



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 15 07 56732 013

**Manufacturer:** Taizhou Xinkang Medical Materials Co., Ltd.

No.18, Wuzhou ( South ) Road  
225300 Taizhou, Jiangsu  
PEOPLE'S REPUBLIC OF CHINA

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

Eiffestraße 80  
20537 Hamburg  
GERMANY



**Product Category(ies):** Sterile Gauze Sponges,  
Sterile Gauze Bandage,  
Sterile Absorbent Cotton Wool,  
Sterile Zig-Zag Absorbent Cotton Wool,  
Sterile Dental Cotton Rolls,  
Sterile Cotton Ball,  
Sterile Cotton Tip Applicator,  
Sterile Gauze Rolls, Sterile Gauze Pads,  
Sterile Surgical Towels,  
Sterile Non-woven Sponges,  
Sterile Triangular Bandage,  
First Aid Kit



*Nguyen Thi Tuyet Ha*

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.:** SH15244EXT01  
**Valid from:** 2015-10-12  
**Valid until:** 2020-10-11

*H.-H. Junker*

Hans-Heiner Junker



Date, 2015-09-07

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

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**Facility(ies):**

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No.18, Wuzhou ( South ) Road, 225300 Taizhou,  
Jiangsu, PEOPLE'S REPUBLIC OF CHINA



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