

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2068432-1

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

Scope: Design and Development, Manufacture and Distribution of 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, Disposable Circumcision Staplers

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 244410603-200
Effective date: 2022-10-28
Expiry date: 2025-02-28
Issue date: 2022-10-28



Fuxiu Sheng
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH • 51105 Köln

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

Contact

Tel. +49 911 655-5225
Mail: service
@de.tuv.com

Date October 28, 2022

Application for: QMS

Certificate No. : SX 2068432-1

Requirement : EN ISO 13485:2016

Dear Madame or Sir

Enclosed please find the new certificate No. SX 2068432-1 replacing the previous certificate.

With effective date of the new certificate, the previous certificate becomes invalid.

Best regards,



Fuxiu Sheng
Certification body

TÜV Rheinland
LGA Products GmbH

Am Grauen Stein
51105 Köln
Germany

Headquarter

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90431 Nuremberg

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Board of Management

Dipl.-Ing.
Jörg Mähler, Spokesman

Dipl.-Kfm.
Dr. Jörg Schlösser

Nuremberg HRB 26013
VAT No.: DE 811835490

Chairman of the
Supervisory Board

Dipl.-Ing. Ralf Scheller

EC Certificate



Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.: HD 2068432-1

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

Products: Disposable Circumcision Staplers, 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

Replaces Approval, Registration No.: HD 60144816 0001

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.

Report No.: 15046198 015

Effective date: 2021-03-16

Expiry date: 2024-05-26

Issue date: 2021-03-16



Fuxiu Sheng
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

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Changzhou Haida Medical Equipment
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Changzhou,
213115 Jiangsu
P.R. China

Contact

Tel. +49 911 655-5225
Mail: service@de.tuv.com

Date March 16, 2021

Application for: Vollst. QMS, Anhang II MDD

Certificate No.: HD 2068432-1
Requirement : Richtlinie 93/42/EWG

Dear Madame or Sir

Enclosed please find the new certificate No. HD 2068432-1 replacing the previous certificate.

With effective date of the new certificate, the previous certificate becomes invalid.

Best regards,



Fuxiu Sheng
Certification body

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