

TÜVRheinland

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. Notified Bodynd LGA Produ

Effective Date:

2016-01-12

Date:

2016-01-12

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.



Doc. 1/1, Rev. 0

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

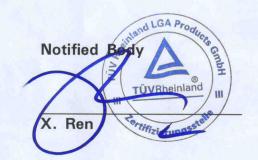
Changzhou City 213012 Jiangsu

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





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

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



Date 2019-05-24



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.:

SX 60135709 0001 15090624 006

Organization:

Report No.:

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

Akkreditierungsstelle D-ZM-14169-01-02

2019-05-24

Certification Body TÜVRheinland ertifizierungs