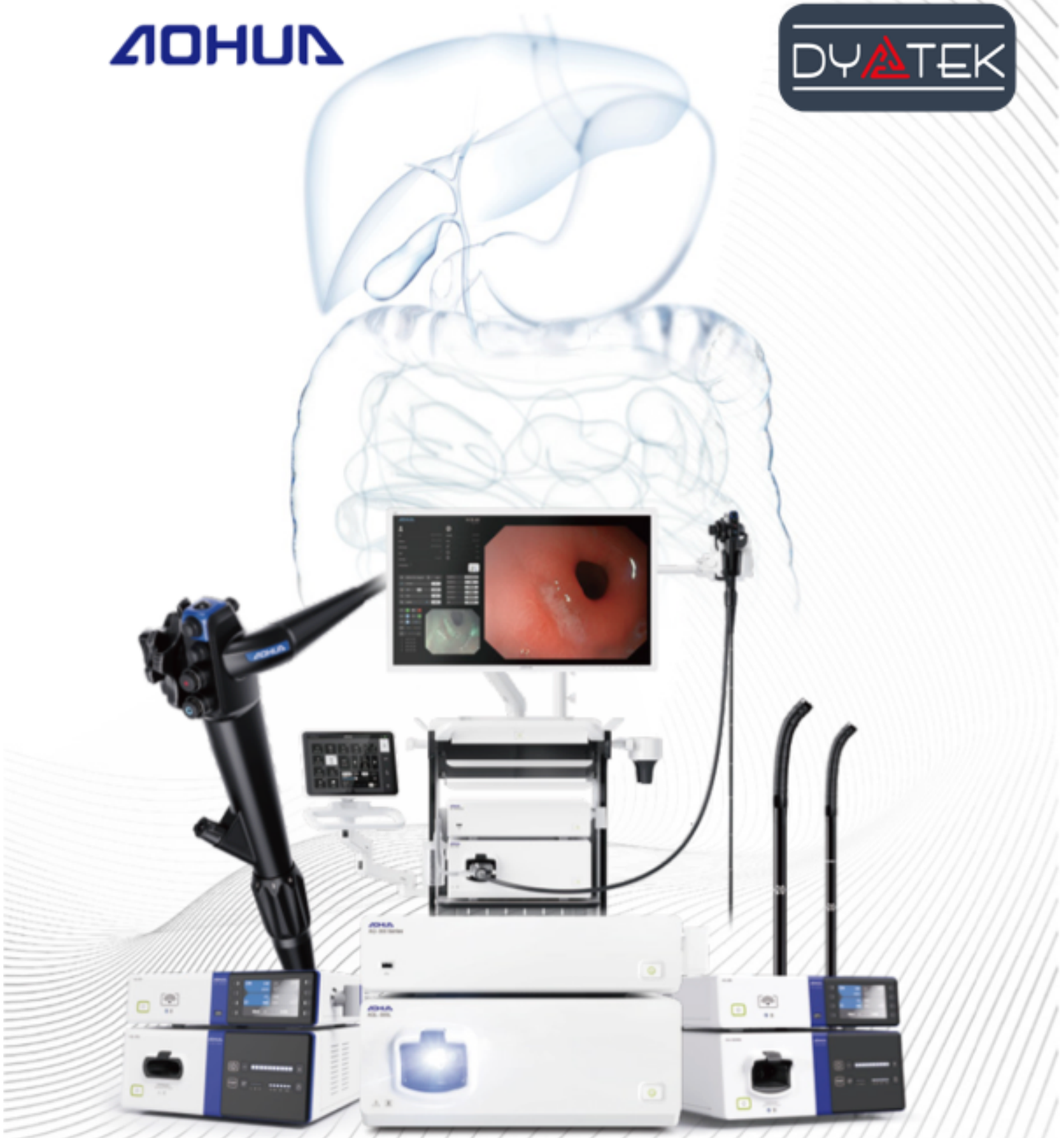
AOHUA

DYATEK



Système d'endoscopie gastro-intestinale

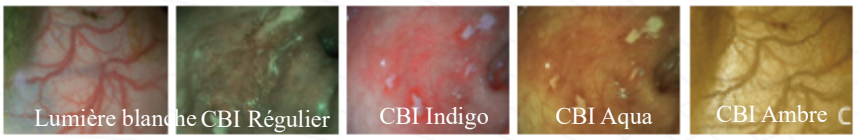
DYATEK
Distributeur exclusif
Tel: 04 94 07 24 24
Info@dyatek.com
www.dyatek.com
Nouvelle Aquitaine - Occitanie - Paca

