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## 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, Zougu 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.

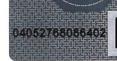
Report No.:

SH17149EXT01

Valid from:

2017-09-18 2022-09-17

Valid until:



Date, 2017-08-14

Stefan Preiß

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

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No. G2S 17 07 45222 014

Facility(ies):

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

Jiangsu Excellence Medical Supplies Co., Ltd. Zouqu Industrial Zone, Zouqu Town, 213144 Changzhou City, Jiangsu Province, 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

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