



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
Video colonoscope	UHD-CL300I, UHD-CL300L, UHD-CL300TI, UHD-CL300TL, UHD-CL300ZI, UHD-CL300ZL	697351970VCL0001S5	The UHD-CL series colonoscopes are intended to be used with an Aohua endoscope imaging processor, light source, and other ancillary equipment in endoscopy, endoscopic diagnosis, and treatment for colonic diseases.	Class IIa; rule 10 rule 5

CONFORMITY ASSESSMENT ROUTE: MDR 2017/745 Annex IX

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
Video colonoscope	UHD-CL300I, UHD-CL300L, UHD-CL300TI, UHD-CL300TL, UHD-CL300ZI, UHD-CL300ZL	2023-12-31	/

Place, Date of issue: Shanghai, China
2023-12-31

SIGNATURE:



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

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