

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

Registration No.: DD 60130227 0001

Report No.:

15050168 007

Manufacturer:

Jiangsu Jiele

Medical Dressing Co., Ltd.

15 Huanxi Street

Diaopu Taizhou Jiangsu 225323

China

Products:

Aspects of manufacture concerned with securing and maintaining sterile conditions: Gauze Sponges, Bandages,

Gauze Rolls, Cohesive Bandages, Dressing Kits

Replaces Approval, Registration No.: DD 60123986 0001

Notified Boo

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Expiry Date:

2022-07-12

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:

2018-09-17

Date:

2018-09-17

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.