TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**Changzhou City Zhiye
Medical Devices Institute
No. 127, Xiacheng Road, Mahang
Changzhou
Jiangsu 213162
China**

has established and applies a quality management system for medical devices for the following scope:

Design and Development, Manufacture and Distribution of Medical Products (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:	2018-05-31
Certificate Registration No.:	SX 60128848 0001
An audit was performed. Report No.:	15059497 008
This Certificate is valid until:	2021-05-30

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date 2018-05-11

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierstelle

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@tuv.com http://www.tuv.com/safety

Digitally signed by Rusu Ghenadie
Date: 2020.01.19 14:26:18 EET
Reason: MoldSign Signature
Location: Moldova

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60128848 0001
Report No.: 15059497 008

Organization:
Changzhou City Zhiye
Medical Devices Institute
No. 127, Xiacheng Road, Mahang
Changzhou
Jiangsu 213162
China

Scope:

Products:
- Non-vascular Stents
- Dilators
- Staplers and Cartridges
- Biopsy Forceps
- Hernia Patchs
- Skin Staplers and Removers
- Disposable Endoscopic Scissors
- Disposable Endoscopic Dissectors
- Disposable Endoscopic Graspers
- Disposable Endoscopic Retrieval Bags
- Disposable Clip Appliers
- Disposable Trocars
- Disposable Suction and Irrigation Tubes
- Disposable Veress Needles
- Hernia Staplers
- Purse Strings Staplers
- Reusable Surgical Staplers
- Disposable Endoscopic Ligating Loops

Certification Body

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TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

X Ren

Date: 2018-05-11

EC Certificate

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

TÜVRheinland®

Registration No.: HD 60128843 0001

Report No.: 15059497 008

Manufacturer:
Changzhou City Zhiye
Medical Devices Institute
No. 127, Xiacheng Road, Mahang
Changzhou
Jiangsu 213162
China

Products: Medical Products

(see attachment for products included)

Replaces Approval, Registration No.: HD 60085899 0001

Expiry Date: 2023-05-30

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: 2018-05-31

Date: 2018-05-11

Notified Body LGA Products GmbH

X. Rep

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.

TÜVRheinland®

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60128843 0001
Report No.: 15059497 008

Manufacturer:
Changzhou City Zhiye
Medical Devices Institute
No. 127, Xiacheng Road, Mahang
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Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

X. Ren

Date: 2018-05-11