

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

**Registration No.:** DD 60144541 0001

**Report No.:** 15096377 002

**Manufacturer:** Jiangsu HanHeng Medical Technology  
Co., Ltd.  
16-B4, #1 North Qingyang Road, Tianning District,  
213017 Changzhou, Jiangsu,  
China

**Products:** Medical Devices  
  
(see attachment for products included)

**Expiry Date:** 2024-05-27

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:** 2019-11-25

**Date:** 2019-11-25

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**

**Attachment to  
Certificate**

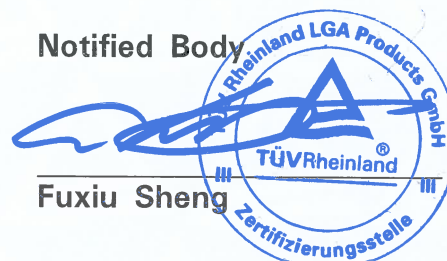
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Aspects of manufacture concerned with securing and maintaining sterile conditions: Gynecological Kits (including Disposable Vaginal Dilators, Disposable Cervical Samplers, Disposable Medical Drapes, Disposable Examination Gloves), Disposable Sampling Swabs, Disposable Cervical Samplers, Disposable Sampling Brushes, Umbilical Cord Clamps

**Date:** 2019-11-25

**Notified Body**



**Fuxiu Sheng**