EC Certificate

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

Registration No.: HD 60147407 0001

Report No.: 15054468 010

Manufacturer:
Hangzhou Kangji
Medical Instrument Co., Ltd.
No. 1668 Chunjiang East Road,Economic
Development Zone,Tonglu
Hangzhou
311501 Zhejiang
P.R. China

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: HD 60117691 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: 2020-03-05

Date: 2020-03-05

Notified Body

Jason Pan

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.

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Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60147407 0001
Report No.: 15054468 010

Manufacturer:
Hangzhou Kangji
Medical Instrument Co., Ltd.
No. 1668 Chunjiang East Road,Economic
Development Zone,Tonglu
Hangzhou
311501 Zhejiang
P.R. China

Products:

- Non-sterile Reusable Electrosurgical Electrodes
- Electrosurgical Electrodes for Single Use
- Disposable Veress Needles
- Disposable Trocars
- Disposable Ligation Clips (Metallic and Non-Metallic)
- Rigid Endoscopes
- Disposable Suction and Irrigation Sets
- Disposable Uterine Manipulator and Vaginal Delineators
- Reusable Uterine Manipulator and Vaginal Delineators
- Specimen Retrieval Bags
- Disposable S.I.L.S. Ports
- Disposable Suction Tubes

Notified Body

Jason Pan

TÜVRheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date: 2020-03-05