

DEKRA Certification B.V.

CERTIFICATION NOTICE

Number : 6064489CN

Initial date : 06 May 2020

Version : 13

Version date : 13 August 2024

The Certification Notice provides actual information concerning the application(s) made by the Certification holder and the product(s) covered by the Certificate(s) as well as information regarding the examination and assessment activities performed by the Certification Body related to the performed Conformity Assessment Procedure(s) and the reference to the relevant documentation.

1 CERTIFICATION HOLDER

Shanghai Aohua Photoelectricity Endoscope Co., Ltd.
No.66, Lane 133, Guangzhong Road, Minhang District
201108 Shanghai
P.R. China
SRN ID.: CN-MF-000030035

2 APPLICATION(S)

The application(s) made by the Certification holder under the provisions of below-mentioned standard(s) conform(s) to the applicable provisions of the EC/UK-Directive/regulation(s), ISO standards and/or other regulations and include(s) the documentation and the relevant undertakings and/or statements required:

The following applications are under the accreditation of **DEKRA Certification B.V.:**

- **MDD:** “Besluit Medische hulpmiddelen”, the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical Devices and the modifications as mentioned in 98/79/EC of October 27, 1998, 2001/104/EC of December 7, 2001 and in 2007/47/EC of September 5, 2007.
- **MDR:** REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC and amended by REGULATION (EU) 2020/561 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 23 April 2020 amending Regulation (EU) 2017/745 on medical devices, as regards the dates of application of certain of its provisions.
- **QMS standards:** EN ISO 13485:2016 (RvA).

3 CERTIFICATION STRUCTURE

3.1 CE Certification Structure

To cover all products included in the application(s), the following scope(s) for the CE-certificates are defined:

MDD

Certificate number	Scope and product categories	Annex	Class & rule	Reference to Declaration of Conformity
6064491CE01	Endoscopic surgical devices Addendum: - Endoscopic Irrigation Pump AFP-1 - Endoscopic CO ₂ Insufflation Devices ACD-1	MDD, Annex V+VII	Class IIa, Rule 11 Class IIa, Rule 11	AH-YF-91.01-DOC-01, A.1 AH-YF-90.01-DOC-01, A.1

Certificate changes after 26 May 2021

N/A

MDR

Certificate number	Devices / groups of devices	Annex	Class & rule	Reference to Declaration of Conformity
6111526CE01	Other active non-implantable surgical devices (MDA0312, Class IIa) Basic UDI-DI: 697351970MD29001F5 Group of Devices: <i>Light source</i> - AQL-200L - AQL-200, AQL-200 Elite - AQL-100, AQL-100L - AQL-300L	MDR, Annex XI part A	Class IIa Rule 12	AQL-200L: AH-YF-85.02-DOC-01 A.0 AQL-100, AQL-100L, AQL-200, AQL-200 Elite: AH-YF-83.00-DOC-01 A.0 AQL-300L: AH-YF-86.01-DOC-01 A.0

Certificate number	Devices / groups of devices	Annex	Class & rule	Reference to Declaration of Conformity
6111526CE02	<p>Active non-implantable imaging devices utilising non-ionizing radiation (MDA0202, Class IIa)</p> <p>Basic UDI-DI: 697351970VCL0001S5</p> <p>Group of Devices: Video Colonoscope</p> <p>Models: UHD-CL300I, UHD-CL300L, UHD-CL300TI, UHD-CL300TL, UHD-CL300ZI, UHD-CL300ZL UHD-CL300PS, UHD-CL300PI, UHD-CL300PL, UHD-CL300TPS, UHD-CL300TPI, UHD-CL300TPL; UHD-CL300ZEI, UHD-CL300ZEL, UHD-CL300ZCI, UHD-CL300ZCL, UHD-CL300DTI, UHD-CL300DTL</p> <p>VCC-P30S, VCC-Q30JI, VCC-1T30L, VCC-Q30S, VCC-Q30I, VCC-Q30L, VCC-Q30JL, VCC-Q50JI, VCC-Q50JL, VCC-1T50JI, VCC-1T50JL; HD-CL1I, HD-CL1IW, HD-CL1L, HD-CL1LW; FHD-CL200I, FHD-CL200L, FHD-CL200JI, FHD-CL200JL; HD-CL120I, HD-CL120L, HD-CL120JI, HD-CL120JL, HD-CL120JIT, HD-CL120JLT, HD-CL120IW, HD-CL120LW</p> <p>VCC-60JI, VCC-60JL, VCC-60JTI, VCC-60JTL, VCC-60JZI, VCC-60JZL, VCC-60JPL, VCC-60JPI</p>	MDR, Annex IX	Class IIa Rule 5, 10	<p>Draft DoC: AH-YF-18.00-DOC-01(A.1)</p> <p>AH-YF-01.00-DOC-01(A.0)</p> <p>AH-YF-48.00-DOC-01(A.0)</p>
	<p>Basic UDI-DI: 697351970VDU0001VM</p> <p>Group of Devices: Video Duodenoscope</p> <p>Model: UHD-ED300V</p> <p>VDU-60T</p>	MDR, Annex IX	Class IIa Rule 5, 10	<p>Draft DoC: AH-YF-18.09-DOC-01(A.0)</p> <p>AH-YF-105.01-DOC-01(A.0)</p>

