



Product Service

CERTIFICATE

No. Q5 17 05 45222 013

Holder of Certificate: **Changzhou Hualian Health Dressing Co., Ltd.**

No.55 Yuejin Road, Zouqu Town
213144 Changzhou
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: Design and Development,
Production and Distribution of
Adhesive Dressing Series (including Zinc Oxide
Adhesive Plaster, Medical Tape, Dressing Tape,
Self-Adhesive Bandage), First-Aid-Kit, Sterile
Hemostasis Adhesive Dressings Series (including
Sterile Wound Plaster, Liquid Transfusion Plaster
and Adhesive Dressing)

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). See also notes overleaf.

Report No.: SH1714916

Valid from: 2017-09-01

Valid until: 2020-08-31



Date, 2017-08-11

Stefan Preiß

Page 1 of 2



Product Service

CERTIFICATE**No. Q5 17 05 45222 013****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):

Jiangsu Excellence Medical Supplies Co., Ltd.
Zouqu Industrial Zone, Zouqu Town, 213144
Changzhou City, Jiangsu Province, PEOPLE'S
REPUBLIC OF CHINA

Changzhou Hualian Health Dressing Co., Ltd.
No.55 Yuejin Road, Zouqu Town, 213144
Changzhou, PEOPLE'S REPUBLIC OF CHINA

Changzhou Hualian Medical Devices Co., Ltd.
4 Floor, Standard Factory, Wujin Export
Processing Zone, No.66 Yanghu Road, Wujin,
213164 Changzhou City, Jiangsu Province,
PEOPLE'S REPUBLIC OF CHINA



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 17 07 45222 014**Manufacturer:****Changzhou Hualian Health
Dressing Co., Ltd.**

No.55 Yuejin Road, Zouqu Town

213144 Changzhou

PEOPLE'S REPUBLIC OF CHINA

**EC-Representative:****Shanghai International Holding
Corp. GmbH (Europe)**

Eiffestraße 80

20537 Hamburg

GERMANY

**Product
Category(ies):****First-Aid-Kit, Sterile Hemostasis
Adhesive Dressing Series (Sterile
Wound Plaster, Liquid Transfusion
Plaster and Adhesive Dressing)**

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.:

SH17149EXT01

Valid from:

2017-09-18

Valid until:

2022-09-17

Date, 2017-08-14

Stefan Preiß



TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

Page 1 of 2



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)

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