



EU Declaration of Conformity

MANUFACTURER
(name and address):

Shanghai Aohua Photoelectricity Endoscope Co.,Ltd.
No.66, Lane133, Guangzhong Road, Minhang District, Shanghai,
201108, P. R. China

SRN:

AUTHORIZED REPRESENTATIVE
(name and address):

Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany

PRODUCTS:

Product Name	Product number	Basic UDI-DI	Description / intended purpose	Classification
Light Source	AQL-300L	697351970MD29001F5	The light source is intended to be used with Aohua endoscopes, endoscope imaging processors, and other ancillary equipment for endoscopic diagnosis, treatment and video observation. It is also designed to supply air through the endoscope while inside the body. Do not use this light source for any propose other than its intended use.	Class IIa; rule 12

CONFORMITY ASSESSMENT ROUTE: MDR 2017/745 Annex XI

We herewith declare under our sole responsibility that the above-mentioned products meet the applicable provisions of the Regulation (EU) 2017/745 for medical devices. All supporting documentation is retained at the premises of the manufacturer.

STANDARDS APPLIED:

Applied standards are listed in the General Safety and Performance Requirements Checklist

NOTIFIED BODY:

DEKRA Certification B.V.
Meander 1051
6825 MJ Arnhem
P.O. Box 5185
6802 ED Arnhem
The Netherlands
Notified body number: **0344**

EU CERTIFICATE:

6111526CE01

EU TECHNICAL DOCUMENTATION
ASSESSMENT CERTIFICATE:

N/A



START OF CE MARKING:

Product Name	Product Number	Date of First CE Marking	First Batch Manufactured under Current Notified Body Number
Light Source	AQL-300L	2023-10-10	/

Place, Date of issue: Shanghai, China
2023-10-10

SIGNATURE:

Pei
General Manager
For and on behalf of Shanghai
Aohua Photoelectricity
Endoscope Co.,Ltd.



Regulatory Affairs Supervisor
For and on behalf of Shanghai Aohua
Photoelectricity Endoscope Co.,Ltd.

