

EC Certificate

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

Registration No.: DD 60133981 0001

Report No.: 15063749 007

Manufacturer: Nantong Jianan

Medical Products Co., Ltd. No. 5, Shanghai Road, Nantong Economic And

Technological Development Zone

226009 Jiangsu

China

Products: Lap Sponges; Aspects of manufacture concerned with

securing and maintaining sterile conditions of Sterile Gauze Sponges, Gauze Bandages, Cutting Gauzes Gauze Ziqzaqs, Gauze Rolls.

(see attachment for additional site included)

Replaces Approval, Registration No.: DD 60088475 0001

Expiry Date: 2023-11-03

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 a n EC type-examination certificate according to Annex III is required.

Effective Date:

2018-11-16

Date:

2018-11-16

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 0193.

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