TÜVRheinland®

EC Certificate

Production Quality Assurance
Directive 93/42/EEC on Medical Devices, Annex V

Registration No.: DD 2068058-1

Manufacturer: Zhejiang Kanglidi Medical Articles CO., LTD.
Dongshan Industrial Zone, Shangwuzhai, Liushi, Yueqing,
325604 Zhejiang, P.R. China

Products: Sterile Hydrocolloid Dressings
For the following medical devices the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions:
Sterile Foam Dressings, Sterile Wound Dressings, First Aid Kits,
Sterile Wound Plasters, Sterile Alginate Wound Dressings, Ostomy Bags and Accessories

Replaces Approval, Registration No.: DD 60115020 0001

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.

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