

EC Certificate



Production Quality Assurance MDD Annex V

Registration No.: DD 2111681-1

Manufacturer: Shandong Kanglilai Medical Apparatus Co., Ltd.
No.8, Xinchang Road, Changyi City,
261300 Shandong Province, P.R. China

Products: Disposable Syringes with Needles
Disposable Infusion Sets
Disposable Intravenous Needles
Disposable Hypodermic Needles
Disposable Blood Transfusion Sets
Disposable Nasogastric Tubes

Aspects of Manufacture Concerned with Securing and
Maintaining Sterile Conditions:

Sterile Urine Bags and Disposable Medical Masks

Replaces Approval, Registration No.: DD 60139113 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
Tillystraße 2 · 90431 Nürnberg · Germany

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