

Jiangsu Province JianErKang Medical Dressing Co., Ltd

ADD : Zhixi Town Jintan Changzhou City Jiangsu China 213251

Tel: +86 519 82444628 Fax: +86 519 82444750

www.chinajek.com

Declaration of Conformity

Date: March 14, 2020

Manufacturer

Name: Jiangsu Province JianErKang Medical Dressing Co., Ltd
Address: Zhixi Town Jintan Changzhou City Jiangsu Province China
Zip Code: 213251
Tel: 0086 519 82444628
Fax: 0086 519 82444750

Products: Disposable medical face mask, 3ply, non sterile
Classification Class I

We herewith declare that the above-mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer and the notified body.

Directives

General applicable directives:
Medical Device Directive: Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC).

Standard:

All applicable harmonized Standards (published in the Official Journal of the European Communities)

Notified Body: TUV Product Service GmbH, Ridlerstr. 65, 80339
Muenchen, Germany

EC-REPRESENTATIVE: SHANGHAI INTERNATIONAL HOLDING CORP GMBH (EUROPE)
EIFFELSTRASSE 80, 20537 HUMBURG GERMANY

Certificate: G2S 052712 0027

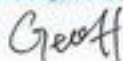
江苏省健尔康医用敷料有限公司

Signature: JIANGSU PROVINCE JIANERKANG MEDICAL DRESSING CO., LTD

Name: Mr. Geoff

Place: Jintan

Position: Manager





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Benannt durch/Designated by
 Zentralstelle der Länder
 für Gesundheitsschutz
 bei Arzneimittel- und
 Medizinprodukte
 ZLG-05-244.10.08



Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)
G2 052712 0028 Rev. 00

Manufacturer: **Jiangsu Province JianErKang**
Medical Dressing Co., Ltd.
 NO.1, Jianerkang Road
 Zhixi Industry Concentration Area, Zhixi Town
 213251 Jintan Changzhou City
 PEOPLE'S REPUBLIC OF CHINA

EC-Representative: Shanghai International Holding Corp. GmbH (Europe)
 Eifelstraße 80, 20537 Hamburg, GERMANY

Product **Sterile Gauze Swab (Sponge) with X-ray,**
Category(ies): Sterile Lap Sponge with X-ray,
Lubricating Jelly

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.: SH1803722
Valid from: 2018-09-03
Valid until: 2023-05-01

Date, 2018-09-03

Stefan Preiß

Page 1 of 2
 TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Riederstraße 65 • 80339 Munich • Germany



TÜV SÜD
ZERTIFIKAT ◆ CERTIFICATE ◆ certificado ◆ CERTIFICADO ◆ CERTIFICAT



Benannt durch/Designated by
 Zentrale Stelle der Länder
 für Gesundheitsbehörden
 bei Arzneimittel- und
 Medizinprodukten
 ZLG-85-244.10.08



EC Certificate

Production Quality Assurance System
 Directive 93/42/EEC on Medical Devices (MDD), Annex V
 (Devices in Class IIa, IIb or III)
G2 052712 0028 Rev. 00

Facility(ies):	Jiangsu Province JianErKang Medical Dressing Co., Ltd. NO.1, Jianerkang Road, Zhixi Industry Concentration Area, Zhixi Town, 213251 Jintan Changzhou City, PEOPLE'S REPUBLIC OF CHINA
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