



PRODUCT OVERVIEW

Discover the fascinating world of
PENTAX Medical endoscopy



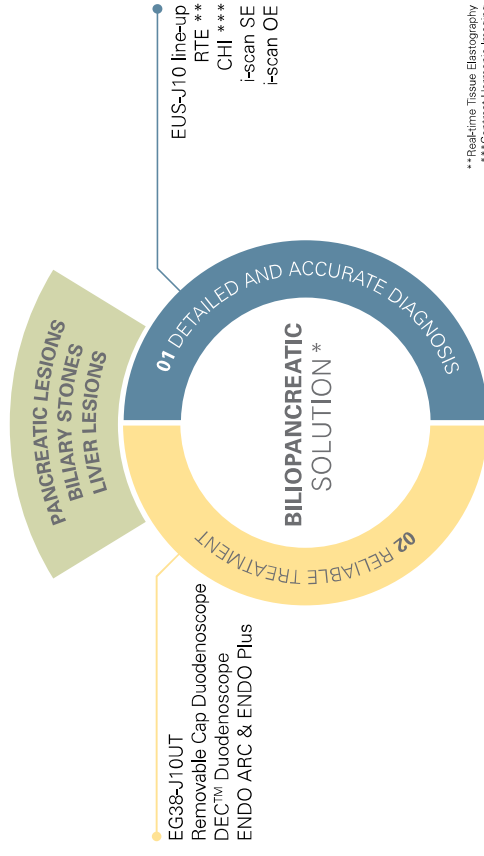
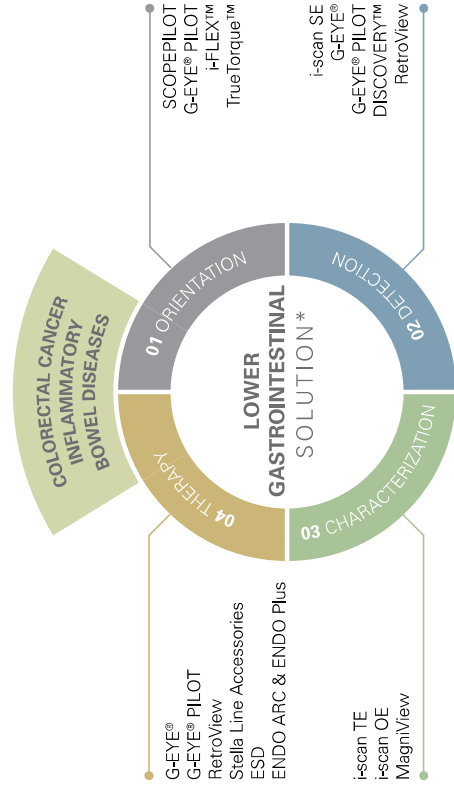
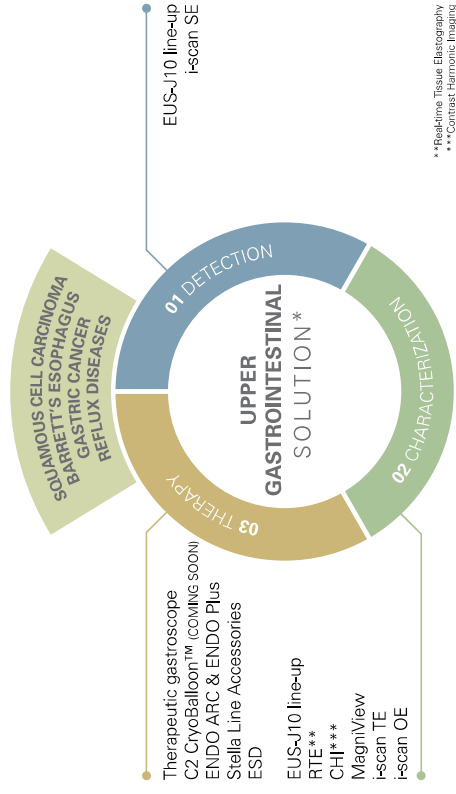


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With a combination of technological innovations and medical responsibility, PENTAX Medical sets new standards for endoscopic diagnosis and therapy.

State-of-the-art medical and technological equipment of the highest quality that come with intelligent system compatibility as well as a comprehensive system program. Furthermore, an efficient endoscope drying and storage system, in addition to an efficient service program provides the highest level of investment security for endoscopists of all relevant disciplines.

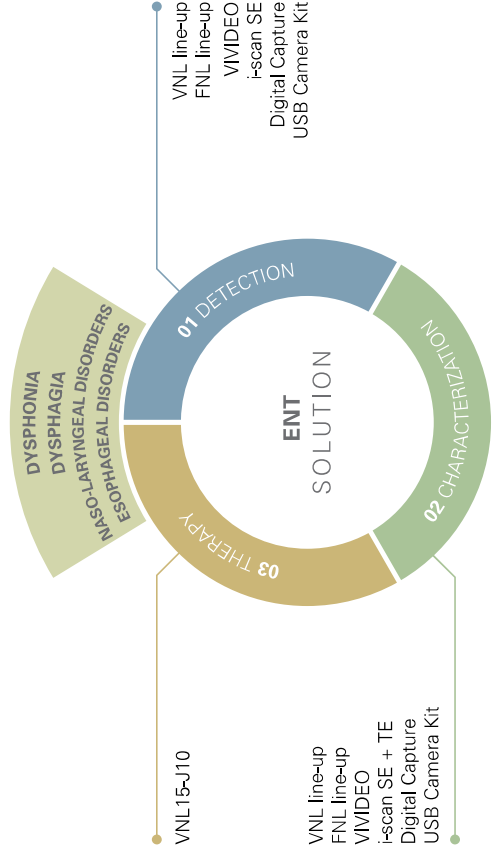
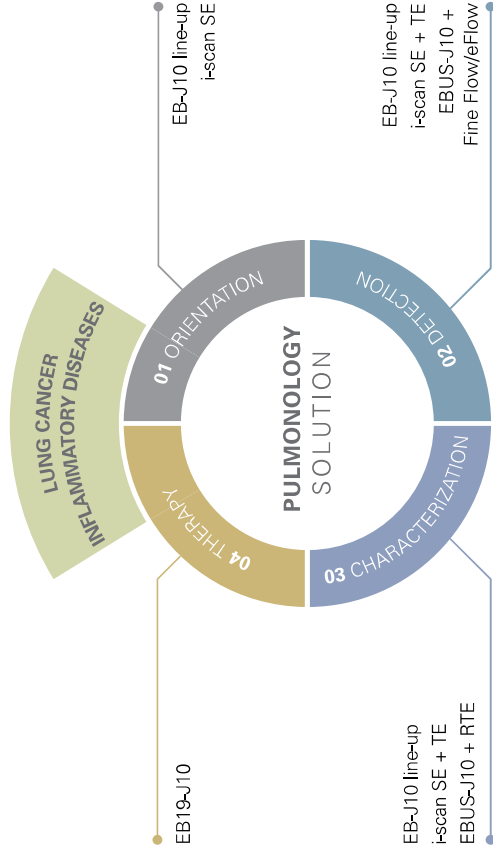
Solutions for every discipline and market



* All PENTAX Medical solutions can be combined with PlasmaTYPHOON and PlasmaBAG system for a complete endoscope drying and controlled storage solution. Please refer to page 64 for solution details.



