

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

**Registration No.:** HD 60107223 0001

**Report No.:** 15090624 001

**Manufacturer:** Changzhou Haiers Medical Devices  
Co., Ltd.  
No. 2188, Longcheng Road  
Changzhou City  
213012 Jiangsu  
China

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

**Expiry Date:** 2021-01-11

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:** 2016-01-12

**Date:** 2016-01-12

Notified Body



X. Ren

**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.:** HD 60107223 0001  
**Report No.:** 15090624 001

**Manufacturer:** Changzhou Haiers Medical Devices  
Co., Ltd.  
No. 2188, Longcheng Road  
Changzhou City  
213012 Jiangsu  
China

**Products:**

- Disposable Circular Staplers
- Disposable Hemorrhoids Staplers
- Disposable Linear Staplers and Reloading Units
- Disposable Linear Cutter Staplers and Reloading Units
- Disposable Trocars
- Disposable Skin Staplers
- Disposable Incision Dilators
- Disposable Endoscopic Linear Cutter Staplers  
and Reloading Units
- Disposable Curved Surgical Staplers and Reloading Units

**Date:** 2016-01-12

**Notified Body**

**X. Ren**



# Certificate

The Certification Body of  
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**Changzhou Haiers Medical Devices  
Co., Ltd.**  
**No. 2188, Longcheng Road**  
**Changzhou City**  
**213012 Jiangsu**  
**China**

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

**Design and Development, Manufacture and Distribution of  
Medical Devices**  
**(see attachment for products 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: 2019-05-24  
Certificate Registration No.: SX 60135709 0001  
An audit was performed. Report No.: 15090624 006  
This Certificate is valid until: 2022-01-29

Certification Body



Date 2019-05-24



M.Sc. M. Aihara

**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**

**Attachment to  
Certificate**

**Registration No.:** SX 60135709 0001  
**Report No.:** 15090624 006

**Organization:** Changzhou Haiers Medical Devices  
Co., Ltd.  
No. 2188, Longcheng Road  
Changzhou City  
213012 Jiangsu  
China

**Scope:**

**Products:**

- Disposable Circular Staplers
- Disposable Hemorrhoids Staplers
- Disposable Linear Staplers and Reloading Units
- Disposable Linear Cutter Staplers and Reloading Units
- Disposable Trocars
- Disposable Skin Staplers
- Disposable Incision Dilators
- Disposable Endoscopic Linear Cutter Staplers  
and Reloading Units
- Disposable Curved Surgical Staplers and Reloading Units



**Certification Body**



**Date:** 2019-05-24

  
**M.Sc. M. Aihara**