



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:

CN-MF-000030035

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
Endoscope Imaging Processor	AQ-300, AQ-300N, AQ-300E, AQ-300S	697351970MD00001CG	AQ-300 endoscope imaging processor is intended to be used with video endoscope and light source manufactured by Aohua in endoscopy, endoscopic diagnosis and endoscopic treatment.	Class IIa; Rule 10

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:

6111526CE02

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
Endoscope Imaging Processor	AQ-300, AQ-300N, AQ-300E, AQ-300S	2024-01-19	/

Place, Date of issue: Shanghai, China
2024-01-19

SIGNATURE:



Peng

Peng Chen
Management Representative
For and on behalf of Shanghai
Aohua Photoelectricity
Endoscope Co.,Ltd.

Wen

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

