TÜVRheinland®

EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60137372 0001

Report No.: 15079024 009

Manufacturer:

Shanghai Aohua Photoelectricity
Endoscope Co., Ltd.
No. 660, Shengang Rd.
Songjiang District
Shanghai 201612
P.R. China

Products:

Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: DD 60100784 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex V 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 V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2020-01-19

Date: 2020-01-19

Notified Body

TÜVRheinland

Fuxiu Sheng

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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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60137372 0001
Report No.: 15079024 009

Manufacturer:
Shanghai Aohua Photoelectricity Endoscope Co., Ltd.
No. 660, Shengang Rd.
Songjiang District
Shanghai 201612
P.R. China

Products:

- Fiber Gastroscopes
- Fiber Colonoscopes
- Fiber Bronchoscopes
- Fiber Laryngoscopes
- Video Gastroscopes
- Video Colonoscopes
- Video Bronchoscopes
- Video Laryngoscopes
- Endoscope Imaging Processors

Date: 2020-01-19

Notified Body

Fuxiu Sheng

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle