TÜVRheinland®

EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60151805 0001

Report No.: 15064567 012

Manufacturer: Changzhou Lookmed
Medical Instrument Co., Ltd.
Building 3, Building 5
No. 10 Chenghe Road
Lijia Town Industry Zone, Wujin
Changzhou City
213176 Jiangsu
P.R. China

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: DD 60132648 0001

Expiry Date: 2023-06-20

The Notified Body hereby declares that the requirements of Annex V 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 V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2021-05-19

Date: 2021-05-19

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Herbert Zhong

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.

Digitally signed by Jighili Tatiana
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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate

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Products:

- Disposable Biopsy Forceps
- Disposable Skin Staplers
- Disposable Skin Plasters
- Disposable Wound Retractors
- Disposable Trocars
- Disposable Retrieval Endo Bags
- Ligation Clips
- Hemorrhoidal Ligators with Anoscopes

For the following medical devices the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions:

- Disposable Cytology Brushes

Notified Body

Date: 2021-05-19

Herbert Zhong

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle