

# Certificate

The Certification Body of  
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**Changzhou Haida Medical  
Equipment Co., Ltd.**  
**Sanhekou Industrial Park**  
**Zhenglu Town, Tanning District**  
**Changzhou**  
**213115 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 13485:2012**  
**EN ISO 13485:2012/AC:2012**

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

Effective Date:

2016-12-13

Certificate Registration No.:

SX 60113928 0001

An audit was performed. Report No.: 15046198 007

This Certificate is valid until:

2019-02-28

Certification Body



Date 2016-12-13



X. Ren

**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 60113928 0001  
15046198 007**

**Organization:**

**Changzhou Haida Medical  
Equipment Co., Ltd.  
Sanhekou Industrial Park  
Zhenglu Town, Tianning District  
Changzhou  
213115 Jiangsu  
China**

**Scope:**

**Products:**

- Disposable Circular Staplers
- Disposable Linear Staplers
- Disposable Hemorrhoids Staplers
- Disposable Linear Cutter Staplers
- Disposable Purse String Staplers
- Disposable Curved Cutter Staplers
- Disposable Endo Cutter Staplers
- Disposable Skin Staplers
- Disposable Trocars
- Disposable Incision Retractors
- Single Incision Laparoscopy Surgery Ports
- Disposable Great Saphenous Vein Strippers
- Disposable Circumcision Staplers



**Deutsche  
Akreditierungsstelle  
D-ZM-14169-01-02**

**Date: 2016-12-13**

**Certification Body**



**X. Ren**





## EC Certificate

TÜVRheinland

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

Registration No.: HD 60113927 0001

Report No.: 15046198 007

### Manufacturer:

Changzhou Haida Medical  
Equipment Co., Ltd.  
Sanhekou Industrial Park  
Zhenglu Town, Tianning District  
Changzhou  
213115 Jiangsu  
China

### Products:

Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: HD 60105960 0001



### Expiry Date:

2021-11-21

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: 2016-12-13

Date: 2016-12-13



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 60113927 0001  
**Report No.:** 15046198 007

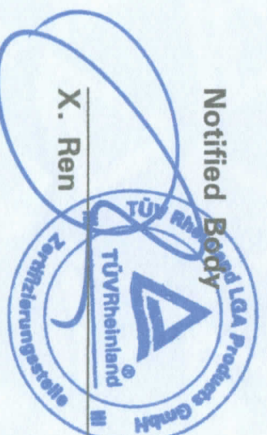
**Manufacturer:**  
**Changzhou Haida Medical  
Equipment Co., Ltd.**  
**Sanhekou Industrial Park**  
**Zhenglu Town, Tianning District**  
**Changzhou**  
**213115 Jiangsu**  
**China**

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**Notified Body**



**Date: 2016-12-13**