Solutions for every discipline and market



Upper GI and Lower GI



Advanced diagnosis and treatment

Upper GI Endoscopes

Product	Insertion Tube ø (mm)	Min. Instrument Channel ø (mm)	Working Length (mm)	Tip angulation up/down (°)	Tip angulation right/left (°)	Field of view (°)	Remarks
EG17-J10 Video Gastroscopy	5.7	2.0	1100	210/120	120/120	140	HD, Transnasal, wide angle
EG27-i10 Video Gastroscopy	9	2.8	1050	210/120	120/120	140	HD+, Close Focus, Optimal ratio outer diameter/working channel
MagniView EG-2990Zi Video Gastroscopy	9.8	2.8	1050	210/120	120/120	140	HD+, Optical Zoom, MagniView, Water Jet System, Compatible with Distal Rubber Hood: OE-A58
EG29-i10 Video Gastroscopy	9.8	3.2	1050	210/120	120/120	140	HD+, Close Focus, Wide Therapeutic Option, Optimal ratio outer diameter/working channel, Water Jet System
EG34-i10 Video Gastroscopy	11.6	3.8	1050	210/120	120/120	140	HD+, Close Focus, Wide Therapeutic Option, Water Jet System
EG-3890TK Video Gastroscopy	12.8	3.8/2.8	1050	180/120	120/120	140	HD, Twin Channel, Water Jet System

Lower GI Endoscopes

Product	Insertion Tube ø (mm)	Min. Instrument Channel ø (mm)	Working Length (mm)	Tip angulation up/down (°)	Tip angulation right/left (°)	Field of view (°)	Remarks
RetroView EC34-i10TM Video Colonoscopy EC34-i10TF Video Colonoscopy EC34-i10TL Video Colonoscopy	11.6	3.2	1300 1500 1700	210/180	160/160	140	HD+, Close Focus, Wide Therapeutic Option, i-FLEX and TrueTorque, Water Jet System, RetroView radius
EC34-i10M Video Colonoscopy EC34-i10F Video Colonoscopy EC34-i10L Video Colonoscopy	11.6	3.8	1300 1500 1700	180/180	160/160	140	HD+, Close Focus, Wide Therapeutic Option, Optimal ratio outer diameter/working channel, i-FLEX and TrueTorque, Water Jet System
MagniView EC-3890MZi Video Colonoscopy EC-3890FZi Video Colonoscopy EC-3890LZi Video Colonoscopy	13.2	3.8	1300 1500 1700	180/180	160/160	140	HD, MagniView, i-FLEX and True-Torque, Water Jet System, Distal Rubber Hood (OE-A59)
EC-3890TLK Video Colonoscopy	13.2	3.8/2.8	1700	180/180	160/160	140	HD, i-FLEX and TrueTorque, Water Jet System, Twin Channel
EC38-i10M Video Colonoscopy EC38-i10F Video Colonoscopy EC38-i10L Video Colonoscopy	13.2	3.8	1300 1500 1700	180/180	160/160	140	HD+, i-FLEX and TrueTorque, Water Jet System
EC38-i10M2 Video Colonoscopy EC38-i10F2 Video Colonoscopy	13.2	3.8	1300 1500	180/180	160/160	140	HD+, i-FLEX and TrueTorque, increased rigidity, Water Jet System

Upper GI and Lower GI



Advanced diagnosis and treatment | G-EYE® System

G-EYE® Endoscopes

Product	Insertion Tube ø (mm)	Min. Instrument Channel ø (mm)	Working Length (mm)	Tip angulation up/down (°)	Tip angulation right/left (°)	Field of view (°)	Remarks
G-EYE34-i10F Video Colonoscope G-EYE34-i10L Video Colonoscope	11.6	3.8	1500 1700	180/180	160/160	140	HD+, Close Focus, Wide Therapeutic Option, Optimal ratio outer diameter/working channel, i-FLEX and TrueTorque, Water Jet System, permanently integrated reusable balloon
G-EYE38-i10F Video Colonoscope G-EYE38-i10L Video Colonoscope	13.2	3.8	1500 1700	180/180	160/160	140	HD+, Close Focus, i-Flex and TrueTorque, Water Jet System, permanently integrated reusable balloon
G-EYE38-i10F2 Video Colonoscope	13.2	3.8	1500	180/180	160/160	140	HD+, i-Flex and TrueTorque, Water Jet System, permanently integrated reusable balloon, increased rigidity
G-EYE38-i10NF G-EYE PILOT Video Colonoscope G-EYE38-i10NL G-EYE PILOT Video Colonoscope	13.2	3.8	1500 1700	180/180	160/160	140	HD+, Water Jet System, Permanently integrated G-EYE® reusable balloon for increased mucosa visualization, Laser treatment, electrosurgery treatment, 3D navigation support

Inflation System

Electrical input voltage [VAC]	Electrical input frequency [Hz]	Dimensions [mm]	Set Pressure Tolerance [mbar]	Inflated Balloon Set Pressure [mbar]
100 - 240	50-60	280 x 195 x 90	±10	Anchoring pressure 70. Unique Controlled Withdrawal™ pressure- 3 intermediate levels

NaviAid™ SPARK²C (Compatible with G-EYE® endoscopes and NaviAid™ AB-F)

NaviAid™ AB-F (Advancing Balloon)

Catheter Length [mm]	Compatible Working Channel [mm]	Balloon Diameter [mm]	Inflated Balloon Set Pressure [mBar]	Set Pressure Tolerance [mBar]	Balloon Inflation System - Power Supply
3,500	≥ 3.7	40	60	± 10	100-240 VAC; 50-60 Hz

Upper GI and Lower GI

Advanced diagnosis and treatment | SCOPEPILOT System

SCOPEPILOT Video Colonoscope

Product	Insertion Tube ø (mm)	Min. Instrument Channel ø (mm)	Working Length (mm)	Direction of view (°)	Tip angulation up/down (°)	Tip angulation right/left (°)	Field of view (°)	Remarks
EC38-i10NF SCOPEPILOT Video Colonoscope	13.2	3.8	1500	Forward	180/180	160/160	140	HD+, Water Jet System, i-FLEX and TrueTorque, 3D navigation support
EC38-i10NL SCOPEPILOT Video Colonoscope	13.2	3.8	1700					
EC34-i10NF SCOPEPILOT	11.6	3.2	1500					
EC34-i10NL SCOPEPILOT	11.6	3.2	1700					

PENTAX Medical Navigation Control Unit NCU-7000

Item	Specifications	
Power	Voltage	100 - 230VAC
	Voltage fluctuation	±10%
	Frequency	50 - 60Hz
	Rated input	150VA
Operating Environment	Ambient temperature	10°C - 30°C
	Relative humidity	30% - 75%
	Air pressure	700 - 1,060hPa
	Ambient temperature	-20°C - 60°C
Storage and Transportation Environment	Relative humidity	10% - 85%
	Air pressure	700 - 1,060hPa
	Digital output: DVI	Resolution of the entire monitor screen: 1920 x 1080p (1 set)
	RCU	1 set
Video Signal	Keyboard	1 set
	USB	1 set (USB 2.0 compliant) USB flash memory
	Recording media	USB flash memory
	Recording format	*USB hard drive is not available JPEG
Image Recording Functions	Excluding protrusions	400mm (W) x 100mm (H) x 400mm (D)
	Maximum dimensions	400mm (W) x 115mm (H) x 400mm (D)
	Weight	7.4kg



Upper GI and Lower GI

Advanced diagnosis | Artificial Intelligence

PENTAX Medical DISCOVERY™ PENTAX Medical Smart Assistant System SAS-M10

PENTAX Medical DISCOVERY™ assists endoscopists in finding potential polyps during a colonoscopy examination

Type	SAS-M10
Display	32" LCD capacitive touch-screen
Max. resolution	3,840 × 2,160
Max. colors	10 bits (8 bits + FRC) / 1.07B colors
Pixel Pitch (mm)	0.1845 × 0.1845
Luminance (cd/m2)	350 (TYP)
Mounting/Holder	VESA 100/200 mm
Size and weight	778 × 478 × 102 mm (W × H × D); 20.6 kg
Power supply	100 – 240 V AC, 50 – 60 Hz
Degree of protection against electric shock / ingress of water	Class I / IPX0
Compatible Video Processors	EPK-i7010, EPK-i7000, EPK-i7000(A), EPK-i5500c, EPK-i5000



Upper GI and Lower GI



Diagnostic and standard therapeutics

Upper GI Endoscopes

Product	Insertion Tube ø (mm)	Min. Instrument Channel ø (mm)	Working Length (mm)	Tip angulation up/down (°)	Tip angulation right/left (°)	Field of view (°)	Remarks
EG-2490K Video Gastroscope	8	2.4	1050	210/120	120/120	140	HD
EG-2790K Video Gastroscope	9	2.8	1050	210/120	120/120	140	HD
EG-2990i Video Gastroscope	9.8	2.8	1050	210/120	120/120	140	HD+, Water Jet System

Lower GI Endoscopes

Product	Insertion Tube ø (mm)	Min. Instrument Channel ø (mm)	Working Length (mm)	Tip angulation up/down (°)	Tip angulation right/left (°)	Field of view (°)	Remarks
RetroView EC-3490TMI Video Colonoscope	11.6	3.2	1300	210/180	160/160	140	HD+, RetroView radius, i-FLEX and TrueTorque, Water Jet System
EC-3890Fi2 Video Colonoscope	13.2	3.8	1500	180/180	160/160	140	HD+, i-FLEX and TrueTorque, Water Jet System
EC-3890Fi Video Colonoscope EC-3890Li Video Colonoscope	13.2	3.8	1500 1700	180/180	160/160	140	HD+, i-FLEX and TrueTorque, Water Jet System
EC-3890TLK Video Colonoscope	13.2	3.8/2.8	1700	180/180	160/160	140	HD, i-FLEX and TrueTorque, Twin Channel, Water Jet System

