.1 Beiyang Road, Hexi Village, Zouqu Town, 213144  
Changzhou City, Jiangsu Province, PEOPLE'S REPUBLIC OF  
CHINA

**Certification Mark:****Scope of Certificate:**

**Production and Distribution of  
Medical Tapes, Wound Plasters,  
Liquid Transfusion Plasters and Adhesive Wound  
Dressings, Ostomy bag, Surgical Mask,  
Medical Face Mask**

**Design, Development, Production and Distribution  
of Alginate Wound Dressing, Foam Wound  
Dressing, Hydrocolloid Wound Dressing**

**Applied Standard(s):**

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

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, 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:Q5 077536 0011 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:Q5 077536 0011 Rev. 01)

**Report No.:** SH2070601  
**Valid from:** 2020-09-20  
**Valid until:** 2023-09-19

**Date,** 2020-09-10

Christoph Dicks  
Head of Certification/Notified Body