



# Certificate

The Certification Body of  
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization  
**Hangzhou Optcla Medical  
Instrument Co., Ltd.**  
No.88 West Baiyunyuan Road, Tonglu  
Hangzhou  
311500 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 13485:2012  
EN ISO 13485:2012/AC:2012**

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

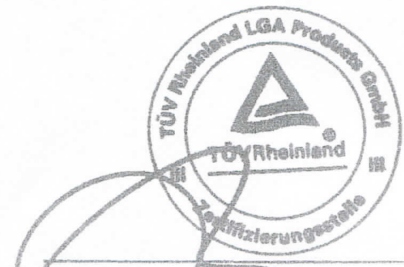
Effective Date: 2016-05-06  
Certificate Registration No.: SX 60110018 0001  
An audit was performed. Report No.: 15093038 001  
This Certificate is valid until: 2019-05-05



Certification Body



Date 2016-05-03



**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail cert-validity@de.tuv.com http://www.tuv.com/safety

TÜV Rheinland  
LGA Products GmbH  
Tillystraße 2, 90431 Nürnberg

Attachment to  
Certificate  
Registration No.: SX 60110018 0001  
Report No.: 15093038 001

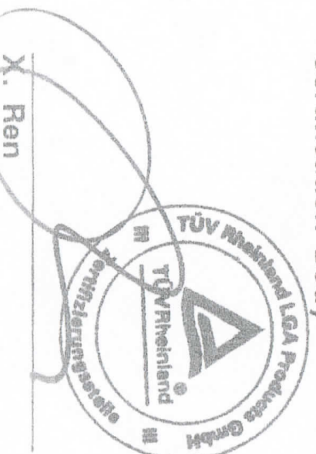
Organization:  
Hangzhou Optica Medical  
Instrument Co., Ltd.  
No.88 West Baiyunyuan Road, Tonglu  
Hangzhou  
311500 Zhejiang  
China

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 Vapour-  
resectoscopes, Hysteroscope and Surgical Instruments,  
Otosopes, 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

Certification Body



Date: 2016-05-03



## 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 Optcla 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.

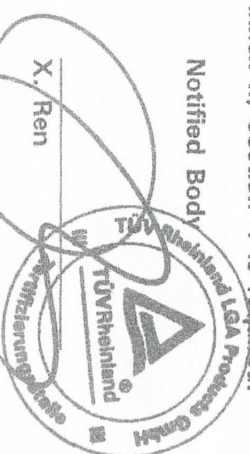
Effective Date:

2016-05-03

Date:

2016-05-03

Notified Body



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

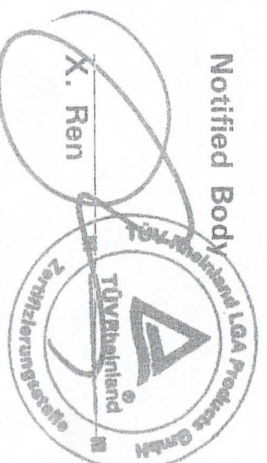
Manufacturer:  
Hangzhou Optcla Medical  
Instrument Co., Ltd.  
No.88 West Baiyunyuan Road, Tonglu  
Hangzhou  
311500 Zhejiang  
China

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



Notified Body



Date: 2016-05-03