

EC Certificate

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

Registration No.: DD 60101257 0001

Report No.:

15065241 003

Manufacturer:

Huaian Angel Medical Instruments

Co., Ltd.

19 East Zhuhai Road

Huaian

223001 Jiangsu

China

Products:

Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: DD 60090034 0001

Expiry Date:

2019-01-26

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:

2015-05-22

Date:

2015-05-22

Notified Body

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. 0

Attachment to Certificate

Registration No.:

DD 60101257 0001 15065241 003

Report No.:

Manufacturer:

Huaian Angel Medical Instruments

Co., Ltd.
19 East Zhuhai Road
Huaian
223001 Jiangsu

China

Products:

- Disposable Suture Needles
- Disposable Surgical Blades & Scalpels with Plastic Handle
- Sterile Blood Lancets
- Surgical Instruments Kits

For the following medical devices the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions:

- Sterile Urinary Drainage Bags Disposable Umbilical Cord-Clamps

Date: 2015-05-22

Notified Body