

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

Registration No.: DD 60137254 0001

Report No.: 15068147 008

Manufacturer: Changzhou Yuekang

Medical Appliance Co., Ltd. Jiaoxi Town, Wujin County 213116 Changzhou, Jiangsu

China

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: DD 60109881 0001

Expiry Date: 2024-03-12

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:

2019-03-13

Date:

2019-03-13

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.



Doc. 1/1, Rev. 0

TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg

Attachment to Certificate

Registration No.: DD 60137254 0001

Report No.: 15068147 008

Manufacturer:

Changzhou Yuekang

Medical Appliance Co., Ltd. Jiaoxi Town, Wujin County 213116 Changzhou, Jiangsu

China

Products:

Disposable Syringes, Disposable Infusion Sets, Disposable Blood Transfusion Sets, Disposable Intravenous Needles, Disposable Hypodermic Needles, Extension Tubes for Single Use, Urine Bags for Single Use, Vaginal Speculums for Single Use, Nelaton Catheters, Suction Catheters, Feeding Tubes, Stomach Tubes, Rectal Tubes, Disposable I.D. Bracelets, Paediatric Urine Collectors, Wound Plasters, Medical Tapes, Medical Dressings, Disposable Insulin Syringes, Disposable Tourniquets

Date: 2019-03-13

