

Product-Information-Sheet

Endoscopic Ancillaries

ENDOCUFF
VISION™



Article number	Article Name	Quantity value	For Use With	Description	Area Compatibility
N3645700	MAJ-1817	1	Olympus light sources: CLV-190, -290SL	Xenon lightbulb	

7. EUPseries

	EUP-B514	EUP-L53L	EUP-O54J	EUP-B715	EUP-C715
Manufacturer	FUJIFILM Healthcare Corporation	FUJIFILM Healthcare Corporation	FUJIFILM Healthcare Corporation	FUJIFILM Healthcare Corporation	FUJIFILM Healthcare Corporation
Type of probe (convex, linear, endocavitary,sector, 3D, 4D...)	convex	linear	linear	convex	convex
Number of elements	192	256	128	160	160
Nature of elements *1 crystals, ceramics, polymers, composite, CMUT	ceramics	ceramics	ceramics	ceramics (multi-layer)	ceramics (multi-layer)
Shape of elements	40R	-	-	50R	50R
Dimension of the skin contact area (mm x mm)	79.8 x 14.8	99.4 x 11	5.5 x 28.7	72.8 x 15	72.8 x 15
Field of view (linear: width, convex: sector angle)	C: 90deg.	L: 92mm	L: 25mm	C: 70deg.	C: 70deg.
Type of scanning: mechanical? Electronic linear? Sector electronics (phased array or curved probe)?	Electronic convex	Electronic linear	Electronic linear	Electronic convex	Electronic convex
For 3D / 4D probes: rotation of the probe (electronic or mechanical)	N/A	N/A	N/A	N/A	N/A
For 3D / 4D probes: sweep angle (in degrees)	N/A	N/A	N/A	N/A	N/A
Nominal Imaging Frequencies	3.5MHz (5-2MHz)	7.5MHz (10-5MHz)	10.0MHz (13-7MHz)	3.5MHz (5-1MHz)	3.0MHz (5-1MHz)
Weight (probe + connection cable)	390	1040	190	320	320
Cable length (cm)	220	220	220	220	220
Fully immersible probe *2	X	N/A	X	N/A	N/A
Sterilization is possible	X	X	X	X	X
Recommended method for decontamination and recommended products (Trade name versus active ingredient)	See Instructon Manual	See Instructon Manual	See Instructon Manual	See Instructon Manual	See Instructon Manual
Reference	Q1E-EP0616	Q1E-EP0348	Q1E-EP1064	Q1E-EP1245	Q1E-EP1011
Recommended method for disinfection and recommended products (Trade name versus active ingredient)	See Instructon Manual	See Instructon Manual	See Instructon Manual	See Instructon Manual	See Instructon Manual
Reference	Q1E-EP0616	Q1E-EP0348	Q1E-EP1064	Q1E-EP1245	Q1E-EP1011
Biopsy guide	X	N/A	N/A	X	X

*1 Suppose "composite" means 2 dimensional cut structure, All coresponding natures of each probe are stated.

*2 When immersing, optional waterproof box "EZU-WB1-H" is necessary. The resistance to water pressure resistance is up to 20 kPa.

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

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