Système d'endoscopie Ultra HD AQ-300

Contribuer nos technologies les plus avancées et les plus innovantes à ce système phare 4K pour vous offrir l'expérience de l'endoscopie du futur

4 modes CBI sur 5LED

L'AQ-300 propose quatre modes de chromoendoscopie obtenus grâce à diverses combinaisons de sa source lumineuse à cinq LED. Ces modes offrent des solutions efficaces, rapides et précises aux défis cliniques dans divers scénarios.



Intelligent

Un modèle innovant d'interaction humain-ordinateur
Découvrez un flux de travail optimisé grâce au modèle AQ-300, notamment la reconnaissance faciale, le contrôle vocal et des paramètres adaptables via un panneau de commande tactile à distance.

Colo Assistance Smart (CSA)

Rigidité réglable / Transmission de force synchrone / Flexion élastique

3 guides de lumière

La pointe endoscopique est conçue avec 3 guides de lumière, assurant un éclairage plus lumineux et plus uniforme, en particulier pour les zones de champ lointain.

Gamme complète

Gastroscope	Colonoscope	Duodénoscope	Ultra mince	Zoom optique

Fonctions et caractéristiques

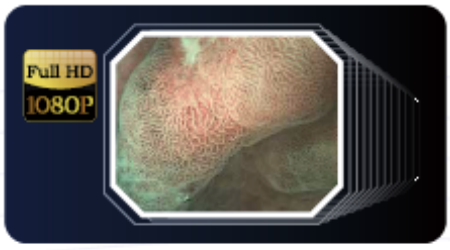
Source de lumière	5LED
Chromoendoscopie	CBI Régulier/CBI Indigo/CBI Aqua /CBI Ambre
Amélioration de l'image	Structure/Bord/Combinaison
Réglage de la luminosité	Mode automatique/manuel
Fonction de zoom numérique	1/1,2/1,5/1,8/2 fois
Fixation et lecture	Fixation de l'image en temps réel et la lecture.
IRIS	Crête/Moyenne/Auto
Stockage USB	Les images et vidéos haute définition peuvent être stockées à tout moment
Affichage de l'image en double	Affichage à la fois de l'image WLI et de l'image CBI

UHD-GT/CL/ED

	Modèle	Longueur de travail	Longueur totale	Diamètre extérieur de l'extrémité distale	Diamètre extérieur du tube d'insertion	Diamètre intérieur du canal de l'instrument	Profondeur de champ	Champ de vision	Plage d'inclinaison
Vidéo Gastroscopes	* UHD-GT300	1100mm	1400mm	9.2mm	9.2mm	2.8mm	2-100mm	145°	U210°D120°L100° R100°
	* UHD-GT300T	1100mm	1400mm	9.8mm	9.6mm	3.2mm	2-100mm	145°	U210°D120°L100° R100°
	* UHD-GT300Z	1100mm	1400mm	9.9mm	9.6mm	2.8mm	1,5-3 mm (Mag) 3-100 mm (Normal)	95° 145°	U210°D120°L100° R100°
	UHD-GT300XP	1100mm	1400mm	5.4mm	5.8mm	2.4mm	2-100mm	140°	U210°D90°L100° R100°
	UHD-GT300XTP	1100mm	1400mm	5.9mm	6.0mm	2.8mm	2-100mm	140°	U210°D90°L100° R100°
Vidéo Coloscopes	* UHD-CL300I	1350mm	1650mm	12.2mm	12.0mm	3.8mm	2-100mm	170°	U180°D180°L160° R160°
	* UHD-CL300L	1700mm	2000mm	12.2mm	12.0mm	3.8mm	2-100mm	170°	U180°D180°L160° R160°
	* UHD-CL300TI	1350mm	1650mm	12.2mm	12.0mm	4.2mm	2-100mm	170°	U180°D180°L160° R160°
	* UHD-CL300TL	1700mm	2000mm	12.2mm	12.0mm	4.2mm	2-100mm	170°	U180°D180°L160° R160°
	* UHD-CL300ZI	1350mm	1650mm	12.8mm	12.0mm	3.8mm	2-3,5 mm (Mag) 3-100 mm (Normal)	90° 170°	U180°D180°L160° R160°
	* UHD-CL300ZL	1700mm	2000mm	12.8mm	12.0mm	3.8mm	2-3,5 mm (Mag) 3-100 mm (Normal)	90° 170°	U180°D180°L160° R160°
	* UHD-CL300PI	1350mm	1650mm	9.8mm	9.8mm	3.2mm	2-100mm	170°	U210°D180°L160° R160°
	* UHD-CL300PL	1700mm	2000mm	9.8mm	9.8mm	3.2mm	2-100mm	170°	U210°D180°L160° R160°
	* UHD-CL300TPI	1350mm	1650mm	10.2mm	10.5mm	3.8mm	2-100mm	170°	U210°D180°L160° R160°
	* UHD-CL300TPL	1700mm	2000mm	10.2mm	10.5mm	3.8mm	2-100mm	170°	U210°D180°L160° R160°
Vidéo Duodénoscope	UHD-ED300V	1250mm	1530mm	13.5mm	11.2mm	4.2mm	4-60mm	100°	U120°D90°L90° R110°

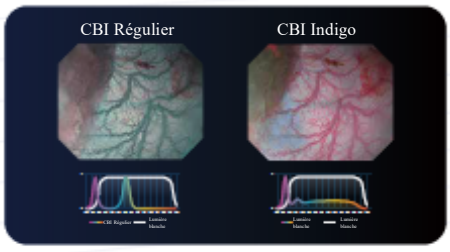
* : Jet d'eau de transfert
Mag : mode de grossissement

AQ-120 Nouveau système d'endoscopie essentiel



Résolution d'image supérieure FHD

Le modèle AQ-120 est équipé d'un capteur CMOS FHD pour fournir une image de haute qualité. Il produit des images de haute qualité avec une excellente définition des contours entre les différents tissus.

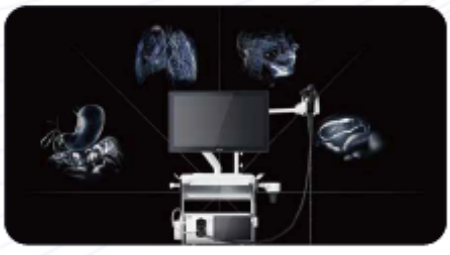


3 lumières LED pratiques avec 2 modes CBI

Les trois sources lumineuses LED du modèle AQ-120 permettent de réaliser deux modes de chromoendoscopie largement utilisés. Ces modes offrent des solutions efficaces, rapides et précises aux défis cliniques dans divers scénarios.

Écran tactile intuitif de 10,1 pouces

L'ensemble du système peut être géré facilement à l'aide d'un écran tactile de 10,1 pouces. Cette interface personnalisée améliore la facilité, la commodité et l'intelligence du contrôle du système.



Applications polyvalentes

Le modèle AQ-120 est conçu pour les endoscopes de dernière génération, en s'inspirant des modèles précédents. Il convient à de nombreux domaines médicaux, notamment la gastro-entérologie, la pneumologie, les soins respiratoires et l'oto-rhino-laryngologie. Ce dispositif répond à un éventail de besoins cliniques, depuis les diagnostics de base jusqu'aux interventions thérapeutiques les plus complexes, tout en offrant des possibilités d'évolution future.

Jet d'eau de transfert

La fonction de jet d'eau de transfert, fourni en standard, facilite votre processus en augmentant votre efficacité.

Gastroscope avec une angulation de 120° vers le bas

Une angulation importante vers le bas améliore la procédure thérapeutique.

Fonctions et caractéristiques

Source de lumière	Source lumineuse 3LED
Chromoendoscopie	CBI Régulier / CBI Indigo
Amélioration de l'image	Structure/Bord/HBE
Réglage de la luminosité	Mode automatique/manuel
Zoom numérique	1,0x, 1,2x, 1,5x, 1,8x, 2,0x, 4,0x
Fixation et lecture	Fixation de l'image en temps réel et la lecture.
IRIS	Crête/Moyenne/Auto
Mémoire interne	500G
Stockage externe	USB
Interface utilisateur	Écran tactile personnalisé de 10,1 pouces

VCC/VGT

	Modèle	Longueur de travail	Longueur totale	Diamètre extérieur de l'extrémité distale	Diamètre extérieur du tube d'insertion	Diamètre intérieur du canal de l'instrument	Profondeur de champ	Champ de vision	Plage d'inclinaison
Vidéo Gastroscopes	* VGT-Q50J	1100mm	1400mm	9.2mm	9.2mm	2.8mm	2-100mm	145°	U210°D120°L100° R100°
	* VGT-1T50J	1100mm	1400mm	9.8mm	9.6mm	3.2mm	2-100mm	145°	U210°D120°L100° R100°
Vidéo Coloscopes	* VCC-Q50JI	1350mm	1650mm	12.2mm	12.0mm	3.8mm	2-100mm	170°	U180°D180°L160° R160°
	* VCC-Q50JL	1700mm	2000mm	12.2mm	12.0mm	3.8mm	2-100mm	170°	U180°D180°L160° R160°
	* VCC-1T50JI	1350mm	1650mm	12.2mm	12.0mm	4.2mm	2-100mm	170°	U180°D180°L160° R160°
	* VCC-1T50JL	1700mm	2000mm	12.2mm	12.0mm	4.2mm	2-100mm	170°	U180°D180°L160° R160°

* : Jet d'eau de transfert

Équipement périphérique

Pompe d'irrigation endoscopique AFP-1

La pompe de rinçage à l'eau évacue le sang, les tissus et les débris pendant la procédure et contribue à assurer une meilleure vue pour les patients qui ne sont pas bien préparés.

- Temps de coupure de 20' après un rinçage continu
- Compatible avec le jet d'eau et le canal d'instrument
- Rinçage puissant et direct en ligne
- Contrôle précis du débit d'eau à 10 niveaux
- Contrôle par pédale
- Corps de machine fermé et tête de pompe amovible

Dispositif d'insufflation endoscopique de CO_2 ACD-1

L'insufflateur de CO_2 régule le gaz carbonique à un niveau sûr et stable pour alimenter les endoscopes. Le gaz CO_2 peut être utilisé pour insuffler la lumière pour un espace plus large, réduire la fumée pendant l'intervention, augmenter le confort du patient et raccourcir le temps de découverte après la procédure.

- Compatible avec les réservoirs de gaz et l'alimentation centralisée
- Conception compacte et facile à utiliser
- Filtrage du gaz avant d'entrer dans la machine
- Mécanisme de décompression en deux étapes

Testeur de fuite automatique ALD-1

Le test de fuite est un test long mais très important qui doit être effectué avant chaque retraitement d'un endoscope. En l'exécutant automatiquement, cela peut économiser du temps et de l'énergie.

- Entièrement automatique, simplement en appuyant sur un bouton
- Compatible avec les endoscopes des grandes marques
- Conception compacte, facile à installer et à utiliser
- Conception IF récompensée

Chariot AET-S2

L'ensemble du système d'endoscopie et les périphériques peuvent être logés dans un seul chariot, avec un support réglable et une protection du bris de roue.

- Ajustez librement selon les besoins
- Alimentation électrique unifiée pour plusieurs appareils
- Interrupteur marche/arrêt à un bouton, simplifiant l'utilisation quotidienne
- Offrir l'installation de plusieurs moniteurs

Moniteur médical S320P/S270H4K

- Moniteur plus lumineux de qualité médicale ultra haute définition 4K de 32 pouces.
- Le grand moniteur médical professionnel de 27 pouces peut afficher les images plus clairement.

Accessoires endothérapeutiques

Pinces à biopsie jetables

Les pinces à biopsie jetables sont destinées à être utilisées avec un endoscope flexible pour aider les médecins à prélever des tissus d'un patient en vue d'un examen histologique.

	Description	Modèle	Caractéristiques
	Coupe ovale avec revêtement	JRQ-Y-1816-PAC	1.8mm D x 1600mm L
		JRQ-Y-2323-PAC	2.3 mm D x 2300mm L
	Coupe alligator avec revêtement	JRQ-Y-1816-EAC	1.8mm D x 1600mm L
		JRQ-Y-2323-EAC	2.3mm D x 2300mm L

Pinces de préhension jetables

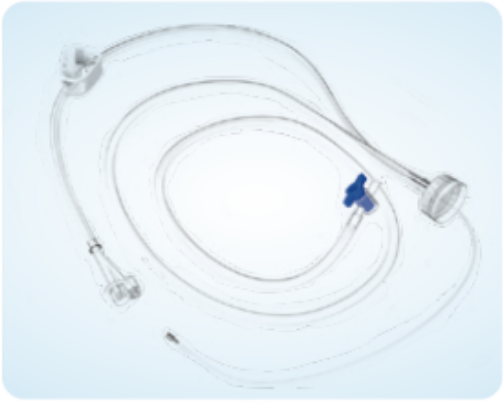
Les pinces de préhension jetables sont destinées à être utilisées avec un endoscope flexible pour aider les médecins à récupérer de manière endoscopique des matières étrangères et endogènes dans le tube digestif et la trachée.

	Description	Modèle	Caractéristiques
	Dents de rat avec mâchoire d'alligator	JRY-QF-1816	1.8mm D x 1600mm L
	Mâchoire d'alligator	JRY-QE-2423	2.4mm D x 2300mm L
	Mâchoire de dent de rat	JRY-QD-2423	2.4mm D x 2300mm L
	Mâchoire de pélican	JRY-QT-2423	2.4mm D x 2300mm L

Brosse de nettoyage

À utiliser pour nettoyer le canal de l'endoscope et le tube d'aspiration.

Description	Modèle	Caractéristiques
À usage unique, une tête	JRX1823	1,8 mm D x 2300 mm L
Réutilisable, une tête	JRF1823	1,8 mm D x 2300 mm L



Tube d'alimentation en air/eau jetable

Le tube d'alimentation en air/eau jetable est destiné à être utilisé avec une pompe à air ou à CO_2 ainsi qu'une source d'eau stérile pour alimenter en air ou en CO_2 et en eau stérile un endoscope pendant les procédures endoscopiques.

Description	Modèle	Caractéristiques
Compatible avec Aohua et Olmypus	JRST-SO-B	Vanne à deux voies Longueur du tuyau 1100 mm

Tube d'irrigation jetable

Le tube d'irrigation jetable est destiné à être utilisé avec une pompe péristaltique ainsi qu'une source d'eau stérile pour alimenter en eau stérile un endoscope pendant les procédures endoscopiques.

Description	Modèle	Caractéristiques
Usage unique	JRIT-IB	Diamètre du tube Φ6,4*1,6 mm Longueur de travail 3250 mm

Kit de valves d'endoscope jetables

Le kit de valves d'endoscope jetables permet d'activer les fonctions des pièces qui composent le modèle.

Description	Modèle	Caractéristiques
Kit à 3 pièces	JRV-G03S	Vannes d'aspiration jetables Air/Eau et de biopsie)

AOHUA

Tel: 04 94 07 24 24
www.dyatek.com

QUALITY MANAGEMENT SYSTEM
CERTIFICATE OF CONFORMITY

Shanghai AOHUA Photoelectricity Endoscope Co., Ltd.

Unified Social Credit Code: 91310112607671054B

No.66, Lane 133 Guangzhong Road, Minhang District, Shanghai 201108, China

has established and applied a quality management system in conformity with

GB/T 19001-2016/ISO 9001:2015

The scope covered by the system is:

design, production for video gastroscopes, video colonoscopes, video bronchoscopes, video laryngoscopes, fiber bronchoscopes, fiber laryngoscopes, portable fiber bronchoscopes, portable fiber laryngoscopes, endoscope imaging processors, endoscope light sources, xenon light sources, video bronchoendoscopes, endoscopic irrigation pumps, endoscopic CO2 insufflation devices, video gastroscopes, video colonoscopes, video endoscope imaging processors, video lower gastroscopes, video duodenoscope, distal cover, video laryngoscope, video gastroscope (the product with qualification requirement shall be limited in its medical registration certification), endoscopic leak detector, veterinary endoscope.

Audit Address: No.66, Lane 133 Guangzhong Road, Minhang District, Shanghai

Certificate Registration: 00322Q30512R3M

Duration of Validity: 2022.12.31—2025.12.30

The validity of this certificate will be maintained through annual surveillance audit.

Certification Body

Shanghai Audit Center Of Quality System 上海体系审核中心

Date Jan.10, 2024 (Exchange Certificate)

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

CNAS

中国认可
国际互认
管理体系
MANAGEMENT SYSTEM
CNAS C003-M

Shanghai Audit Center of Quality System

No.258 Wuyi Road, Shanghai P.R.China http://www.sac.org.cn

This certificate information can be found at the official website (www.cnca.gov.cn) of Certification and Accreditation Administration of the People's Republic of China (CNCA)

Shanghai Aohua Photoelectricity Endocsope Co., Ltd.
No.66, Lane133, Guangzhong Road, Minhang District, 201108, Shanghai, P. R. China
Fax: +86-21-67681019 Tel: +86-21-67681019 Web: www.aohua.com

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 UHD-CL300PI UHD-CL300PL UHD-CL300PS UHD-CL300TPI UHD-CL300TPL UHD-CL300TPS UHD-CL300ZEI UHD-CL300ZEL UHD-CL300ZCI UHD-CL300ZCL UHD-CL300DTI UHD-CL300DTL	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

Shanghai Aohua Photoelectricity Endocsope Co., Ltd.
No.66, Lane133, Guangzhong Road, Minhang District, 201108, Shanghai, P. R. China
Fax: +86-21-67681019 Tel: +86-21-67681019 Web: www.aohua.com

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	/
Video colonoscope	UHD-CL300PI UHD-CL300PL UHD-CL300PS UHD-CL300TPI UHD-CL300TPL UHD-CL300TPS	2024-08-13	/
Video colonoscope	UHD-CL300ZEI UHD-CL300ZEL UHD-CL300ZCI UHD-CL300ZCL	2024-08-13	/
Video colonoscope	UHD-CL300DTI UHD-CL300DTL	2024-08-13	/

Place, Date of issue: Shanghai, China
2024-08-13

SIGNATURE:

Peng Chen

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

Qian Chunjian

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

Shanghai Aohua Photoelectricity Endocsope Co., Ltd.
No.66, Lane133, Guangzhong Road, Minhang District, 201108, Shanghai, P. R. China
Fax: +86-21-67681019 Tel: +86-21-67681019 Web: www.aohua.com

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 gastroscope	UHD-GT300 UHD-GT300T UHD-GT300Q UHD-GT300Z UHD-GT300XP UHD-GT300XTP UHD-GT300ZE UHD-GT300ZC UHD-GT300DT	697351970VGT0001WH	The UHD-GT series gastroscopes are intended to be used with an Aohua endoscope imaging processor, light source, and other ancillary equipment in endoscopy, endoscopic diagnosis, and treatment for diseases of the stomach.	Class IIa; rule 10, rule 5

CONFORMITY ASSESSMENT ROUTE: MDR 2017/745 Annex IX

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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

Shanghai Aohua Photoelectricity Endocsope Co., Ltd.
No.66, Lane133, Guangzhong Road, Minhang District, 201108, Shanghai, P. R. China
Fax: +86-21-67681019 Tel: +86-21-67681019 Web: www.aohua.com

START OF CE MARKING:

Product Name	Product Number	Date of First CE Marking	First Batch Manufactured under Current Notified Body Number
Video gastroscope	UHD-GT300 UHD-GT300T UHD-GT300Q UHD-GT300Z	2024-01-19	/
Video gastroscope	UHD-GT300XP UHD-GT300XTP	2024-08-13	/
Video gastroscope	UHD-GT300ZE UHD-GT300ZC	2024-08-13	/
Video gastroscope	UHD-GT300DT	2024-08-13	/

Place, Date of issue: Shanghai, China
2024-08-13

SIGNATURE:

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

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

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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 Duodenoscope	UHD-ED300V	697351970VDU0001VM	The UHD-ED300V Video Duodenoscope is intended to be used with an AOHUA endoscope imaging processor, light source, and other ancillary equipment in endoscopy, endoscopic diagnosis, and endoscopic treatment for duodenum.	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.

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START OF CE MARKING:

Product Name	Product Number	Date of First CE Marking	First Batch Manufactured under Current Notified Body Number
Video duodenoscope	UHD-ED300V	2024-01-19	/

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

SIGNATURE:

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

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

Shanghai Aohua Photoelectricity Endocsope Co., Ltd.
, Lane133, Guangzhong Road, Minhang District, Shanghai, 201108, P. R. China
Fax: +86-21-67681019 Tel: +86-21-67681019 Web: www.aohua.com

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
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 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: 6111526CE01

EU TECHNICAL DOCUMENTATION ASSESSMENT CERTIFICATE: N/A

Shanghai Aohua Photoelectricity Endocsope Co., Ltd.
, Lane133, Guangzhong Road, Minhang District, Shanghai, 201108, P. R. China
Fax: +86-21-67681019 Tel: +86-21-67681019 Web: www.aohua.com

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:

Peng Chen
General Manager
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.

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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 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

Shanghai Aohua Photoelectricity Endocsope Co., Ltd.
, Lane133, Guangzhong Road, Minhang District, Shanghai, 201108, P. R. China
Fax: +86-21-67681019 Tel: +86-21-67681019 Web: www.aohua.com

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 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.

DEKRA Certification B.V.

CERTIFICATION NOTICE

Number : 6064489CN	Initial date : 06 May 2020
Version : 10	Version date : 19 January 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/0; AH-YF-90.01-DOC-01, A/0

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:** *Light source* - AQL-200L - AQL-200, AQL-200 Elite - AQL-100, AQL-100L - AQL-300L	MDR, Annex XI part A	Class IIa Rule 12	Draft DOC: AQL-200L: AH-YF-85.02-DOC-01, A.0 AQL-200, AQL-200 Elite, AQL-100, AQL-100L: 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
6111526CE 02	**Active non-implantable imaging devices utilising non-ionizing radiation (MDA0202, Class IIa)** **Basic UDI-DI:** 697351970VCL0001S5 **Group of Devices:** Video Colonoscope Models: UHD-CL300I, UHD-CL300L, UHD-CL300TI, UHD-CL300TL, UHD-CL300ZI, UHD-CL300ZL 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; HDCL120I, HD-CL120L, HD-CL120JI, HDCL120JL, HDCL120JIT, HDCL120JLT, HDCL120IW, HDCL120LW	MDR, Annex IX	Class IIa Rule 5, 10	Draft DoC: AH-YF-18.00-DOC-01(A.0) AH-YF-01.00-DOC-01(A.0)
	Basic UDI-DI: 697351970VDU0001VM **Group of Devices:** Video Duodenoscope Model: UHD-ED300V	MDR, Annex IX	Class IIa Rule 5, 10	Draft DoC: AH-YF-18.09-DOC-01(A.0)
	Basic UDI-DI: 697351970VGT0001WH **Group of Devices:** Video Gastroscope Models: UHD-GT300, UHD-GT300T, UHD-GT300Q, UHD-GT300Z; 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	MDR, Annex IX	Class IIa Rule 5, 10	Draft DoC: AH-YF-17.00-DOC-01(A.0) AH-YF-02.00-DOC-01(A.0)

Certificate number	Devices / groups of devices	Annex	Class & rule	Reference to Declaration of Conformity
	Basic UDI-DI: 697351970VBC0001NM **Group of Devices:** Video Bronchoscope 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; MBC-4, MBC-5, MBC-6	MDR, Annex IX	Class IIa Rule 5, 10	Draft DoC: AH-YF-06.00-DOC-01(A.0) AH-YF-05.00-DOC-01(A.0)
	Basic UDI-DI: 697351970VRL0001Y8 **Group of Devices:** Video Laryngoscope Models: VRL-1T30, VRL-Q30, VRL-XQ30, VRL-H30, VRL-XQ50H, VRL-Q50H; VRL-X300, VRL-XQ300H, VRL-N300H	MDR, Annex IX	Class IIa Rule 5, 10	Draft DoC: AH-YF-07.00-DOC-01(A.0)
	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)

Certificate number	Devices / groups of devices	Annex	Class & rule	Reference to Declaration of Conformity
	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	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)

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 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:

N/A

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 source	MAF (signed 2021-10-12)	MDR, Annex XI Part A	6111526CE01 6064489CN06	6111526-TDR01-R0 (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	MAF	MDR,	6111526CE02	6130354-

assessment of **Error! Reference source not found.**	(signed 2022-07-05)	Annex IX	6064489CN09	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)

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, 2nd surveillance (MDD) and 2nd initial MDR in accordance with Clients QMS, EN	MAF (signed 2021-10-12) MAF (signed	MDD, Annex V under Art. 120 of MDR MDR, Annex XI Part A	6064489; 6064491CE01; 6111526CE01 6064489CN07	6130353-AR05-R0 (17 May 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 13485:2016 - RvA accredited, MDD 93/42/EEC, MDR Annex XI part A and MDR Annex IX	2022-07-05)	MDR, Annex IX		

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:

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

Certificate number	Initial date	Renewal date	Revision date*	Expiry date
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	17 May 2023 (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.

19 January 2024

Signature of Certification Manager Date

DEKRA Certification B.V, Arnhem, The Netherlands