Upper GI and Lower GI

Diagnostic and standard therapeutics

Processors

EPK-3000 DEFINA Video Processor with i-scan	
Light source	150W Xenon
Advanced imaging modalities	Digital image enhancement (i-scan SE, CE, TE)
Digital output	DVI-D
Analog output	RGB, Y/C, composite
User Interface	Control panel, keyboard
Digital Zoom	yes
Dimensions (W x H x D)	350 x 180 x 485 mm
EPK-i5000 Video Processor with i-scan	
Digital output	SXGA (native resolution) via DVI-D
Analogue output	RGB, Y/C, composite, VGA
i-scan virtual chromoendoscopy	Quick access via i-scan keys 1, 2, 3
Light source	300W Xenon
Dimensions (W x H x D / weight)	400 x 205 x 485 mm / 22.0 kg



Upper GI and Lower GI



Diagnostic and standard therapeutics | IMAGINA System

Upper GI Endoscope IMAGINA

Product	Insertion Tube ø (mm)	Min. Instrument Channel ø (mm)	Working Length (mm)	Tip angulation up/down (°)	Tip angulation right/left (°)	Field of view (°)	Remarks
EG29-i10c IMAGINA Video Gastroscope	9.8	3.2	1050	210/120	120/120	140	HD+ image, LED, Water Jet System

Lower GI Endoscopes IMAGINA

Product	Insertion Tube ø (mm)	Min. Instrument Channel ø (mm)	Working Length (mm)	Tip angulation up/down (°)	Tip angulation right/left (°)	Field of view (°)	Remarks
EC34-i10cM IMAGINA Video Colonoscope EC34-i10cF IMAGINA Video Colonoscope EC34-i10cL IMAGINA Video Colonoscope	11.6	3.8	1300 1500 1700	180/180	160/160	140	HD+ image, i-FLEX and TrueTorque, Water Jet System, LED
EC38-i10cF2 IMAGINA Video Colonoscope	13.2	3.8	1500	180/180	160/160	140	HD+ image, i-FLEX and TrueTorque, Water Jet System, LED, increased rigidity
EC38-i10cM IMAGINA Video Colonoscope EC38-i10cF IMAGINA Video Colonoscope EC38-i10cL IMAGINA Video Colonoscope	13.2	3.8	1300 1500 1700	180/180	160/160	140	HD+ image, i-FLEX and TrueTorque, Water Jet System, LED

IMAGINA G-EYE® Endoscopes

Product	Insertion Tube ø (mm)	Min. Instrument Channel ø (mm)	Working Length (mm)	Tip angulation up/down (°)	Tip angulation right/left (°)	Field of view (°)	Remarks
G-EYE34-i10cF Video Endoscope G-EYE34-i10cL Video Endoscope	11.6	3.8	1500 1700	180/180	160/160	140	HD+ image, i-FLEX and TrueTorque, Water Jet System, LED, permanently integrated reusable balloon
G-EYE38-i10cF2 Video Endoscope	13.2	3.8	1500	180/180	160/160	140	HD+ image, i-FLEX and TrueTorque, Water Jet System, LED, permanently integrated reusable balloon
G-EYE38-i10cM Video Endoscope G-EYE38-i10cF Video Endoscope G-EYE38-i10cL Video Endoscope	13.2	3.8	1300 1500 1700	180/180	160/160	140	HD+ image, i-FLEX and TrueTorque, Water Jet System, LED, permanently integrated reusable balloon

Processor IMAGINA

Product	Light Source	Advanced imaging modalities	Video Output	Digital	Input	Printer-specific output	User Interface	Digital Zoom	Dimensions (W x H x D / weight)
EPK-i6500c IMAGINA Video Processor with i-scan and LED Technology	LED (build into the endoscope, not into the processor)	Digital image enhancement (SE, CE, TE)	DVI, VGA	DVI	Y/C	7 inch customizable, smartphone-like touchscreen	Up to x 2.0	400 x 172.6 x 471mm / 13kg	

Upper GI and Lower GI



Basic diagnosis and treatment

Upper GI Endoscopes

Product	Insertion Tube ø (mm)	Min. Instrument Channel ø (mm)	Working Length (mm)	Tip angulation up/down (°)	Tip angulation right/left (°)	Field of view (°)	Remarks
EG-2490K Gastroscope 90K	8.0	2.4	1050	210/120	120/120	140	
EG-2790K Gastroscope 90K	9.0	2.8	1050	210/120	120/120	140	
EG-2990K Gastroscope 90K	9.8	2.8	1050	210/120	120/120	140	
EG-3890TK Gastroscope 90K	12.8	3.8/2.8	1050	180/120	120/120	140	

Lower GI Endoscopes

Product	Insertion Tube ø (mm)	Min. Instrument Channel ø (mm)	Working Length (mm)	Tip angulation up/down (°)	Tip angulation right/left (°)	Field of view (°)	Remarks
EC-3490FK Colonoscope 90K	11.6	3.8	1500	180/180	160/160	140	
EC-3490LK Colonoscope 90K	11.6	3.8	1700	180/180	160/160	140	
EC-3890FK2 Colonoscope 90K	13.2	4.2	1500	180/180	160/160	140	Insertion tube with increased rigidity in comparison with standard equipment
EC-3890FK Colonoscope 90K	13.2	4.2	1500	180/180	160/160	140	
EC-3890LK Colonoscope 90K	13.2	4.2	1700	180/180	160/160	140	
EC-3890TLK Colonoscope 90K	13.2	3.8/2.8	1700	180/180	160/160	140	

Upper GI and Lower GI



Basic diagnosis and treatment | Versa System *

Upper GI Endoscopes

Product	Insertion Tube ø (mm)	Min. Instrument Channel ø (mm)	Working Length (mm)	Tip angulation up/down (°)	Tip angulation right/left (°)	Field of view (°)	Remarks
EG27-V10c VERSA Video Gastroscope EG29-V10c VERSA Video Gastroscope	9 9,6	2,8	1050	210/90	100/100	140	HD, LED

Lower GI Endoscopes

Product	Insertion Tube ø (mm)	Min. Instrument Channel ø (mm)	Working Length (mm)	Tip angulation up/down (°)	Tip angulation right/left (°)	Field of view (°)	Remarks
EC38-V10cL VERSA Video Colonoscope EC38-V10cM VERSA Video Colonoscope	12,8	3,7	1650 1300	180/180	160/160	140	HD, LED

Processor

EPK-V1500c VERSA Video Processor with HD and LED Technology

Video output	Y/C, DVI, RGB, SYNC, AV
Imaging enhancement	E-stressed mucosal morphology or profile for increasing the sharpness of endoscopic images. Profile enhance level has four gears to choose from.
Light source	LED
Dimensions (W x H x D / weight)	452 x 167 x 456 mm / 11.5 kg
Color tone adjustment	"R," "B" adjustment: ±25 steps
Brightness adjustment	"Y" adjustment: ±25 steps
Freeze, save, review	Endoscopic images can be frozen and saved, so that images can be reviewed
Gain control	(OFF 1, 2 and 3)
Metering mode	Average; Peak
White balance adjustment	Press the white balance switch to perform the white balance adjustment.
Voltage	100 - 240VAC
Power frequency	50Hz/60Hz
Air flow	2 steps (H/L)

Upper GI and Lower GI

Peripherals and Accessories

Recommended Leak Testers

Product	Remarks
SHA-P6 Automatic Leakage Tester	
Manual Leakage Tester for VERSA*	only for VERSA system

Recommended Trolleys

Product	Remarks
Classic Cart with Insulation Transformer	
PTV10c - Endoscopic Trolley	
Uni-Cart	
Uni Cart DISCOVERY	

Recommended Monitors

Product	Remarks
21" EndoVue Monitor	
24" EndoVue Monitor	
27" Radiance Ultra Monitor	
32" EndoVue Monitor	
PENTAX ZeroWire G2 Pair, for 32" Monitor	
PENTAX ZeroWire G2 Pair, for 27" Monitor	

Pumps

Product	Remarks
EGA-500 - irrigation pump	
EGA-501 - CO ₂ insufflator	
Senator30 - suction pump	

*available only in selected countries



Electrosurgery

Main Units

Product	Remarks
ARC 400 Electrosurgical Unit	
ARC PLUS Unit for ARC 400	
ENDO ARC Electrosurgical Unit	
ENDO PLUS Unit for ENDO ARC	
Fuego Basic Trolley II	

Basic Accessories for ENDO ARC

Product	Remarks
Monopolar Cable Endoscopy 2,8 mm Socket 4 mm	
Single Use Cable Return Plate 4,5 m	
Split Neutral Electrode, 90 cm ² , EASY (100 pieces)	

Basic Accessories for ARC 400

Product	Remarks
Monopolar Cable Endoscopy 2,8 mm Socket Comfort	
Single Use Cable Return Plate 4,5 m	
Split Neutral Electrode, 110 cm ² , EASY (100 pieces)	

Consumables for ENDO PLUS and ARC PLUS

Product	Remarks
Disposable Filters (50 pieces)	
Reusable Cable for Flexible Argon Probe Comfort 2,5 m	
Disposable Flexible Argon Probe, Ø 2,3 mm, 2,2 m (10 pieces)	
Disposable Flexible Argon Probe, Ø 3,2 mm, 2,2 m (10 pieces)	
Disposable Flexible Argon Probe, Ø 1,5 mm, 3 m (10 pieces)	
Disposable Flexible Argon Probe, Ø 2,3 mm, 3 m (10 pieces)	
Disposable Flexible Argon Probe, 90°, Ø 2,3 mm, 2,2 m (10 pieces)	

Biliopancreatic



Advanced diagnosis and treatment

ERCP Endoscopes

Product	Insertion Tube ø (mm)	Min. Instrument Channel ø (mm)	Working Length (mm)	Tip angulation up/down (°)	Tip angulation right/left (°)	Field of view (°)	Remarks
ED32-i10 Video DEC™ Duodenoscope	10.8	3.2	1250	120/90	105/90	105 (retro 15)	HD, DEC™ (Disposable Elevator Cap)
ED34-i10T2 Video DEC™ Duodenoscope	11.6	4.2	1250	120/90	105/90	100 (retro 10)	HD, DEC™ (Disposable Elevator Cap)
ED34-i10T Video Duodenoscope	11.6	4.2	1250	120/90	105/90	100 (retro 10)	HD, detachable distal-end cap

Endoscopic Ultrasound (EUS) Endoscopes

Product	Insertion Tube ø (mm)	Min. Instrument Channel ø (mm)	Working Length (mm)	Tip angulation up/down (°)	Tip angulation right/left (°)	Field of view (°)	Remarks
EG34-J10U Ultrasound Video Gastroscope	11.6	2.8	1250	160/130	120/120	120	Convex, RTE**, dCHI***, Frequency (MHz) 5 – 13, Scan angle (°) 150
EG38-J10UT Ultrasound Video Gastroscope	12.8	4.0	1250	160/130	120/120	120	Convex, RTE**, dCHI***, Frequency (MHz) 5 – 13, Scan angle (°) 150
EG36-J10UR Ultrasound Video Gastroscope	12.1	2.4	1250	150/70	70/70	140	Radial, RTE**, dCHI*** Frequency (MHz) 5 – 13, Scan angle (°) 360

Processor

EPK-i7010 OPTIVISTA plus Video Processor with i-scan and i-scan OE

Light source	300W Xenon
Advanced imaging modalities	Digital image enhancement (i-scan SE, CE, TE) Optical image enhancement (i-scan OE)
Digital output	HD-SDI, DVI
Analog output	RGB, S-Video, composite video
User interface	Touch screen, TwinMode
Digital zoom	yes
Dimensions (W x H x D)	400 x 205 x 520 mm

**Real-time Tissue Elastography
***Dynamic Contrast Harmonic Imaging

Biliopancreatic



Diagnostic and standard therapeutics

ERCP Endoscopes

Product	Insertion Tube ø (mm)	Min. Instrument Channel ø (mm)	Working Length (mm)	Tip angulation up/down (°)	Tip angulation right/left (°)	Field of view (°)	Remarks
ED34-i10T2 Video DEC™ Duodenoscope	11.6	4.2	1250	120/90	105/90	100 (retro 10)	HD+, DEC™ (Disposable Elevator Cap)
ED34-i10T Video Duodenoscope	11.6	4.2	1250	120/90	105/90	100 (retro 10)	HD+, detachable distal-end cap

Endoscopic Ultrasound (EUS) Endoscopes

Product	Insertion Tube ø (mm)	Min. Instrument Channel ø (mm)	Working Length (mm)	Tip angulation up/down (°)	Tip angulation right/left (°)	Field of view (°)	Remarks
EG34-J10U Ultrasound Video Gastroscope	11.6	2.8	1250	160/130	120/120	120	Convex, RTE*, dCHI**, Frequency (MHz) 5 –13, Scan angle (°) 150
EG38-J10UT Ultrasound Video Gastroscope	12.8	4.0	1250	160/130	120/120	120	Convex, RTE*, dCHI**, Frequency (MHz) 5 –13, Scan angle (°) 150
EG36-J10UR Ultrasound Video Gastroscope	12.1	2.4	1250	150/70	70/70	140	Radial, RTE*, dCHI**, Frequency (MHz) 5 –13, Scan angle (°) 360

Processors

EPK-i7010 OPTIVISTA plus Video Processor with i-scan and i-scan OE	
Light source	300W Xenon
Advanced imaging modalities	Digital image enhancement (i-scan SE, CE, TE) Optical image enhancement (i-scan OE)
Video output	HD-SDI, DVI
Analog output	RGB, S-Video, composite video
User interface	Touch screen, TwinMode
Digital zoom	yes
Dimensions (W x H x D)	400 x 205 x 520 mm

EPK-i5000	
Digital output	SXGA (native resolution) via DVI-D
Analog output	RGB, Y/C, composite, VGA
User interface	Control panel, keyboard
i-scan virtual chromoendoscopy	Quick access via i-scan keys 1, 2, 3
Light source	300W Xenon
Dimensions (W x H x D / weight)	400 x 205 x 485 mm / 22.0 kg

*Real-time Tissue Elastography
**Dynamic Contrast Harmonic Imaging

Biliopancreatic



Basic diagnosis and treatment

ERCP Endoscope

Product	Insertion Tube ø (mm)	Min. Instrument Channel ø (mm)	Working Length (mm)	Tip angulation up/down (°)	Tip angulation right/left (°)	Field of view (°)	Remarks
ED34-i10T Video Duodenoscope	11.6	4.2	1250	120/90	105/90	100 (retro 10)	HD, detachable distal-end cap

Endoscopic Ultrasound (EUS) Endoscopes

Product	Insertion Tube ø (mm)	Min. Instrument Channel ø (mm)	Working Length (mm)	Tip angulation up/down (°)	Tip angulation right/left (°)	Field of view (°)	Remarks
EG34-J10U Ultrasound Video Gastroscope	11.6	2.8	1250	160/130	120/120	120	Convex, RTE*, dCHI**, Frequency (MHz) 5 –13, Scan angle (°) 150
EG38-J10UT Ultrasound Video Gastroscope	12.8	4.0	1250	160/130	120/120	120	Convex, RTE*, dCHI**, Frequency (MHz) 5 –13, Scan angle (°) 150
EG36-J10UR Ultrasound Video Gastroscope	12.1	2.4	1250	150/70	70/70	140	Radial, RTE*, dCHI**, Frequency (MHz) 5 –13, Scan angle (°) 360

Processor

EPK-i5000				
Digital output	SXGA (native resolution) via DVI-D			
Analog output	RGB, Y/C, composite, VGA			
User interface	Control panel, keyboard			
i-scan virtual chromoendoscopy	Quick access via i-scan keys 1, 2, 3			
Light source	300W Xenon			
Dimensions (W x H x D / weight)	400 x 205 x 485 mm / 22.0 kg			

