



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

Registration No.: DD 60100784 0001

Report No.: 15079024 001

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

Products: Videoscopes and Fiberscopes
(see attachment for products included)
Replaces Approval, Registration No.: DD 60029224 0001

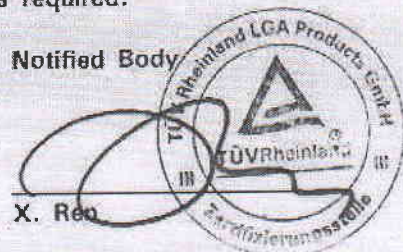
Expiry Date: 2020-04-22

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: 2015-04-23

Date: 2015-04-23

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**

Doc. 1/1, Rev. 0

**Attachment to
Certificate**

Registration No.: DD 60100784 0001
Report No.: 15079024 001

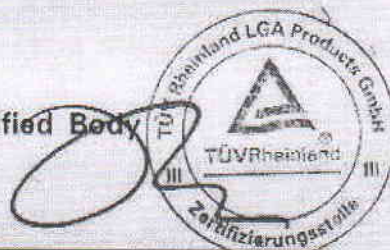
Manufacturer: Shanghai Aohua Photoelectricity
Endoscope Co., Ltd.
No. 660, Shengang Rd.
Songjiang District
Shanghai 201612
China

Products:

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

Date: 2015-04-23

Notified Body



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Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization
**Shanghai Aohua Photoelectricity
Endoscope Co., Ltd.**
No. 660, Shengang Rd.
Songjiang District
Shanghai 201612
China

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

Manufacture and Distribution of Videoscopes and Fiberscopes
(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: 2018-04-23
Certificate Registration No.: SX 60126825 0001
An audit was performed. Report No.: 15079024 006
This Certificate is valid until: 2021-04-22

Certification Body



Date 2018-04-20



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Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60126825 0001
Report No.: 15079024 006

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

Scope: Products:

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

Certification Body



Date: 2018-04-20

