



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

**Registration No.:** DD 60136001 0001

**Report No.:** 15065241 009

**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 60101257 0001

**Expiry Date:** 2024-01-26

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:** 2019-01-27

**Date:** 2019-01-17

Notified Body



Herbert Zhong

**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**

**Registration No.:** DD 60136001 0001  
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**Manufacturer:** Huaian Angel Medical Instruments  
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**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:** 2019-01-17

**Notified Body**