Certificate number	Devices / groups of devices	Annex	Class & rule	Reference to Declaration of Conformity
	<p>Basic UDI-DI: 697351970VGT0001WH</p> <p>Group of Devices: Video Gastroscope</p> <p>Models: UHD-GT300, UHD-GT300T, UHD-GT300Q, UHD-GT300Z; UHD-GT300XTP, UHD-GT300XP, UHD-GT300ZE, UHD-GT300ZC, UHD-GT300DT</p> <p>VGT-1T30J, VGT-Q30, VGT-Q30J, VGT-Q50J, VGT-1T50J; HD-GT1, HD-GT1P, HD-GT120, HD-GT120J, HD-GT120JT, HD-GT120P; FHD-GT200, FHD-GT200J, FHD-GT200JT</p> <p>VGT-60J, VGT-60JT, VGT-60XP, VGT-60JZ</p>	MDR, Annex IX	Class IIa Rule 5, 10	<p>Draft DoC: AH-YF-17.00-DOC-01(A.1)</p> <p>AH-YF-02.00-DOC-01(A.0)</p> <p>AH-YF-49.00-DOC-01(A.0)</p>
	<p>Basic UDI-DI: 697351970VBC0001NM</p> <p>Group of Devices: Video Bronchoscope</p> <p>Models: VBC-1T30, VBC-Q30, VBC-XQ50, VBC-T50, VBC-T50H, VBC-Q50, VBC-Q50H; VBC-XQ30, VBC-ST30; VBC-XQ300, VBC-N300, VBC-T300, VBC-N300H, VBC-T300H;</p> <p>MBC-4, MBC-5, MBC-6</p>	MDR, Annex IX	Class IIa Rule 5, 10	<p>Draft DoC: AH-YF-06.00-DOC-01(A.0)</p> <p>AH-YF-05.00-DOC-01(A.0)</p>
	<p>Basic UDI-DI: 697351970VRL0001Y8</p> <p>Group of Devices: Video Laryngoscope</p> <p>Models: VRL-1T30, VRL-Q30, VRL-XQ30, VRL-H30, VRL-XQ50H, VRL-Q50H; VRL-X300, VRL-XQ300H, VRL-N300H</p>	MDR, Annex IX	Class IIa Rule 5, 10	<p>Draft DoC: AH-YF-07.00-DOC-01(A.0)</p>

Certificate number	Devices / groups of devices	Annex	Class & rule	Reference to Declaration of Conformity
	Basic UDI-DI: 697351970VCH0001QR Group of Devices: Video Choledochoscope Models: VPB-XQ300, VPB-N300H	MDR, Annex IX	Class IIa Rule 6, 10	Draft DoC: AH-YF-34.00-DOC-01(A.0)
	Basic UDI-DI: 697351970VUT00014A Group of Devices: Video Ureterorenoscope Model: VRP-XQ300	MDR, Annex IX	Class IIa Rule 5, 6 10	Draft DoC: AH-YF-35.00-DOC-01(A.0)
	Basic UDI-DI: 697351970VCT0001UV Group of Devices: Video Cystoscope Model: VUB-N300H	MDR, Annex IX	Class IIa Rule 5, 10	Draft DoC: AH-YF-36.00-DOC-01(A.0)
	Basic UDI-DI: 697351970MD00001CG Group of Devices: Endoscope imaging processor Models: AQ-300, AQ-300N, AQ-300E, AQ-300S; AC-1, AQ-100, AQ-200, AQ-120 AQ-130, AQ-150, AQ-160, AQ-120 Pro, AQ-130 Pro, AQ-150 Pro, AQ-160 Pro	MDR, Annex IX	Class IIa Rule 10	Draft DoC: AH-YF-56.00-DOC-01(A.0) AH-YF-53.00-DOC-01(A.0) AH-YF-58.00-DOC-01(A.0)

The products described in the above mentioned certification holder's "Declaration of Conformity" form an integral part of this Certification Notice.

