

## 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 11 53056 020

Manufacturer:

Kunshan Jiehong Nonwoven

Product Co., Ltd.

895 Xinle Rd., Dianshanhu Town

215345 Kunshan

PEOPLE'S REPUBLIC OF CHINA



**EC-Representative:** 

Shanghai International Holding

Corp. GmbH (Europe)

Eiffestraße 80 20537 Hamburg **GERMANY** 

**Product** 

Category(ies):

Surgical Gowns, Surgical Drapes,

Sterile Instrumental Cover. Sterile Protective Cover

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.:

SH17031EXT01

Valid from:

2018-01-10 2023-01-09

Valid until:



Date. 2018-01-05

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

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Facility(ies):

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Kunshan Jiehong Nonwoven Product Co., Ltd. 66 Qiansheng Rd., Dianshanhu Town, 215345 Kunshan, PEOPLE'S REPUBLIC OF CHINA

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