

EC Certificate



Production Quality Assurance MDD Annex V

Registration No.: DD 2158963-1

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

Products: Fiber Gastrosopes, Fiber Colonoscopes, Fiber Bronchoscopes, Fiber
Laryngoscopes, Video Gastrosopes, Video Colonoscopes, Video
Bronchoscopes, Video Laryngoscopes, Endoscope Imaging Processors

Replaces Approval, Registration No.: DD 60137372 0001

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.

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TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.