TÜVRheinland®

EC Certificate

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

Registration No.: DD 60086519 0001

Report No.: 15061139 001

Manufacturer:

Products: Aspects of manufacture concerned with securing and maintaining sterile conditions of Sterile Wound Plasters, Sterile Wound Dressings, Sterile Non-adherent Pads

Replaces Approval, Registration No.: DD 60021952 0001

Expiry Date: 2018-07-24

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.

Notified Body

Effective Date: 2013-07-25

Date: 2013-07-25

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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.