



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-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)
Eiffestraße 80, 20537 Hamburg, GERMANY

Product Category(ies):

**Sterile Gauze Swab (Sponge) with X-ray,
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



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