

EC Certificate

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

Registration No.: DD 60113937 0001

Report No.: 15045630 008

Manufacturer: Huaian Tianda Medical

Instruments Co., Ltd.

No.106, East Songjiang Road, Huaiyin Economic & Technological

Development Zone

223002 Huaian City, Jiangsu

China

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: DD 60041602 0001

Expiry Date: 2021-10-26

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: 2016-10-27

Date: 2016-10-14

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

Notified

. Ren

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 60113937 0001

Report No.: 15045630 008

Manufacturer: Huaian Tianda Medical

Instruments Co., Ltd.

No.106, East Songjiang Road, Huaiyin Economic & Technological

Development Zone

223002 Huaian City, Jiangsu

China

Products:

- Disposable Surgical Blades (with and without handle)
- Sterile Blood Lancets
- Disposable Safety Lancets
- Alcohol Pads

Aspects of manufacture concerned with securing and maintaining sterile conditions:

- Umbilical Cord Clamps
- Urine Bags

Date: 2016-10-14

