

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. 01 100 080127/01

Certificate Holder:

OLYMPUS

Olympus Europa SE & Co. KG
Wendenstr. 14-18
D - 20097 Hamburg

Scope:

Marketing, sales and servicing of optical, opto-digital, electronic and mechanical systems as well as associated accessories and consumables in the field of imaging and audio products, endoscopy, microscopy and industry

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity:

The certificate is valid in conjunction with the main certificate from 2017-07-16 until 2020-07-15.


2017-06-30

Lab. R.A.

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com



 **TÜVRheinland®**
Precisely Right





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

Registration No.: HD 60123878 0001

Report No.: 12018179 022

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 and additional sites included)

Replaces Approval, Registration No.: HD 60078827 0001

Expiry Date: 2022-11-02

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: 2017-11-03

Date: 2017-10-12



Notified Body

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 D197.





TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev.0

**Attachment to
Certificate**

Registration No.: HD 60123878 0001
Report No.: 12018179 022

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 Cautey Units
- Integrated Endosurgery Systems
- Endoscopic Regulation/Control Units

Electrosurgical Equipment

Probes and Transducers for Ultrasonic Lithotriptors

Laparoscopic Insufflators

Ultrasound Surgical Equipment

Disinfecting Units

Capsule Endoscopes and Systems

Ultrasound Diagnostic Imaging Systems

Date: 2017-10-12



Notified Body

M. Aihara
M.Sc. M. Aihara



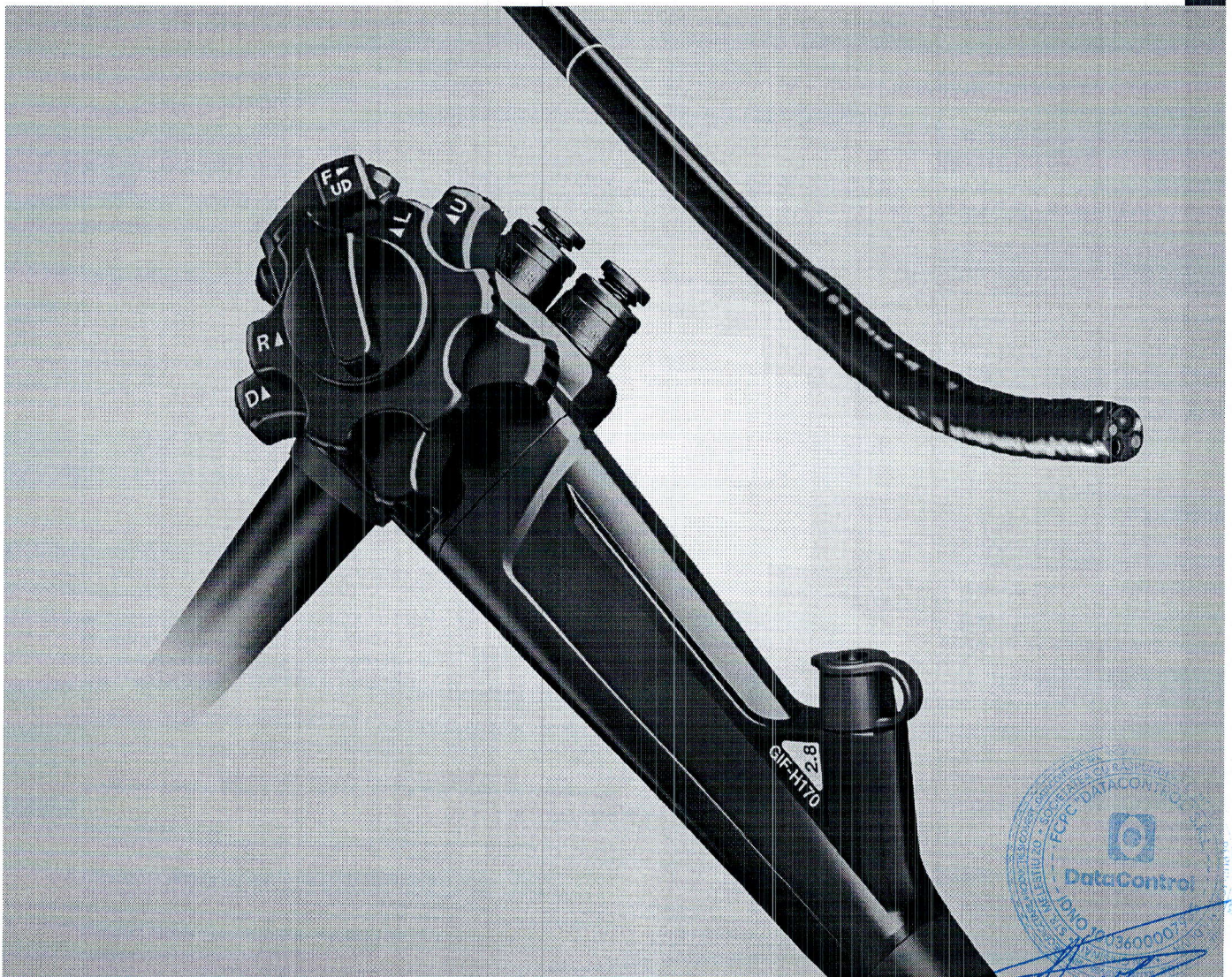
OLYMPUS

Your Vision, Our Future

Optera

GIF-H170

Outstanding HDTV image quality with a slimmer outer diameter



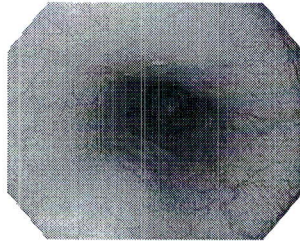
GIF-H170



Main features

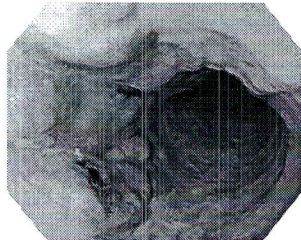
HDTV image quality

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



NBI (Narrow Band Imaging)

NBI facilitates the 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.

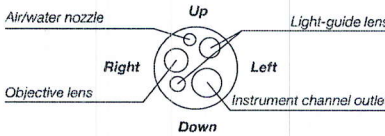

Slim Design

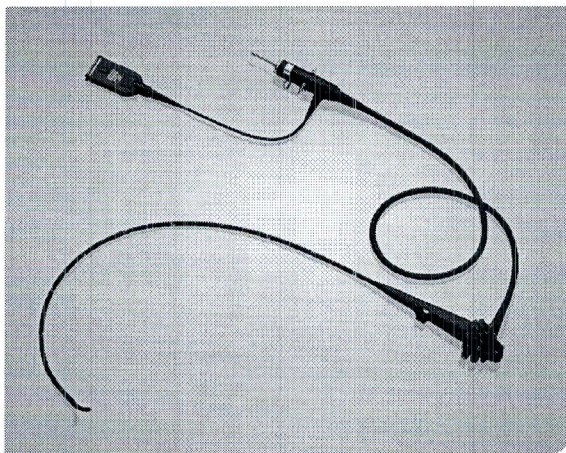
GIF-H170 offers an excellent balance of both size and performance with its 9.2 mm outer diameter.

Waterproof Connector

The newly designed connector is fully submersible and therefore eliminates the need for a water-resistant cap, while minimising 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	
		
Instrument channel	Channel inner diameter	2.8 mm
	Minimum visible distance	3 mm from the distal end
	Direction from which endotherapy accessories enter and exit the endoscopic image	
High-frequency	Cauterisation treatment	Available
Bending section	Angulation range	Up 210° Down 90° Right 100° Left 100°
	Total length	1,350 mm



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

OLYMPUS

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