



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

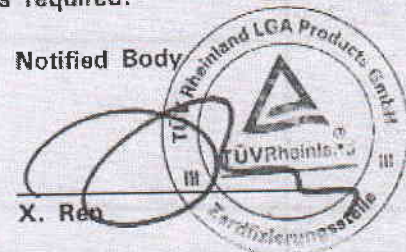
Expiry Date: 2020-04-22

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



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.

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

Certification Body



Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date: 2018-04-20



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



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>



QUALITY MANAGEMENT SYSTEM CERTIFICATE OF CONFORMITY

Shanghai AOHUA Photoelectricity Endoscope Co., Ltd.

A, Room 2017, Building 13, No.4299 Jindu Road, Minhang District, Shanghai 201108, China

has established and applied a quality management system in conformity with

GB/T 19001-2008/ISO 9001:2008

The scope covered by the system is:

design, production and relevant activities for fiber gastroscopes, fiber colonoscopes, fiber bronchoscopes, fiber laryngoscopes, video gastroscopes, video colonoscopes, endoscope imaging processors, endoscope light sources, xenon light sources, endoscope washers, video bronchoscopes, video laryngoscopes (the product with qualification requirement shall be limited in its medical registration certification), industrial fiber endoscopes, industrial videoscopes, industrial endoscope light sources, mine drilling imaging device (including main unit and probe)

Audit Address: No.660 Shengang Road, Songjiang District, Shanghai (Except Optics Workshop of 2F, No.5 Building)

Certificate Registration: 00313Q20986R0M

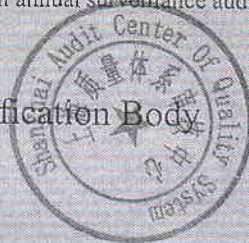
Duration of Validity: 2013.12.31—2016.12.30

The validity of this certificate will be maintained through annual surveillance audit.

Director

J.D. Wang

Certification Body



Date

Dec.31, 2013



MANAGEMENT SYSTEM
CNAS C003-Q



Shanghai Audit Center of Quality System

No.258 Wuyi Road, Shanghai P.R.China <http://www.sac.org.cn>