EC Certificate

TÜVRheinland®

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

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.

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Doc. 1/1, Rev. 0

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

FIRMA DE PRODUCERE ȘI COMERȚ "SOGNO" S.R.L. REPUBLICA MOLDOVA, mun.CHIȘINĂU IDNO 1004600013854 Sogno® S.R.L.

Notified Body

Date: 2016-05-03

X. Ren

TÜVRheinland LGA Products GmbH Zertifizierungsstelle