

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

Registration No.: HD 60142054 0001

Report No.: 15072389 009

Manufacturer: Victor Medical Instruments
Co., Ltd.
No. 21 Huafeng Road
Dingyan Subdistrict, Wujin District
213018 Changzhou, Jiangsu Province
China

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: HD 60135102 0001

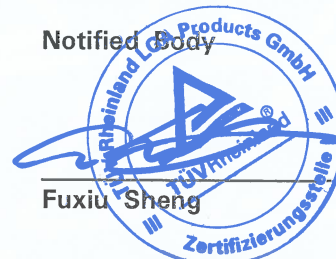
Expiry Date: 2024-05-27

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: 2019-08-27

Date: 2019-08-27

Notified Body



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**

Registration No.: HD 60142054 0001
Report No.: 15072389 009

Manufacturer: Victor Medical Instruments
Co., Ltd.
No. 21 Huafeng Road
Dingyan Subdistrict, Wujin District
213018 Changzhou, Jiangsu Province
China

Products:

- Single Use Circular Staplers
- Single Use Linear Staplers
- Single Use Linear Cutters
- Reloads of Single Use Endoscopic Linear Cutter Staplers
- Single Use Purse-String Instruments
- Single Use Curved Cutters
- Single Use Hemorrhoidal Staplers
- Single Use Endo Clip Applicators
- Single Use Skin Staplers & Removers
- Single Use Trocars
- Single Use Endoscopic Retrievers
- Single Use Endoscopic Suction and Irrigation Cannula
- Veress Needles
- Single Use Endoscopic Staplers

Date: 2019-08-27

Notified Body



TÜV Rheinland LGA Products GmbH • 51105 Köln

Victor Medical Instruments
Co., Ltd.
No. 24-4 Changyang Road, West Taihu Science and Technology
Industrial Park, Changzhou,
213115 Jiangsu
P.R. China

Contact

Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com
Date May 13, 2022

Application for : QMS
Certificate No. : HD 60142054 0001
Requirement : Richtlinie 93/42/EWG
Confirmation letter ID : 2019-08-27_HD 60142054 0001
Report no. : 244361573-200

Dear Madame or Sir,

Update of information to Certificate no. HD 60142054 0001, issued on 15.03.2022

The change notification received on 19.03.2021 related to the information stipulated on the above mentioned certificate was assessed and information confirmed.

We confirm that the change notification is not considered a significant change in design or intended purpose under Regulation (EU) 2017/745 on medical devices (MDR), Article 120(3).

With this document we would like to confirm the following updated information to the afore mentioned certificate

Revised Manufacturer address

Old Manufacturer address: No. 21 Huafeng Road, Dingyan Subdistrict, Wujin District, Changzhou, 213018, Jiangsu, P.R. China

New Manufacturer address: No. 24-4 Changyang Road, West Taihu Science and Technology Industrial Park, Changzhou, 213115 Jiangsu, P.R. China

Best regards,



Fuxiu Sheng
Certification body

MS-0045446 rev 0

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