

EC CERTIFICATE

Number: 6064491CE01

Production Quality Assurance

Directive 93/42/EEC on Medical devices, Annex V
(Devices in Class IIa, IIb or III)

Manufacturer:

Shanghai Aohua Photoelectricity Endoscope Co., Ltd.
No.66, Lane 133, Guangzhong Road, Minhang District
201108 Shanghai
P.R. China

For the product category(ies)

Endoscopic surgical devices

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents, that form the basis of this certificate:

Certification Notice 6064489CN, initially dated 31 March 2021
Addendum, initially dated 31 March 2021

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for the manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex V of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III or Class IIb devices an additional EC type-examination certificate according to Annex III is mandatory. The necessary information related to the quality assurance system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 26 May 2024
Issued for the first time: 31 March 2021

DFKRA Certification B.V

.....
Managing Director

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Certification Manager

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DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-product-safety.com Company registration 09085396

ADDENDUM

Belonging to certificate: 6064491CE01

1/1

CE MARKING OF CONFORMITY MEDICAL DEVICES

Endoscopic surgical devices

Issued to:

Shanghai Aohua Photoelectricity Endoscope Co. Ltd.
No.66, Lane 133, Guangzhong Road, Minhang District
201108 Shanghai
P.R. China

This certificate covers the following product(s):

- Endoscopic Irrigation Pump AFP-1
- Endoscopic CO₂ Insufflation Devices ACD-1

Initial date: 31 March 2021

Revision date: 22 May 2021

DEKR



B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

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