

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

Registration No.: DD 60132648 0001

Report No.: 15064567 007

Manufacturer:

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

Products:

(see attachment for products included)

Replaces Approval, Registration No.: DD 60113807 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:

2018-09-17

Date:

2018-09-17



TÜV Rheinland LGA Products GmbH - Tillystraße 20431 Nürnberg TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.



Doc. 1/1, Rev. 0

TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg

Attachment to Certificate Registration No.: Report No.:

DD 60132648 0001 15064567 007

Manufacturer:

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

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
- Disposable Umbilical Clamps and Cutters

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

- Disposable Cytology Brushes



Date: 2018-09-17