

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



Date 2018-03-02

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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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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