

EU Certificate

Quality Management System

REGULATION (EU) 2017/745 on Medical Devices, Annex IX Chapter I, Section 2 and 3 and Chapter III

Registration No.: HZ 2156843-1



Manufacturer: **Jiangsu Vedkang Medical Science and Technology Co., Ltd.**

No. 52, Guoxiang Road,
Wujin Economic Development Zone,
Changzhou
213149 Jiangsu
P.R. China

EUDAMED Single
Registration No.: CN-MF-000008462

Products:

Products of class IIb:

K020101 - MONO- AND BIPOLAR DEVICES, SINGLE-USE
MONO- AND BIPOLAR SURGICAL INSTRUMENTS, SINGLE-USE
- Disposable Endoscopic Submucosal Dissection Knives

Products of class IIa:

G030101 - GASTROINTESTINAL ENDOSCOPY, BALLOON CATHETERS

- Gastrointestinal and Biliary Balloon Catheters

- 3-Stage Balloon Dilation Catheters

G030201 - DIGESTIVE ENDOSCOPY, NEEDLES

- Injection Needles

G030301 - POLYPECTOMY SNARES

- Disposable Cold Snare

G030501 - DIGESTIVE ENDOSCOPY, RETRIEVAL DEVICES

- Disposable Grasping Forceps

G030801 - GASTROINTESTINAL ENDOSCOPY, FORCEPS, SINGLE-USE

- Disposable Non-electric Biopsy Forceps

R070201 - BRONCHOSCOPIC SURGERY FORCEPS, SINGLE-USE

- Disposable Non-electric Biopsy Forceps

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled. If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.: 244420676-200

Effective date: 2023-11-22

Expiry date: 2028-11-21

Issue date: 2023-11-22



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlgm.de
BS-MDR-091



P. Xiang Sheng
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

EU Certificate

Quality Management System
REGULATION (EU) 2017/745 on Medical Devices, Annex IX Chapter I,
Section 2 and 3 and Chapter III

Registration No.: HZ 2156843-1



Manufacturer: **Jiangsu Vedkang Medical Science and Technology Co., Ltd.**
No. 52, Guoxiang Road,
Wujin Economic Development Zone,
Changzhou
213149 Jiangsu
P.R. China
Products of class I, sterile:
K010201 - MINIMALLY INVASIVE SURGERY SURGICAL INSTRUMENTS,
SINGLE-USE
- Disposable Spray Catheters
The scope of certification is limited to the aspects relating to establishing, securing and maintaining sterile conditions

Authorised representative(s): Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany

Certificate history		
Revision:	Description:	Issue date:
0	Initial Revision	2023-11-22

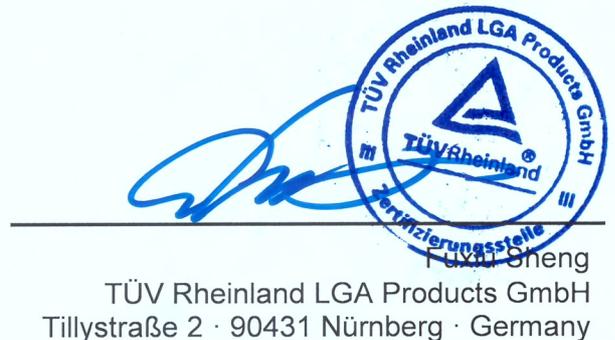


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TÜV Rheinland LGA Products GmbH • 51105 Köln

**Jiangsu Vedkang Medical Science and
Technology Co., Ltd.**

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Date November 23, 2023

Application for: QMS

Certificate No. : HZ 2156843-1

Requirement : REGULATION (EU) 2017/745 on Medical Devices, Annex IX
Chapter I, Section 2 and 3 and Chapter III

Dear Madame or Sir,

Your Quality Management System has been audited and fulfills the above-mentioned requirement.

Enclosed please find the certificate No. HZ 2156843-1.

Best regards,



Fuxiu Sheng
Certification body

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