

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

C.D.H

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

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

Date, 2020-09-10

Christoph Dicks
Head of Certification/Notified Body