

**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

Fuxiu Sheng



**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**

**Attachment to  
Certificate**

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**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:** 2020-10-08

**Notified Body**



**Fuxiu Sheng**

