

OLYMPUS[®]

Your Vision, Our Future

**EVIS LUCERA
ELITE**

EVIS LUCERA ELITE BRONCHOVIDEOSCOPE

BF-1TQ290

Therapeutic bronchoscope with high resolution image quality and a 3.0 mm instrument channel



Main Features

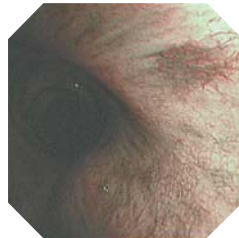
Excellent image

High-resolution image quality comparable to our previous flagship model (BF-6C260).



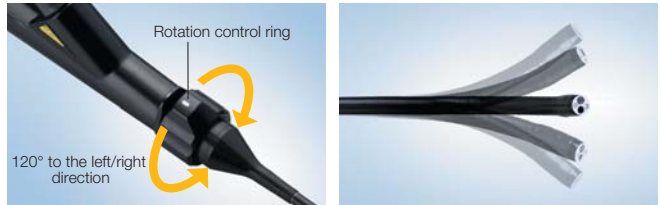
NBI (Narrow Band Imaging)

NBI is an optical image enhancement technology that improves the visualisation of vessels on the mucosal surface. NBI is now twice as bright as the CV-260, CLV-260SL and BF-1T260.



Insertion tube rotation function

The insertion tube can be rotated left or right up to 120 degrees by simply turning a ring on the control section of the scope. This supports easier operation and smoother insertion with less operator fatigue.



Wider Channel Diameter

The instrument channel diameter has been increased to 3.0 mm, which expands the ability of using various types of EndoTherapy devices such as large-cup biopsy forceps, while increasing suction volume.

Waterproof one-touch connector

A new connector design minimises the effort required for setup prior to and in between cases. In addition, it is fully submersible and eliminates the need for a water-resistant cap and the associated risk of an expensive repair due to accidental immersion.



Specifications

Optical System	Field of view	120°	
	Direction of view	Forward viewing	
	Depth of field	2-100 mm	
	Image quality	Q-image	
Insertion Tube	Distal end outer diameter	5.9 mm	
	Distal end enlarged		
	Insertion tube outer diameter		6.0 mm
	Working length		600 mm
	Insertion tube rotation function		Yes

Instrument Channel	Channel inner diameter	3.0 mm
	Minimum visible length	3.0 mm from the distal end
Bending Section	Direction from which EndoTherapy accessories enter and exit the endoscopic image	
	Angulation range	
Electro-Cautery instrument Compatibility	Yes	
Laser Compatibility	Nd: YAG, 810nm diode	
Compatible EVIS LUCERA System	Video System Center OLYMPUS CV-290 Xenon Light Source OLYMPUS CLV-290SL, CLV-290	

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



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

**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:

/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

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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

