

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

**Registration No.:** DD 60127660 0001

**Report No.:** 15096257 002

**Manufacturer:** PENTAX-Aohua Medical  
Technologies Co., Ltd.  
East of 3rd Floor, Block C  
Building 1  
No. 5 Shenwang Road, Minhang District  
201108 Shanghai  
China

**Products:**

- Video Gastrosopes
- Video Colonoscopes
- Endoscope Imaging Processors

**Expiry Date:** 2023-04-22

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:** 2018-05-07

**Date:** 2018-05-07



**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.



TÜVRheinland®

LGA

Precisely Right.

**Business Stream Products  
Certification Department**

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

PENTAX-Aohua Medical  
Technologies Co., Ltd.  
East of 3rd Floor, Block C  
No. 5 Shenwang Road, Minhang Distri  
201108 SHANGHAI  
CHINA

Contact

Tel. +49 911 655-5225  
Mail [service@de.tuv.com](mailto:service@de.tuv.com)

Date May 07, 2018

**Application for : QMS**

Certificate No. : SX 60127661 Sheet 0001  
Device : Only for QM-System audit  
Test requirement : EN ISO 13485:2016

Dear Madame or Sir,

Your Quality Management System has been tested and found to be in accordance with the above mentioned requirements.

Enclosed please find the certificate  
No. SX 60127661 0001.

Kind regards

Certification body

S. Liu

Test sample: no, documentation available

TÜV Rheinland  
LGA Products GmbH

Tillystraße 2  
90431 Nürnberg

Tel. +49 911 655-5225  
Fax +49 911 655-5226  
Mail [service@de.tuv.com](mailto:service@de.tuv.com)  
Web [www.tuv.com/safety](http://www.tuv.com/safety)

Board of Management

Dipl.-Ing.  
Jörg Mähler, Spokesman

Dipl.-Kfm.  
Dr. Jörg Schlösser

Chairman of the  
Supervisory Board

Dipl.-Ing.  
Ralf Scheller

Nuremberg HRB 26013  
VAT No.: DE 811835490