

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

Registration No.: DD 60103475 0001

Report No.: 15085363 001

Manufacturer: Taizhou Kangjian Medical

Equipments Co., Ltd.

The Machine Electricity Zone (Hang Ni Kan) of Yuhuan County Zhejiang Province 317600

China

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: DD 60090434 0001

Expiry Date: 2020-09-27

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 Bo

Effective Date: 2015-09-28

Date: 2015-09-28

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

X. Ren

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