TÜVRheinland®

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

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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.

淮安市天达医疗器械有限公司 TIANDA MEDICAL(HUAIAN) CO., LTD

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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
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:

- 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

Notified Body

Date: 2020-10-08

Fuxiu Sheng

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

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