



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



*S. Preis*

**Date,** 2017-08-14

Stefan Preis

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

Page 1 of 2



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#### 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