*Real-time Tissue Elastography
**Dynamic Contrast Harmonic Imaging

Biliopancreatic

Peripherals and Accessories

Recommended Leak Tester

Product	Remarks
SHA-P6 Automatic Leakage Tester	

Recommended Trolleys

Product	Remarks
Classic Cart with Insulation Transformer	

Recommended Monitor

Product	Remarks
27" Radiance Ultra Monitor NDS	

Accessories

Product	Remarks
OE-A65 Sterile Disposable Elevator Cap (DEC™)	DEC™ (Disposable Elevator Cap). To be used with ED32-i10 Video DEC™ Duodenoscope
OE-A63 Sterile Disposable Elevator Cap (DEC™)	To be used with ED34-i10T2 Video DEC™ Duodenoscope
OE-A65 Detachable Distal-End Cap	To be used with ED34-i10T Video Duodenoscope

Pumps

Product	Remarks
EGA-500 - irrigation pump	
EGA-501 - CO ₂ insufflator	
Senator30 - suction pump	



Electrosurgery

Main Units

Product	Remarks
ARC PLUS Unit for ARC 400	
ENDO ARC Electrosurgical Unit	
ENDO PLUS Unit for ENDO ARC	
Fuego Basic Trolley II	

Basic Accessories for ENDO ARC

Product	Remarks
Monopolar Cable Endoscopy 2,8 mm Socket 4 mm	
Single Use Cable Return Plate 4,5 m	
Split Neutral Electrode, 90 cm ² , EASY (100 pieces)	

Basic Accessories for ARC 400

Product	Remarks
Monopolar Cable Endoscopy 2,8 mm Socket Comfort	
Single Use Cable Return Plate 4,5 m	
Split Neutral Electrode, 110 cm ² , EASY (100 pieces)	

Consumables for ENDO PLUS and ARC PLUS

Product	Remarks
Set of Sterile Filters (50 pieces)	
Cable for Flexible Argon Probe Comfort 2,5 m (Reusable)	
Flexible Argon Probe, Ø 2,3 mm, 2,2 m (10 pieces)	
Flexible Argon Probe, Ø 3,2 mm, 2,2 m (10 pieces)	
Flexible Argon Probe, Ø 1,5 mm, 3 m (10 pieces)	
Flexible Argon Probe, Ø 2,3 mm, 3 m (10 pieces)	
Flexible Argon Probe, 90°, Ø 2,3 mm, 2,2 m (10 pieces)	

Pulmonology

Advanced diagnosis and treatment

Endoscopes

Product	Insertion Tube ø (mm)	Min. Instrument Channel ø (mm)	Working Length (mm)	Tip angulation up/down (°)	Field of view (°)	Remarks
EB11-J10 Video Bronchoscope	3.9	1.2	600	210/130	120	HD, STERRAD® compatible
EB15-J10 Video Bronchoscope	5.2	2.0	600	210/130	120	HD, STERRAD® compatible
EB19-J10 Video Bronchoscope	6.4	2.8	600	180/130	120	HD, STERRAD® compatible
EB19-J10U Ultrasound Video Bronchoscope	6.3	2.2	600	120/90	100	Convex, Frequency [MHz] 5-13** , Scan angle 75°, RTE*

Processors

EPK-i7010 OPTIVISTA plus Video Processor with i-scan and i-scan OE		EPK-3000 DEFINA Video Processor with i-scan	
Light source	300W Xenon	Light source	150W Xenon
Advanced imaging modalities	Digital image enhancement (i-scan SE, CE, TE) Optical image enhancement (i-scan OE)	Advanced imaging modalities	Digital image enhancement (i-scan SE, CE, TE)
Digital output	HD-SDI, DVI	Digital output	DVI-D
Analog outputs	RGB, S-Video, composite video	Analog outputs	RGB, Y/C, composite
User interface	Touch screen, TwinMode	User Interface	Control panel, keyboard
Digital zoom	yes	Digital Zoom	yes
Dimensions (W x H x D)	400 x 205 x 520 mm	Dimensions (W x H x D)	350 x 180 x 485 mm

*Real-time Tissue Elastography

**For details on frequency, refer to the instructions for use provided with the ultrasound scanning unit





Diagnostic and standard therapeutics

Endoscopes

Product	Insertion Tube ø (mm)	Min. Instrument Channel ø (mm)	Working Length (mm)	Tip angulation up/down (°)	Field of view (°)	Remarks
EB15-J10 Video Bronchoscope	5.2	2.0	600	210/130	120	HD, STERRAD® compatible
EB19-J10U Ultrasound Video Bronchoscope	6.3	2.2	600	120/90	100	Convex, Frequency [MHz] 5-13*, Scan angle [°] 75, RTE*
EB19-J10 Video Bronchoscope	6.4	2.8	600	180/130	120	HD, STERRAD® compatible

Processor

EPK-3000 DEFINA Video Processor with i-scan	
Light source	150W Xenon
Advanced imaging modalities	Digital image enhancement (i-scan SE, CE, TE)
Digital output	DVI-D
Analog output	RGB, Y/C, composite
User Interface	Control panel, keyboard
Digital Zoom	yes
Dimensions (W x H x D)	350 x 180 x 485 mm

*Real-time Tissue Elastography

Pulmonology



Basic diagnosis and treatment

Endoscopes

Product	Insertion Tube ø (mm)	Min. Instrument Channel ø (mm)	Working Length (mm)	Tip angulation up/down (°)	Field of view (°)	Remarks
FB-8V Fiber Bronchoscope	2.8	1.15	600	180/130	100	Suction Control Valve
FB-15V Fiber Bronchoscope	4.9	2.1	600	180/130	120	Suction Control Valve
FB-18V Fiber Bronchoscope	6.0	2.7	600	180/130	120	Suction Control Valve
FB-19TV Fiber Bronchoscope	6.2	3.0	600	180/130	120	Suction Control Valve
FB-15RBS Portable Fiber Bronchoscope	4.9	1.95	600	180/130	100	Portable, LSV Solutions (Light Source Versatility), Plastic Suction Control Valve
FB-18RBS Portable Fiber Bronchoscope	6.0	2.55	600	180/90	100	Portable, LSV Solutions (Light Source Versatility), Plastic Suction Control Valve

Light Source

BS-LL1 LED Light Source Battery-type - for BS series only	
Dimensions	32 mm (W) x 32 mm (H) x 88 mm (D)
Weight	0.11 kg
Power supply	Lithium Battery DC3V
Power consumption [W]	250 mW max.
Lamp	White LED
Pressure [hPa]	700-1060

Endoscopic camera	
S181P USB Camera	
Sensor	CCD 1/4" high sensitivity
Resolution of the sensor	(725 x 582) PAL / (768 x 494) NTSC
Weight [g]	210
Cable length	3m, Ø 5mm
iCe Technology, Electronic anti-noiré filter for flexible fiberoscope, 2 x programmable buttons, 1 x USB 2.0 output	

Pulmonology

Peripherals and Accessories

Recommended Leak Tester

Product	Remarks
SHA-P6 Automatic Leakage Tester	

Recommended Trolley

Product	Remarks
Classic Cart with Insulation Transformer	

Recommended Monitor

Product	Remarks
27" Radiance Ultra Monitor NDS	

Accessories

Product	Remarks
OF-B205 Single Use Suction Control Valves (10 pieces)	To be used with EB11-J10, EB15-J10, EB19-J10 and EB19-J10U



Intubation



Advanced diagnosis and treatment

Endoscope

Product	Insertion Tube ø (mm)	Min. Instrument Channel ø (mm)	Working Length (mm)	Tip angulation up/down (°)	Field of view (°)	Remarks
EB11-J10 Video Bronchoscope	3.9	1.2	600	210/130	120	HD, STERRAD® compatible
EB15-J10 Video Bronchoscope	5.2	2.0	600	210/130	120	HD, STERRAD® compatible
EB19-J10 Video Bronchoscope	6.4	2.8	600	180/130	120	HD, STERRAD® compatible

Processor

EPK-3000 DEFINA Video Processor with i-scan	
Light source	150W Xenon
Advanced imaging modalities	Digital image enhancement (i-scan SE, CE, TE)
Digital output	DVI-D
Analog output	RGB, Y/C, composite
User Interface	Control panel, keyboard
Digital Zoom	yes
Dimensions (W x H x D)	350 x 180 x 485 mm

Intubation



Basic diagnosis and treatment

Endoscopes

Product	Insertion Tube ø (mm)	Min. Instrument Channel ø (mm)	Working Length (mm)	Tip angulation up/down (°)	Field of view (°)	Remarks
FI-7RBS Portable Fiber Intubation Scope	2.4	-	600	130/130	95	portable, LSV (Light Source Versatility) Solution
FI-9RBS Portable Fiber Intubation Scope	3.1	1.15	600	130/130	90	portable, LSV (Light Source Versatility) Solution, Suction Control Valve
FI-10RBS Portable Fiber Intubation Scope	3.5	1.31	600	130/130	90	portable, LSV (Light Source Versatility) Solution, Suction Control Valve
FI-13RBS Portable Fiber Intubation Scope	4.2	1.72	600	160/130	95	portable, LSV (Light Source Versatility) Solution, Suction Control Valve
FI-16RBS Portable Fiber Intubation Scope	5.2	2.55	600	160/130	95	portable, LSV (Light Source Versatility) Solution, Suction Control Valve

Light Source

BS-LL1 LED Light Source Battery-type - for BS series only	
Dimensions	32 mm (W) x 32 mm (H) x 88 mm (D)
Weight	0.11 kg
Power supply	Lithium Battery DC3V
Power consumption	250 mW max.
Lamp	White LED
Pressure [hPa]	700-1060

Endoscopic camera

SI181P USB Camera	
Sensor	CCD 1/4" high sensitivity
Resolution of the sensor	(725 x 582) PAL / (768 x 494) NTSC
Weight [g]	210
Cable length	3m, Ø 5mm
iCe Technology. Electronic anti-noiré filter for flexible fiberoptic, 2 x programmable buttons, 1 x USB 2.0 output	

Intubation

Peripherals and Accessories

Recommended Leak Tester

Product	Remarks
SHA-P6 Automatic Leakage Tester	

Recommended Trolley

Classic Cart with Insulation Transformer	
Weight [kg]	70
Dimensions - H x W x D [mm]	1309 x 614 x 625
Cart load capacity	150

Recommended Monitor

Product	Remarks
27" Radiance Ultra Monitor	



Advanced diagnosis and treatment

Endoscopes

Product	Insertion Tube ø (mm)	Min. Instrument Channel ø (mm)	Working Length (mm)	Tip angulation up/down (°)	Field of view (°)	Remarks
VNL8-J10 Video Naso-Pharyngo-Laryngoscope	2.9	-	300	130/130	80	HD, STERRAD® compatible
VNL11-J10 Video Naso-Pharyngo-Laryngoscope	3.6	-	300	130/130	80	HD, STERRAD® compatible
VNL15-J10 Video Naso-Pharyngo-Laryngoscope	4.9	2.0	300	130/130	80	HD, STERRAD® compatible



Processor

EPK-i7010 OPTIVISTA plus Video Processor with i-scan and i-scan OE

Light source	300W Xenon
Advanced imaging modalities	Digital image enhancement (i-scan SE, CE, TE) Optical image enhancement (i-scan OE)
Digital output	HD-SDI, DVI
Analog output	RGB, S-Video, composite video
User interface	Touch screen, TwinMode
Digital zoom	yes
Dimensions (W x H x D)	400 x 205 x 520 mm

Light Source

Product	Remarks
Laryngeal Strobe	

Digital Capturing Module

KAY9372HD Digital Capture

Product Name	9372HD Digital Capture
Processor and Memory	Intel® Core™ i7 CPU 2.6 GHz; 16GB system RAM
Storage	Four removable hard drives (1 TB each); internal hard drive (1 TB)
Operating System	Microsoft® Windows 10 and Microsoft® Word for reports
Additional Hardware	DVD+RW drive with CD-R/RW writing capability
Connectivity	DICOM (option)
Software	Video and audio capture, processing, and playback; patient examination database management features; printing
Fluoroscopy	Optional scan converter allows conversion of various and specialized input video formats to standard formats for recording and processing
Dimensions (W x H x D / weight)	211 x 444 x 495mm / 13.7kg

Diagnostic and standard therapeutics

Endoscopes

Product	Insertion Tube ø (mm)	Min. Instrument Channel ø (mm)	Working Length (mm)	Tip angulation up/down (°)	Field of view (°)	Remarks
VNL8-J10 HD Video Naso-Pharyngo-Laryngoscope	2.9	-	300	130/130	80	HD, STERRAD® compatible
VNL11-J10 HD Video Naso-Pharyngo-Laryngoscope	3.6	-	300	130/130	80	HD, STERRAD® compatible
VNL15-J10 HD Video Naso-Pharyngo-Laryngoscope	4.9	2.0	300	130/130	80	HD, STERRAD® compatible
VNL9-CP VIVIDEO Video Naso-Pharyngo- Laryngoscope	3.3	-	300	120/120	90	Only compatible with CP-1000 Video processor



Processors

EPK-3000 DEFINA Video Processor with i-scan	
Light source	150W Xenon
Advanced imaging modalities	Digital image enhancement (i-scan SE, CE, TE)
Digital output	DVI/D
Analog output	RGB, Y/C, composite
User Interface	Control panel, keyboard
Digital Zoom	yes
Dimensions (W x H x D)	350 x 180 x 485 mm
CP-1000 VIVIDEO Video Processor	
Video output	DVI/D, VGA
Image Format	SXGA [1280 x 1024@60p], XGA [1024 x 768@60p], 720p [1280 x 720@60p] HDTV, 1080p [1920 x 1080@30p] HDTV
Image Recording	Integrated function, external USB storage device
Dimensions (W x H x D)	75 x 340 x 380 mm

Digital Capturing Module

KAY9372HD Digital Capture	
Product Name	9372HD Digital Capture
Processor and Memory	Intel® Core™ i7 CPU 2.6 GHz; 16GB system RAM
Storage	Four removable hard drives (1 TB each); internal hard drive (1 TB)
Operating System	Microsoft® Windows 10 and Microsoft® Word for reports
Additional Hardware	DVD+RW drive with CD-R/RW writing capability
Connectivity	DICOM (option)
Software	Video and audio capture, processing, and playback; patient examination database management features; printing
Fluoroscopy	Optional scan converter allows conversion of various and specialized input video formats to standard formats for recording and processing
Dimensions (W x H x D / weight)	211 x 444 x 495mm / 13.7kg

Light Source

Product		Remarks
Laryngeal Strobe		



Basic diagnosis and treatment

Endoscopes

Product	Insertion Tube ø (mm)	Min. Instrument Channel ø (mm)	Working Length (mm)	Tip angulation up/down (°)	Field of view (°)	Remarks
FNL-7RP3 Fiber Naso-Pharyngo-Laryngoscope	2.4	-	300	130/130	75	
FNL-10RP3 Fiber Naso-Pharyngo-Laryngoscope	3.5	-	300	130/130	75	
FNL-10RBS Fiber Naso-Pharyngo-Laryngoscope	3.5	-	300	130/130	85	portable

Light Source

Product	Remarks
BS-LL1 LED Light Source Battery-type	
Laryngeal Strobe	

Endoscopic Camera

S181P USB Camera	
Sensor	CCD 1/4" high sensitivity
Resolution of the sensor	(725 x 582) PAL / (768 x 494) NTSC
Weight	210g
Cable length	3m, Ø 5mm
iCe Technology, Electronic anti-noiré filter for flexible fibroscope, 2 x programmable buttons, 1 x USB 2.0 output	

Peripherals and Accessories

Recommended Leak Tester

Product	Remarks
SHA-P6 Automatic Leakage Tester	

Recommended Trolleys

Product	Remarks
Cart for VIVIDEO with Insulation Transformer	
PENTAX SVS Trolley	

Recommended Monitors

Product	Remarks
21" EndoVue Monitor	
24" EndoVue Monitor	
27" Radiance Ultra Monitor NDS	

Accessories

Product	Remarks
OF-B205 Single Use Suction Control Valves (10 pieces)	To be used with VNL 15-J10





Diagnostic and standard therapeutics

Endoscope

Product	Insertion Tube ø (mm)	Min. Instrument Channel ø (mm)	Working Length (mm)	Tip angulation up/down (°)	Field of view (°)	Remarks
ECY-1575K Video Cystoscope	5.2	2	400	210/130	120	STERRAD® compatible

Processor

EPK-3000 DEFINA Video Processor with i-scan	
Light source	150W Xenon
Advanced imaging modalities	Digital image enhancement (i-scan SE, CE, TE)
Video output	DVI-D
Analog output	RGB, Y/C, composite
User Interface	Control panel, keyboard
Digital Zoom	yes
Dimensions (W x H x D)	350 x 180 x 485 mm



