

EC Certificate

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

Registration No.:

DD 60147743 0001

Report No.:

15045630 014

Manufacturer:

Huaian Tianda Medical Instruments Co., Ltd.

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

Development Zone

223002 Huaian City, Jiangsu

P.R. China

Products:

Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: DD 60113937 0001

Expiry Date:

2024-05-26

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:

2020-10-08

Date:

2020-10-08

Notified Body

Reinland

Notified Body

Reinland

Fuxiu Sheng

Reinland

Rei

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.



TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev.

Attachment to

Certificate

Registration No.: Report No.:

DD 60147743 0001

15045630 014

Manufacturer:

Huaian Tianda Medical Instruments Co., Ltd.

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

Development Zone

223002 Huaian City, Jiangsu

P.R. 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

Date: 2020-10-08

- Urine Bags

Notified Body

Fuxiu Sheng

TÜVRheinland