

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

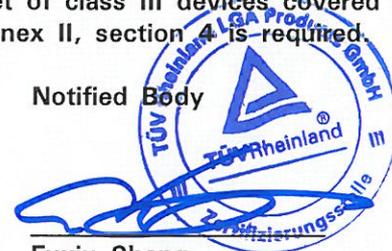
Expiry Date: 2024-05-27

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

**Attachment to
Certificate**

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:

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

Business Stream Products
Certification Department



TÜVRheinland®

LGA

Precisely Right.

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

Jiangsu Vedkang Medical Science &
Technology Co., Ltd.
No. 52, Guoxiang Road
Wujin Economic Development Zone
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213149 JIANGSU
CHINA

Contact

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Date July 22, 2019

Application for : **Vollst. QMS, Anhang II MDD**
Certificate No. : HD 60141076 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 60141076 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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