

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

**Registration No.:** HD 60141076 0001

**Report No.:** 15082678 007

**Manufacturer:** Jiangsu Vedkang Medical Science &  
Technology Co., Ltd.  
No. 52, Guoxiang Road  
Wujin Economic Development Zone  
Changzhou  
213149 Jiangsu  
China

**Products:** Medical Devices  
  
(see attachment for products included)  
  
Replaces Approval, Registration No.: HD 60136146 0001

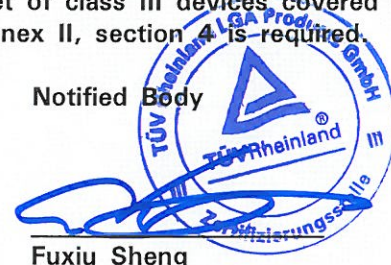
**Expiry Date:** 2024-05-27

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:** 2019-07-22

**Date:** 2019-07-22

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**

Doc. 1/1, Rev. 0

**Attachment to  
Certificate**

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**Products:**

Disposable Polyp Snares, Injection Needles, Disposable  
Non-electric Biopsy Forceps, Gastrointestinal and Biliary  
Balloon Catheters, Stone Extraction Baskets, Stone  
Extraction Balloons, Non-vascular Guidewires, Disposable  
Nasal Biliary Drainage Tubes, Disposable Endoscopic  
Hemoclips, Disposable Cytology Brushes, Disposable Bougie  
Dilators, Disposable Grasping Forceps, Disposable Hot  
Biopsy Forceps, Kyphoplasty Balloon Catheters, Disposable  
Cold Snares;

Aspects of manufacture concerned with securing and  
maintaining sterile conditions:

Disposable Spray Catheters, Balloon Inflators, Disposable  
Bite Blocks, Biopsy Valve, Polyp Traps, Cleaning Brushes  
for Endoscope

**Date:** 2019-07-22

**Notified Body**



**Fuxiu Sheng**