

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

**Registration No.:** DD 60141341 0001

**Report No.:** 15096370 002

**Manufacturer:** Yingtai Suzhou Medical Technology  
Co., Ltd.  
No.390, Yongjin Road, Miaoqiao Street  
Tangqiao Town  
Zhangjiagang  
215615 Jiangsu  
P.R. China

**Products:** Disposable Circumcision Staplers, Disposable Laparoscopic  
Trocars  
Aspects of manufacture concerned with securing and  
maintaining sterile conditions: Surgical Gowns, Sterile  
Surgical Procedure Kits

**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:** 2020-05-09

**Date:** 2020-05-09

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.

**EC Certificate**  
**Directive 93/42/EEC Annex II, excluding Section 4**  
**Full Quality Assurance System**  
**Medical Devices**

**Registration No.:** HD 60141352 0001

**Report No.:** 15096370 002

**Manufacturer:** Yingtai Suzhou Medical Technology  
Co., Ltd.  
No.390, Yongjin Road, Miaoqiao Street  
Tangqiao Town  
Zhangjiagang  
215615 Jiangsu  
P.R. China

**Products:** Disposable Circular Staplers, Disposable Anorectal Staplers,  
Disposable Laparoscopic Cutting Staplers, Disposable Linear  
Cutting Staplers, Rubber Surgical Gloves

**Expiry Date:** 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 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 II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

**Effective Date:** 2020-05-09

**Date:** 2020-05-09

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.

# Certificate

The Certification Body of  
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**Yingtai Suzhou Medical Technology  
Co., Ltd.**  
No.390, Yongjin Road, Miaoqiao Street  
Tangqiao Town  
Zhangjiagang  
215615 Jiangsu  
P.R. China

has established and applies a quality management system for medical devices  
for the following scope:

**(see attachment for scope included)**

Proof has been furnished that the requirements specified in

**EN ISO 13485:2016**

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2020-05-09  
Certificate Registration No.: SX 60141331 0001  
An audit was performed. Report No.: 15096370 002  
This Certificate is valid until: 2022-08-13

Certification Body



Date 2020-05-09



**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**

Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>



**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

Doc. 1/1, Rev.0

**Attachment to  
Certificate**

**Registration No.:** SX 60141331 0001  
**Report No.:** 15096370 002

**Organization:** Yingtai Suzhou Medical Technology  
Co., Ltd.  
No.390, Yongjin Road, Miaoqiao Street  
Tangqiao Town  
Zhangjiagang  
215615 Jiangsu  
P.R. China

**Scope:**

Design and Development, Manufacture and Distribution of  
Disposable Circular Staplers, Disposable Anorectal Staplers,  
Disposable Laparoscopic Cutting Staplers, Disposable Linear  
Cutting Staplers, Rubber Surgical Gloves

Manufacture and Distribution of Disposable Circumcision  
Staplers, Disposable Laparoscopic Trocars, Surgical Gowns,  
Sterile Surgical Procedure Kits

**Certification Body**



**Date:** 2020-05-09

  
**Herbert Zhong**

