

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

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 60135550 0001
Report No.: 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



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

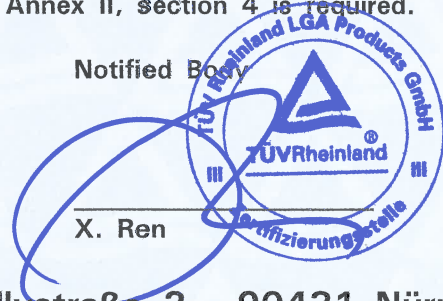
The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, 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

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

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
Zhenglu Town, Tianning District
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213115 Jiangsu
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Date: 2016-12-13

Notified Body

