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 Gastroscopes
- Video Colonoscopes
- Endoscope Imaging Processors

Digitally signed by Ceaicovschi Tudor
Date: 2022.12.09 15:29:27 EET
Reason: MoldSign Signature
Location: Moldova

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

Notified Body
S. Liu

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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Business Stream Products
Certification Department

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

PENTAX-Aohua Medical
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CHINA

Contact

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Mail 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

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