



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

Registration No.: HD 60110017 0001

Report No.: 15093038 001

Manufacturer: Hangzhou Optica Medical
Instrument Co., Ltd.
No.88 West Baiyunyuan Road, Tonglu
Hangzhou
311500 Zhejiang
China

Products: Medical Devices
(see attachment for products included)

Replaces Approval, Registration No.: HD 60038654 0001

Expiry Date: 2021-05-02

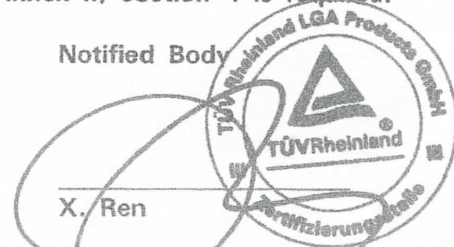
The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, 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: 2016-05-03

Date: 2016-05-03

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.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: HD 60110017 0001
Report No.: 15093038 001

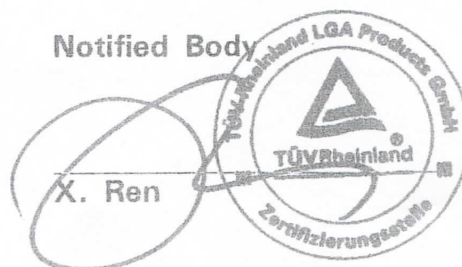
Manufacturer: Hangzhou Optica Medical
Instrument Co., Ltd.
No.88 West Baiyunyuan Road, Tonglu
Hangzhou
311500 Zhejiang
China

Products:

- Medical Titanium Clips with/without Clip Applicators
- Medical Vapour-resectoscopes
- Disposable Electrode Surgical Instruments
- Rigid Endoscopes
- Disposable Endoscopy Surgical Instruments
- Reusable Electrode Surgical Instruments

Date: 2016-05-03

Notified Body



Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**Hangzhou Optcla Medical
Instrument Co., Ltd.
No.2 Fengxiang Road
Economic Development Zone, Tonglu
Hangzhou
311508 Zhejiang
China**

has established and applies a quality management system for medical devices
for the following scope:

**Design and Development, Manufacture
and Distribution of Medical Devices
(see attachment for products included)**

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2018-03-02
Certificate Registration No.: SX 60127154 0001
An audit was performed. Report No.: 15093038 004
This Certificate is valid until: 2021-03-01

Certification Body



Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date 2018-03-02

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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X. Ren

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60127154 0001
Report No.: 15093038 004

Organization: Hangzhou Optica Medical
Instrument Co., Ltd.
No.2 Fengxiang Road
Economic Development Zone, Tonglu
Hangzhou
311508 Zhejiang
China

Scope:

Products:
Cysto-urethrosopes, Sinoscope and Surgical Instruments,
Operation Cutting Aspirators, Sigmoid-proctoscope and
Surgical Instruments, Medical Cold Light Sources, Hold
Laryngoscopes, Irrigation Pumps, Medical Resectoscopes,
Hysteroscope and Surgical Instruments, Oscopes,
Laryngoscopes, Rigid Endoscopes, Disposable
Endoscopy Surgical Instruments, Medical Titanium Clips
with/without Clip Applicators, Disposable Electrode
Surgical Instruments, Endoscope Camera Systems, Reusable
Electrode Surgical Instruments, Lithotriptoscope
Instruments, Gynecology Instruments, Laparoscopic
Instruments, Microlaryngoscope Instruments,
Disposable Camera Sleeves

Certification Body



Date: 2018-03-02

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