Basic diagnosis and treatment

Endoscope

Product	Insertion Tube ø (mm)	Min. Instrument Channel ø (mm)	Working Length (mm)	Tip angulation up/down (°)	Field of view (°)	Remarks
FCY-15RBS Fiber Cystoscope	4.9	2.1	400	220/120	125 (A), 83 (W)	portable

Light Source

Product	Remarks
BS-LL1 LED Light Source Battery-type	
Laryngeal Strobe	

Urology

Peripherals and Accessories

Recommended Leak Tester

Product	Remarks
SHA-P6 Automatic Leakage Tester	

Recommended Trolley

Product	Remarks
ITD Classic Trolley With Insulation Transformer	

Recommended Monitors

Product	Remarks
PENTAX ZeroWire G2 Pair, for 27" Monitor	
27" Radiance Ultra Monitor	



Endoscope Drying and Storage

Endoscope Drying and Storage

PlasmaTYPHOON

Characteristic / Parameter	Value
Reference	Typhoon V2TD
Power supply / electrical network	220-240V
Frequency	50 Hz
Dimensions (length / width / height)	250 / 250 / 250 mm (9.8 / 9.8 / 9.8 in)
Pressure regulator - delivery pressure	0 to 5 bar (72.52 psi)
Pressure of the medical air at the gas inlet	3 bar (43.51 psi)
Minimal gas flowrate	60 l/min
Weight	7.5 kg

PlasmaTYPHOON* Drying Cycles

Endoscope type	Drying cycle time
Gastroscope, duodenoscope, enteroscope, colonoscope	2 min 30 s
Bronchoscope, ultrasound bronchoscope (EBUS), nasoscope, ureterscope, cystoscope (channel diam. > 1.5mm)	1 min 30 s
Pediatric bronchoscope, nasoscope, ureterscope, cystoscope (channel diam. <1.5mm)	1 min
Gastrointestinal ultrasound endoscope (EUS)	5 min

PlasmaBAG**

Description	Reference	Characteristics
Standard PlasmaBAG	PBag	size: 60cm x 50cm, packaging: 400 units
XL PlasmaBAG	PBagXL	size: 70cm x 64cm, packaging: 250 units
XXL PlasmaBAG	PBagXXL	size: 84cm x 60cm, packaging: 300 units

PlasmaBAG is a single-use bag specifically designed for endoscope storage using the PlasmaTYPHOON system. PlasmaBAG must be used in combination with PlasmaTYPHOON.




*Compatible with Olympus, Storz, Wolf and Fujifilm endoscopes. Compatible also with cystoscopes.
 ** For Urology endoscopes storage in PlasmaBAG, please check local regulations regarding need to reprocess after storage.



Product Compatibility Chart

Discipline	Market/Application	Endoscope Series	Processors / Lightsources									PlasmaTYPHOON and PlasmaBAG
			EPK-i7010 OPTIVISTA plus	EPK-3000 DEFINA	EPK-i5000	EPK-i5500c IMAGINA	EPK-V1500c VERSA	CP-1000 VIVIDEO Video Processor	KAY9372HD Digital Capture	BS-LL1 LED Light Source Battery-type	USB camera head	
Upper GI and Lower GI	Advanced diagnosis and treatment	i10	X		X							X
		K10	X	X	X							X
		90i	X		X							X
		90K	X	X	X							X
	Diagnostic and standard therapeutics	i10c				X						X
Biliopancreatic	Basic diagnosis and treatment	V10c					X					X
	Advanced diagnosis and treatment	i10, J10U	X									X
	Diagnostic and standard therapeutics	i10, J10U	X	X (J10U)	X							X
	Basic diagnosis and treatment	i10, J10U	X	X (J10U)	X							X
	Advanced diagnosis and treatment	i10, J10, J10U	X	X (J10, J10U)								X
Pulmonology	Diagnostic and standard therapeutics	J10, J10U, 70K	X	X							X (RBS-series) X (V-series)	X
	Basic diagnosis and treatment	V/ RBS										X
	Advanced diagnosis and treatment	70K		X								X
Intubation	Basic diagnosis and treatment	RBS									X	X
	Advanced diagnosis and treatment	J10	X	X								X
ENT	Diagnostic and standard therapeutics	J10, CP	J10	J10				CP				X
	Basic diagnosis and treatment	RP3, RBS		X						RBS	RP3, RBS	X
	Diagnostic and standard therapeutics	75K										X*
Urology	Basic diagnosis and treatment	RBS									X	X
												X*

*For storage in PlasmaBAG please check local regulations regarding need to reprocess after storage in PlasmaBAG

Device	Manufacturer 	 	Notified Body (if applicable) and Medical Device classes
All Others	HOYA Corporation 6-10-1 Nishi-shinjuku, Shinjuku-ku Tokyo 160-0023, Japan	PENTAX Europe GmbH Julius-Vosseler-Str. 104 22527 Hamburg, Germany	TÜV Süd CE0123 Medical Device classes I, Is, IIa, and IIb
Digital Capture 9372HD	PENTAX of America, Inc. 3 Paragon Drive, Montvale NJ 07645, USA	PENTAX Europe GmbH Julius-Vosseler-Str. 104 22527 Hamburg, Germany	Medical Device class I
VERSA System	PENTAX-Aohua Medical Technologies Co. Ltd. East of 3rd Floor, Block C, Building 1, No.5 Shenwang Road, Minhang District, 201108 Shanghai, PR. China	PENTAX Europe GmbH Julius-Vosseler-Str. 104 22527 Hamburg, Germany	TÜV Rheinland CE0197 Medical Device classes I and IIa
G-EYE® System	Smart Medical Systems Ltd. 5 HaNofar St. Ra'anana 4366404, Israel	MedNet GmbH Borkstraße 10 48163 Münster, Germany	MEDCERT CE0482 Medical Device classes I and IIa
Medical Monitors and PENTAX ZeroWire	NDS Surgical Imaging LLC 5750 Hellyer Avenue San Jose, California 95138, USA	Novanta Europe GmbH Parkring 57-59, 85748 Garching, Germany	Medical Device class I
Trolleys	ITD GmbH Sportplatzstraße 3 84381 Johanniskirchen, Germany	—	Medical Device class I
PENTAX Medical USB Camera	SOPRO ZAC Athélia IV, Avenue des Genévriers 13705 La Ciotat, Cedex, France	—	Medical Device class I
Endo Stratus™ Endoscopic Irrigation Pump and CO₂ Insufflator	Medivators Inc. 14605 28th Ave N, Minneapolis MN 55447, USA	Cantel Medical (Italy) S.r.l., Vai Laurentina, 169, 00040 Pomezia (RM), Italy	NSAI CE0050 Medical Device class IIa
ARC PLUS, ARC 400, ENDO PLUS, ENDO ARC Units, Basic Accessories and Consumables	BOWA-electronic GmbH & Co. KG Heinrich-Hertz-Strasse 4-10 72810 Gomaringen, Germany	—	TÜV Süd CE0123 Medical Device classes I and IIb
Senator 30 Suction Pump	Ardo medical AG Gewerbstraße 19 6314 Unterägeri, Switzerland	Ardo medical GmbH Argelsrieder Feld 10 82234 Oberpfaffenhofen, Germany	TÜV Süd CE0123 Medical Device class IIa
PlasmaTYPHOON and PlasmaBAG	PLASMABIOTICS SAS 116 Quai de Bezons 95106 Argenteuil Cedex, France	—	Medical Device class I
ENDO PLUS and ARC PLUS filter set	Pall Medical - A Division of Pall International Sarl Avenue de Tivoli 3, CH-1700 Fribourg, Switzerland	Pall Genedisc Technologies 1 Rue du Courtil Centre d'Affaires Cicea - Bat 1 35170 Bruz, France	ECM CE1282 Medical Device class IIa

Distributors

EMEA Headquarters

Germany

PENTAX Europe GmbH
Julius-Vosseler-Straße 104
22527 Hamburg
T +49 40 / 5 61 92 - 0
F +49 40 / 5 60 42 13
info.emea@pentaxmedical.com

Italy

PENTAX Italia S.r.l.
Via Dione Cassio, 15
20138 Milano
T +39 / 02 50 99 58 1
F +39 / 02 50 99 58 60
marketing.lifecare@pentaxitalia.it

Spain

SIMMEDICA – Sistemas Integrales
de Medicina, S.A.
Avenida del Sistema Solar 25
28830 San Fernando de Henares
Madrid
T +34 91 / 301 62 40
F +34 91 / 751 31 15
sim@simmedica.com