4 QUALITY SYSTEM STRUCTURE

The assessment of the applied Quality System of the certification holder is primarily covered by the assessment based on the standards identified in the table below.

QMS certificates issued by DEKRA Certification:

Certificate number	Scope of certificate	QS Standard(s) (incl. Accreditation Authority)
6064489	Design, Development, Manufacture and Distribution of Endoscopic CO ₂ Insufflation Devices, Endoscopic Irrigation Pumps, Endoscope Systems including Endoscopes, Imaging Processors, Light Sources. and Endoscopic Instruments in the area of endoscopic surgery or examination	EN ISO 13485:2016- RvA accredited

Exclusions:	NA
Non-Applications:	7.5.5 particular requirements for sterile medical devices, 7.5.7 particular requirements for validation of processes for sterile medical devices and sterile barrier systems, 7.5.9.2 particular requirements for implantable medical devices

5 ADDITIONAL LOCATION(S)

The relevant additional sites covered by a Quality System under responsibility of the Certification holder are identified in the table below.

NA

6 SUBCONTRACTED REGULATORY REPRESENTATION

The Certification Holder's subcontracted regulatory representation, covered by a QA/RA agreement, is identified in the table below.

Company name / city / country	Type of service to Certification holder
Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse 80, 20537 Hamburg, Germany	EU Authorized representative

7 SUBCONTRACTOR(S) / OUTSOURCING

The critical subcontractors performing processes, which results are not or cannot be verified by the Certification holder and/or the critical contractors to which relevant processes have been outsourced are identified in the table below:

Company name / address	Type of service to Certification holder	QS standard and name certifier	Certificate number and expiry date
Hangzhou Fuyang Jingrui Medical Technology Co., Ltd. #99 Waizhougongwu, Guanqian Village, Yinhu, Fuyang District 311402 Hangzhou, Zhejiang China	Critical Subcontractor for manufacture of Distal cover	EN ISO 13485:2016 Issued by DEKRA	6054173 1 January 2026
Zhejiang Huanyi Sterilization Technology Co., Ltd. No. 199, Mingzhu Avenue, Leidian Town Deqing County, Hangzhou City, 313219 Zhejiang, China	Subcontractor of EO sterilization for Distal cover Subcontracted by Hangzhou Fuyang	EN ISO 13485:2016 and EN ISO 11135:2014, issued by TÜV Rheinland LGA Products GmbH	Cert. No.: SX 2104885-1, expiry date: 2027-06-24

8 EVALUATION OF TECHNICAL DOCUMENTATION

The examination and assessment of the Design Dossier(s), verification or examination/assessment of the technical documentation and/or the verification of manufactured products / batches are identified in the table below.

Brief notification description	Reference to client's MAF or NoC	Regulation/Directive & Conformity Assessment Route	Applies to following certificate number(s) and CN version	Report or review letter (+ date of approval)
initial TD assessment of Endoscopic Irrigation Pumps	n/a	MDD, Annex V under Art. 120 of MDR	6064491CE01; 6064489CN03	6064491-TDR02-R0 (approved on 31 March 2021)
initial TD assessment of Endoscopic CO ₂ Insufflation	n/a	MDD, Annex V under Art. 120 of MDR	6064491CE01; 6064489CN04	6064491-TDR01-R0 (approved on 22 May 2021)
initial MDR certification of light	MAF (signed	MDR, Annex XI Part A	6111526CE01 6064489CN06	6111526-TDR01-R0

source	2021-10-12)			(approved on 20 February 2023)
NOC adding models of light source	NOC (date 2023-05-22)	MDR, Annex XI Part A	6111526CE01 6064489CN08	6171916-RL03-R0 (approved on 10 October 2023)
initial TD assessment of Error! Reference source not found.	MAF (signed 2022-07-05)	MDR, Annex IX	6111526CE02 6064489CN09	6130354-TDR02-R0 (25 December 2023)
NOC adding devices for Video Colonoscope (new models), Video Duodenoscope, Video Gastroscope, Video Bronchoscope, Video Laryngoscope, Video Choledochoscope, Video Ureterorenoscope, Video Cystoscope, Endoscope imaging processor	NOC (date 2023-12-22)	MDR, Annex IX	6111526CE02 6064489CN10	6130354-RL05-R0 (19 January 2024)
NOC adding models for Video Colonoscope, Video Duodenoscope, Video Gastroscope, Endoscope imaging processor	NOC (date 2024-04-29)	MDR, Annex IX	6111526CE02 6064489CN13	6199730-RL08-R0 (13 August 2024)

Based on the results of the activities performed, it has been determined that the design of the product(s) (DE/TD/TE examination) or the product(s), including the variant(s) (other conformity assessment routes), stated in this Certification Notice, fulfill(s) the relevant regulations.

