



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, Zougu Town

213144 Changzhou City, Jiangsu Province PEOPLE'S REPUBLIC OF CHINA

Product Wound Plasters,

Category(ies): 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







Product Service

Certificate

No. Q5 077536 0011 Rev. 01

Holder of Certificate: Changzhou Major

Medical Products Co., Ltd.

No.1 Beiyang Road, Hexi Village, Zougu Town 213144 Changzhou City, Jiangsu Province

PEOPLE'S REPUBLIC OF CHINA

Changzhou Major Medical Products Co., Ltd. Facility(ies):

No.1 Beiyang Road, Hexi Village, Zougu 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**

EN ISO 13485:2016 Applied Standard(s):

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

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

2020-09-10

Christoph Dicks

Head of Certification/Notified Body

Date,