

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev. 0

**Attachment to
Certificate**

Registration No.: DD 60136230 0001
Report No.: 16806484 003

Manufacturer: Shandong Kangli Medical Equipment
Technology Co., Ltd.
No. 206 National Road
Shizhong District, Zaozhuang City
277117 Shandong Province
China

Products:

- Hydrocolloid Wound Dressings
- Calcium Alginate Wound Dressings

**Aspects of manufacture concerned with securing and
maintaining sterile conditions:**

- sterile surgical gowns
- sterile surgical caps
- sterile surgical masks
- sterile surgical drapes
- sterile draw sheets
- sterile self-adhesive wound dressings
- sterile gauze bandages
- sterile surgical packs
- disposable transfer sheets

Date: 2019-11-05

Notified Body



EC Certificate
Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

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Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: DD 60114021 0001

Expiry Date: 2021-10-25

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2019-11-05

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TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC
concerning medical devices with the identification number 0197.