EC Certificate

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

TÜVRheinland

Registration No.: HD 60132442 0001

Report No.: 15060022 007

Manufacturer:
Jiangsu Maslech Medical
Technology Co., Ltd.
Building G39, The Third Period
Factory Area, China Medical City
Taizhou City
225300 Jiangsu
China

Products:
Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: HD 60109154 0001

Expiry Date: 2023-06-08

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: 2018-09-18

Date: 2018-09-18

Notified Body

X. Ren

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.

TÜVRheinland

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Certificate
Registration No.: HD 60132442 0001
Report No.: 15060022 007

Manufacturer: Jiangsu Maslech Medical
Technology Co., Ltd.
Building G39, The Third Period
Factory Area, China Medical City
Taizhou City
225300 Jiangsu
China

Products:

Implantable Ligating Clips, Disposable Biopsy Forceps, Disposable Retrieval Devices, Disposable Sheath Trocars, Disposable Cervical Brushes, Disposable Suction Irrigation Devices

Aspects of manufacture concerned with securing and maintaining sterile conditions:

Laryngoscopes, Manual Suction Units

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

X. Ren

Date: 2018-09-18