

金士達實業（武漢）有限公司
KINGSTAR INDUSTRIES (WUHAN) CO., LTD.

Huanhu Road, Jinyinhu, Dongxihu District, Wuhan, Hubei, China, 430040
TEL: +86-27-8577 3988 FAX: +86-27-8577 7688 Website: www.kingstarmedical.cn



Declaration of Conformity

Manufacturer: Kingstar Industries (Wuhan) Co., Ltd.

Address: Huanhu Road, Jinyin Hu, Dong Xi Hu District, 430048 Wuhan PEOPLE'S
REPUBLIC OF CHINA

European Representative: Karl Beese GmbH & Co.

Address: Großer Kamp 12-14 22885 Barsbüttel GERMANY

Product Name: X-ray detectable sponges (classification II a)

Gauze Sponges (classification I)

Model Number: Please refer to List of CE-labeled Products,


Classification (MDD, Annex IX): II a , I

Conformity Assessment Route: MDD93/42/EEC Annex V, section 3.

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

Signature:

Date:


11. 04. 2013

Position: President

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Product Name: Sterile Gauze Sponges,

Sterile Gauze Cutting,

Sterile Gauze Balls,

Sterile Lap Sponges,

Sterile Gauze Bandages,

Sterile Elastic Bandages,

Sterile Non-woven Sponges,

Sterile Non-woven Balls,

Sterile First Aid Dressing series,

Sterile Surgical Dressing Sheet,

Sterile Wound Dressing,

Sterile Adhesive Dressing series

(Sterile wound plaster, adhesive surgical dressing),

Sterile Eye Pad, First Aid Kits,

Sterile surgical Dressing kits

No. AM20110002

Declaration of Conformity

Manufacture: Allmed Medical Products Co, Ltd

Address: Room 1911, Hanggang Fuchun Business Building, 6031th Shennan
Middle Road, Shenzhen 518040, P. R. C.

European Representative: Shanghai International Trading Corp. GmbH
(Hamburg)

Address: Eiffestrasse Eiffestrasse 80, 20537 Hamburg, Germany

Product Name: X-ray Detectable Sponges

UMDNS Code: 13705

Model Number: Please refer to List of CE-labeled Products.

Classification (MDD, Annex IX): II_a

Conformity Assessment Route: MDD93/42/EEC Annex V, section 3.

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

DIRECTIVES

Medical Device Directive: The object of the declaration described above is in conformity with the Council Directive MDD 93/42/EEC amended by 2007/42/EC.

Standard Applied: All applicable harmonised standard (published in the official journal of the European Communities).

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstrasse 65, 80339 München, Germany

Identification number: CE0123

(EC) Certificate(s): G2 11 07 53379 010

Expire date of the Certificate: 2014-09-08

Start of CE Marking: 200X-XX-XX (Not start)

Place, Date of Issue: Guangdong, 2011-11-07

Signature:  2011.11.07
Name:

Director of Corporate QA & RA
Position: