

OLYMPUS[®]

Your Vision, Our Future

Optera

GASTROINTESTINAL VIDEOSCOPE

GIF-H170

Outstanding HDTV image quality while keeping a slimmer outer diameter



Main Features

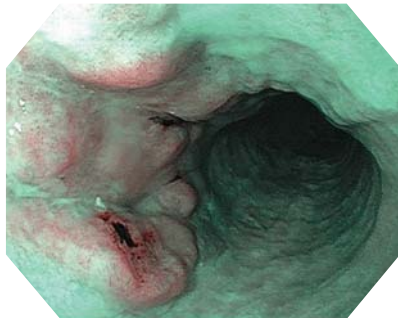
HDTV Image Quality

HDTV captures and displays clear images with precise details and accurate colors, helping you to perform more advanced procedures.



NBI (Narrow Band Imaging)

NBI facilitates observation of capillaries and other structures on the mucosal surface. It helps identify suspicious areas.



Close Focus

Close focus enables you to obtain an enlarged, close-up image by moving the scope tip as close as 2 mm from the mucosa.

Slim Design

GIF-H170 offers an excellent balance of both size and performance with its 9.2 mm outer diameter.

Waterproof Connector

The newly designed connector is fully submersible and therefore eliminates the need for a water-resistant cap, while minimizing the risk of damage due to accidental immersion.



Specifications

Optical System	Field of view	140°
	Direction of view	Forward viewing
	Depth of field	2-100 mm
Insertion Section	Distal end outer diameter	9.2 mm
	Distal end enlarged	
	Insertion tube outer diameter	9.2 mm
	Working length	1030 mm

Instrument Channel	Channel inner diameter	2.8 mm
	Minimum visible distance	3.0 mm from the distal end
High-frequency	Direction from which endotherapy accessories enter and exit the endoscopic image	
	Cauterization treatment	Available
Bending Section	Angulation range	Up 210°
		Down 90°
		Right 100° Left 100°
Total Length	1350 mm	

Specifications, design and accessories are subject to change without any notice or obligation on the part of the manufacturer.

Certificate



Quality Management System EN ISO 13485:2016

Registration No.: SX 2158445-1

Organization: OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho
Hachioji-shi, Tokyo
192-8507 Japan

Scope: Design and Development, Manufacture, Distribution, Service, Quality Assurance, Regulatory Affairs, Planning, Delivery support of Endoscopes, Endotherapy devices, Light Sources, Imaging Processors, Endoscope Position Detecting Units, Electrothermal Cautery Units, Integrated Endosurgery Systems, Endoscopic Regulation/Control Units, Camera Heads/Pumps/Monitors/Recorders for Endoscopy, Electrosurgical Equipment, Capsule Endoscopes and Systems, Laparoscopic Insufflators, Ultrasound Diagnostic Imaging Systems, Disinfecting Units, Ultrasound Surgical Equipment, Ultrasonic surgical system generator, Ultrasonic surgical system transducer, Hard-tissue ultrasonic surgical system holder/tip, Probes and Transducers for Ultrasonic Lithotriptors, Sterile Non Active Instruments used in conjunction with Endoscopes, Sterile Endotherapy Devices used in conjunction with Endoscopes, Sterile Non Active Devices used in conjunction with Medical Ultrasound Diagnostic Imaging Systems and Water Container, Water Supply Tube, Water Feeding valve and Foot Switch for Pump

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 150242490-301

Effective date: 2022-03-07

Expiry date: 2024-07-26

Issue date: 2022-03-07



Ning Chang

Ning N. C. Chang

TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany



Digitally signed by Grabazei Alexandru
Date: 2024.02.26 09:22:01 EET
Reason: MoldSign Signature

Location: Moldova

Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 2158445-1

Organization: OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho
Hachioji-shi, Tokyo
192-8507 Japan

The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o OLYMPUS MEDICAL SYSTEMS CORP. Ishikawa Office 2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507 Japan	Design and Development, Service, Administration, Management, Quality Assurance, Regulatory Affairs, Planning, Delivery support
/02	c/o OLYMPUS MEDICAL SYSTEMS CORP. Shinjuku Monolith Office Shinjuku Monolith, 3-1 Nishishinjuku 2-chome, Shinjuku-ku, Tokyo 163-0914 Japan	Quality Assurance for domestic market
/03	c/o OLYMPUS MEDICAL SYSTEMS CORP. Shirakawa Facility 3-1 Okamiyama, Odakura, Nishigo-mura, Nishishirakawa-gun, Fukushima 961-8061 Japan	Service and Quality Assurance

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Certificate

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Registration No.: SX 2158445-1

Organization: OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho
Hachioji-shi, Tokyo
192-8507 Japan

The scope of certification also covers the following:

/04 c/o OLYMPUS MEDICAL SYSTEMS Quality Assurance
CORP.
Aizu Facility
3-1-1 Niiderakita,
Aizuwakamatsu-shi, Fukushima
965-8520 Japan

TÜVRheinland®

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Registration No.: SX 2158445-1

Organization: OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho
Hachioji-shi, Tokyo
192-8507 Japan

The scope of certification also covers the following:

/05	c/o OLYMPUS MEDICAL SYSTEMS CORP. Aomori Facility 2-248-1 Okkonoki, Kuroishi-shi, Aomori 036-0357 Japan	Quality Assurance of Endoscopes, Endotherapy devices, Light Sources, Imaging Processors, Endoscope Position Detecting Units, Electrothermal Cautery Units, Integrated Endosurgery Systems, Endoscopic Regulation /Control Units, Camera Heads/Pumps/Monitors /Recorders for Endoscopy, Electrosurgical Equipment, Capsule Endoscopes and Systems, Laparoscopic Insufflators, Ultrasound Diagnostic Imaging Systems, Disinfecting Units and Ultrasound Surgical Equipment, Probes and Transducers for Ultrasonic Lithotriptors, Sterile Non Active Instruments used in conjunction with Endoscopes, Sterile Endotherapy Devices used in conjunction with Endoscopes, Sterile Non Active Devices used in conjunction with Medical Ultrasound Diagnostic Imaging Systems and Water Container, Water Supply Tube, Water Feeding valve and Foot Switch for Pump
		Design and Development of Endotherapy Devices, Sterile Endotherapy Devices used in conjunction with Endoscopes

Report No.: 150242490-301

Effective date: 2022-03-07

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Tillystraße 2 · 90431 Nürnberg · Germany



EC Certificate
Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60149405 0001

Report No.: 12018179 053

Manufacturer: OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho,
Hachioji-shi, Tokyo
192-8507 Japan

Products: Design and Development, Manufacture of Medical Endoscopy
Systems, Diagnostic, Operation and Treatment Products

(see attachments for products included)

Replaces Approval, Registration No.: HD 60144066 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2020-05-12

Date: 2020-05-12



Notified Body

M. Aihara
M.Sc. M. Aihara

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC
concerning medical devices with the identification number 0197.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: HD 60149405 0001
Report No.: 12018179 053

Manufacturer: OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho,
Hachioji-shi, Tokyo
192-8507 Japan

Products included:

Medical Endoscopy Systems:

- Endoscopes
- Endotherapy Devices
- Imaging Processors
- Pumps for Endoscopy
- Light Sources
- Position Detecting Units
- Electrothermal Cautery Units
- Integrated Endosurgery Systems
- Endoscopic Regulation/Control Units
- Electrosurgical Equipment
- Probes and Transducers for Ultrasonic Lithotriptors
- Laparoscopic Insufflators
- Ultrasound Surgical Equipment
- Ultrasonic Surgical System generator
- Ultrasonic Surgical System transducer
- Hard-tissue ultrasonic surgical system holder/tip
- Disinfecting Units
- Capsule Endoscopes and Systems
- Ultrasound Diagnostic Imaging Systems

Date: 2020-05-12

Notified Body

M. Aihara
M.Sc. M. Aihara