9 EVALUATION OF QUALITY MANAGEMENT SYSTEM

The applied Quality System has been assessed to determine whether this Quality System complies with the applicable requirements of the EC/UK-Directive/regulation, ISO standard(s) and/or other regulations as specified in this Certification Notice. This is described in the audit report(s) mentioned in the table below.

The examinations up to the last renewal, dated 25 November 2022 are described in Certification Notice 6064489CN06 dated 20 February 2023.

Activity (audit/substantial change) brief description	Reference to client's MAF or NoC or n/a	Regulation/Directive & Conformity Assessment Route	Applies to following certificate number(s) and CN version	Report or review letter (+ date of approval)
ISO renewal and scope expansion, 2 nd surveillance (MDD) and 2 nd initial MDR in accordance with Clients QMS, EN ISO 13485:2016 - RvA accredited, MDD 93/42/EEC, MDR Annex XI part A and MDR Annex IX	MAF (signed 2021-10-12) MAF (signed 2022-07-05)	MDD, Annex V under Art. 120 of MDR MDR, Annex XI Part A MDR, Annex IX	6064489; 6064491CE01; 6111526CE01 6064489CN07	6130353-AR05-R0 (17 May 2023)
1 st surveillance and scope extension of ISO, MDR, MDD surveillance audit (December 2023)	MAF (signed 2023-07-20)	MDD, Annex V under Art. 120 of MDR MDR, Annex XI Part A MDR, Annex IX	6064489; 6064491CE01; 6111526CE01 6111526CE02 6064489CN11	6167332-AR06-R0 (Approved on 20 February 2024)
Subcontractor audit at Hangzhou Fuyang Jingrui (November 2023)	MAF (signed 2023-07-20)	MDR, Annex XI Part A MDR, Annex IX	6064489; 6064489CN11.1	6167332-AR07-R1 (Approved on 2 April 2024)
UnA audit (May 2024)	n/a	MDR, Annex XI Part A MDR, Annex IX	6064491CE01; 6111526CE01 6111526CE02 6064489CN11.3	6187296-UnA01-R0 (Approved on 4 June 2024)

DEKRA Certification has determined by examination and assessment that the applied Quality System(s) comply with the relevant requirements in accordance with the applied conformity assessment procedure(s) of the EC/UK-Directive/regulation, ISO standard(s) and/or other regulations as specified in this Certification Notice.

10 CONCLUSION

10.1 Conclusion DEKRA Certification B.V.

DEKRA Certification B.V. declares, based on the results of the examination and assessment activities performed, that the applied Conformity Assessment Procedures are executed by the

Certification holder in accordance with the provisions of the EC-Directive/regulation, ISO standards and/or other regulations.

With regards to CE certification, the compliance of the products concerned with the Essential Requirements/GSPR (Annex I) of the EC-Directive/regulation remain, according to the provisions of this Directive/regulation, at all times the full responsibility of the Certification holder.

The following certificates will be issued under the conditions of the signed certification agreement with DEKRA Certification B.V. CA-22-7401180:

The expired MDD certificate 6064491CE01 (as listed in the table below) shall continue to be subject to surveillance by DEKRA Certification per Regulation (EU) 2023/607 amending Regulations (EU) 2017/745, under the conditions of the signed agreement CA-21-7454639.

MDD

Certificate number	Initial date	Renewal date	Revision date*	Expiry date
6064491CE01	31 March 2021	-	22 May 2021 (A)	26 May 2024

MDR

Certificate number	Initial date	Renewal date	Revision date*	Expiry date
6111526CE01	20 February 2023	-	10 October 2023	1 February 2028
6111526CE02	25 December 2023	-	19 January 2024	1 February 2028

ISO

Certificate number	Standard	Initial date	Effective date*	Expiry date
6064489	EN ISO 13485:2016 (RvA)	6 May 2020	20 February 2024 (C)	1 May 2026

* C for certificate, A for addendum

The right to use the DEKRA Certification B.V. Identification Number **0344**, as stated in the relevant Certificate(s) and under the conditions of said Agreement, only applies to the CE-Certified product(s) covered by this Certification Notice.



13 August 2024

Signature of Certification Manager

Date

DEKRA Certification B.V, Arnhem, The Netherlands