

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

**Registration No.:** HD 60150282 0001

**Report No.:** 15073963 012

**Manufacturer:** Changzhou JiuHong  
Medical Instrument Co., Ltd.  
No. 256 Mingxin Middle Road  
Wujin District  
Changzhou  
213164 Jiangsu  
P.R. China

**Products:** Medical Devices  
  
(see attachment for products and additional site included)  
  
Replaces Approval, Registration No.: HD 60137560 0001

**Expiry Date:** 2024-05-26

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:** 2020-07-09

**Date:** 2020-07-09



Notified Body

Fuxiu Sheng

**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**

**Attachment to  
Certificate**

**Registration No.:** HD 60150282 0001  
**Report No.:** 15073963 012

**Manufacturer:** Changzhou Jiuhong  
Medical Instrument Co., Ltd.  
No. 256 Mingxin Middle Road  
Wujin District  
Changzhou  
213164 Jiangsu  
P.R. China

**Products:**

Disposable Endoscopic Hemoclips, Disposable Polyp Snares,  
Disposable Electric Biopsy Forceps, Disposable Non-electric  
Biopsy Forceps, Disposable Cytology Brushes,  
Gastrointestinal and Biliary Balloon Catheters, Grasping  
Forceps, Non-vascular Guidewires, Stone Extraction Balloons,  
Stone Extraction Baskets, Kyphoplasty Balloon Catheters,  
Multiple Band Ligators, Injection Needles, Balloon  
Kyphoplasty Kits;

Aspects of manufacture concerned with securing and  
maintaining sterile conditions:

Disposable Bite Blocks, Cleaning Brushes for Endoscope,  
Bougie Dilator Sets, Balloon Inflators, Biopsy Valves,  
Polyp Traps, Disposable Medical Masks

**Site included:**

Changzhou Jiuhong Medical Instrument Co., Ltd.  
No. 87, Majia Road, Lingjia Village, Hutang Town,  
Wujin District, Changzhou, Jiangsu 213164, China

**Notified Body**

**Date:** 2020-07-09

  
**Fuxiu Sheng**

**Business Stream Products**  
**Certification Department**



**TÜVRheinland®**

**LGA**

**Precisely Right.**

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

Changzhou Jiuhong  
Medical Instrument Co., Ltd.  
No. 256 Mingxin Middle Road  
Wujin District  
Changzhou  
213164 JIANGSU  
P.R. CHINA

Contact

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Date July 16, 2020

**Application for : Vollst. QMS, Anhang II MDD**

Certificate No. : HD 60150282 Sheet 0001

Device : Only for QM-System audit

Test requirement : Richtlinie 93/42/EWG

Dear Madame or Sir,

Enclosed please find the new certificate No. HD 60150282 0001 replacing the previous certificate.

With effective date of the new certificate, the previous certificate (number see new certificate) becomes invalid.

Kind regards

Certification body

Fuxiu Sheng

Test sample: no, documentation available

TÜV Rheinland  
LGA Products GmbH

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90431 Nürnberg

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