

# 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, Tianning 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 13485:2016**

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

Effective Date: 2019-11-05  
Certificate Registration No.: SX 60135550 0001  
An audit was performed. Report No.: 15046198 010  
This Certificate is valid until: 2022-02-28

Certification Body



Date 2019-11-05



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

Doc. 1/1, Rev. 0

**Attachment to  
Certificate  
Registration No.:  
Report No.:**

**SX 60135550 0001  
15046198 010**

**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



**Certification Body**



**Date: 2019-11-05**





TÜVRheinland®

**EC Certificate**  
**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

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**

Doc. 1/1, Rev. 0

**Attachment to  
Certificate**

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

**Manufacturer:** Changzhou Haida Medical  
Equipment Co., Ltd.  
Sanhekou Industrial Park  
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213115 Jiangsu  
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**Products:**

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**Date:** 2016-12-13

**Notified Body**