United Kingdom

PENTAX U.K. Limited
PENTAX House
Heron Drive, Langley
Slough SL3 8PN
T +44 17 53 / 79 27 33
F +44 17 53 / 79 27 94
medical.uk@pentaxmedical.com

France

PENTAX France Life Care S.A.S.
116 quai de Bezons
B.P. 204
95106 ARGENTEUIL CEDEX
T +33 1 / 3025 7575
F +33 1 / 3025 7445
clients.fr@pentaxmedical.com

Russia

Moscow Representative office
of PENTAX Europe GmbH (Germany)
1-ya Tverskaya-Yamskaya ulitsa, 25,
stroenie 1, 6th floor
125047, Moscow
T +7 495 995 10 91
F +7 495 995 10 91 (fax ext. 234)

Turkey

PENTAX Turkey
Veko Giz Plaza, Meydan Sokak
No:3/43 343396
Maslak – Istanbul
T +90 212 / 705 05 26
F +90 212 / 705 05 0

Netherlands

PENTAX Nederland B.V.
Edisonring 6
6669NB Dodewaard
T +31 88 / 5 30 30 30
F +31 88 / 5 30 30 40
info.nl@pentaxmedical.com

These products must be used only by healthcare professionals. Before usage and for detailed product specifications, please refer to the instructions for use. In the interest of technical process, specifications may change without notice.

Latest update: July 2021











www.pentaxmedical.com

PENTAX
MEDICAL

LCM/01/07/21/152000202 MGEN-3003EN-EVMEA Rev 1

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- ENT & Speech >
- Urology >
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- Accessories >**

Accessories List

Sl No	Accessory Image	Accessory Title	Linked Products
1		OE-C12 WATER JET CHECK VALVE ADAPTER	Colonoscopes <ul style="list-style-type: none"> i10 Series Video Colonoscopes UltraSlim EC-2990i Video Colonoscope Gastrosopes <ul style="list-style-type: none"> MagniView EG-2990Zi Video Gastroscope i10 Series Video Gastrosopes More...
2		OF-B118 WATER JET CONNECTOR CAP	Colonoscopes <ul style="list-style-type: none"> i10 Series Video Colonoscopes UltraSlim EC-2990i Video Colonoscope Gastrosopes <ul style="list-style-type: none"> MagniView EG-2990Zi Video Gastroscope i10 Series Video Gastrosopes More...
3		OS-A43H WHITE BALANCE ADJUSTER	Video Processors <ul style="list-style-type: none"> EPK-5000 High-Definition Video Processor
4		OS-43 IMAGE CAPTURE SOFTWARE ENDOIMAGE2	Video Processors <ul style="list-style-type: none"> EPK-5000 High-Definition Video Processor
5		OF-Z11 SILICONE OIL	Duodenoscopes <ul style="list-style-type: none"> 90K Series Video Duodenoscopes Portable Fiber Ureteroscope <ul style="list-style-type: none"> FUR-9RBS Portable Fiber Ureteroscope More...
6		OF-Z5 BITE BLOCK	Duodenoscopes <ul style="list-style-type: none"> 90K Series Video Duodenoscopes Gastrosopes <ul style="list-style-type: none"> MagniView EG-2990Zi Video Gastroscope Transnasal EG16-K10 Video Gastroscope More...
7		OF-D6 EYEPiece CAP	Portable Fiber Ureteroscope <ul style="list-style-type: none"> FUR-9RBS Portable Fiber Ureteroscope Portable Fiber Bronchoscopes <ul style="list-style-type: none"> RBS Series Portable Fiber Bronchoscopes More...
8		OF-D1 EYEPiece CAP	Fiber Bronchoscopes <ul style="list-style-type: none"> V Series Fiber Bronchoscopes
9		OF-D3 EYESHIELD	Fiber Bronchoscopes <ul style="list-style-type: none"> V Series Fiber Bronchoscopes
10		OS-H4 WATER BOTTLE ASSEMBLY	Video Processors <ul style="list-style-type: none"> EPK-5000 High-Definition Video Processor

Products

Gastroenterology
Endoscopic
Ultrasound
Pulmonology
ENT & Speech
Urology
Advanced Imaging
Video Equipment
Accessories &
Peripherals

Services

Our Customer
Commitment
Why PENTAX
Medical Service
Service Programs
Consulting &
Analytics
Support Center

Training

Local Training
Forward Program

News & Events

Events
News

Careers

Current Openings

About Us

World of Intelligence
Worldwide Locations
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PENTAX Medical
Overview
HOYA, Parent
Company
Message from Global
President
Company History
Sustainability

Social Media

YouTube | in

Imprint
Privacy Policy
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Social Media Policy
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The **MagniView** endoscopes.

A step forward in characterisation.

The PENTAX Medical MagniView endoscopes join the outstanding HD+ image series with an optical zoom function. In combination with i-scan, the MagniView endoscopes provides a new standard for daily practice, supporting enhanced characterisation in a wide range of procedures, with its 136 times magnified image.

Advanced ergonomics and graduated flexibility of the insertion tube, increases both patient and physician comfort.

MagniView: HD+ and Optical Zoom technology combined.

HD+, Optical Zoom technology and i-scan - the perfect combination for improved characterisation.



Powerful magnification

- The optical zoom technology magnifies the image 136 times, allowing for detailed surface structure observation and supporting enhanced characterisation.



Excellent imaging capabilities

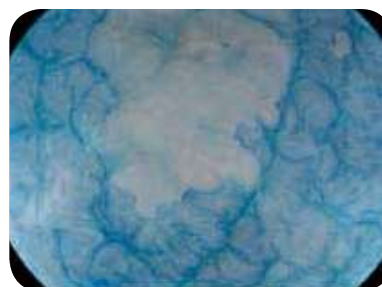
- The combination of i-scan, HD+ and magnification in a standard endoscope provides state-of-the-art technology in detection and characterisation in daily clinical routine.

Fully functional endoscope

- Designed to have the same working channel and equivalent outer diameter as a standard diagnostic endoscope, with optical magnification capabilities. Easy to position, easy control of magnification and advanced ergonomic design.



Magnified endoscopic image



Magnified endoscopic image

MagniView VIDEO ENDOSCOPES

	Product	Insertion tube [ø mm]	Distal end [ø mm]	Instrument channel [ø mm]	Working length [mm]	Field of view [mm]	Tip deflection up/down [°]	Tip deflection right/left [°]	Remarks
Gastroscope	EG-2990Zi	9.8	10.6	2.8	1,050	140	210/120	120/120	HD+, MagniView, Water Jet System
Colonoscopes	EC-3890LZi	13.2	13.0	3.8	1,700	140	180/180	160/160	HD+, MagniView, GDF, Water Jet System
	EC-3890FZi	13.2	13.0	3.8	1,500	140	180/180	160/160	HD+, MagniView, GDF, Water Jet System
	EC-3890MZi	13.2	13.0	3.8	1,300	140	180/180	160/160	HD+, MagniView, GDF, Water Jet System

* Distal Rubber Hood: OE-A58 compatible with EG-2990Zi, OE-A59 compatible with EC-3890Zi series

PENTAX doesn't take any liability for the accuracy of the content as laid out in this brochure. In the interest of technical progress specifications are subject to change without notice. Details concerning the compatibility with other medical devices are to be found within the corresponding Instructions for Use.

PENTAX Europe GmbH

Julius-Vosseler-Straße 104 · 22527 Hamburg · Tel.: +49 40 / 5 61 92 - 0
Fax: +49 40 / 5 60 42 13 · www.pentaxmedical.com

PENTAX
MEDICAL



EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 044963 0035 Rev. 01

Manufacturer:**Fazzini s.r.l.**

SS Padana Superiore 317
20090 Vimodrone (MI)
ITALY

**Product
Category(ies):**

**Suction pumps, Powered nebulisers, diaphragm, piston and
ultrasonic, Rebreathing bags and anesthesia masks,
Reanimation bags and face masks, Nasal cannula and
connecting tubes for oxygen and aerosol therapy**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:G2_044963_0035 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:G2_044963_0035_Rev_01)

Report No.:

ITA1466063

Valid from:

2021-03-29

Valid until:

2024-05-26

Date, 2021-03-29

Christoph Dicks
Head of Certification/Notified Body



EU DECLARATION OF CONFORMITY

We ; HOYA Corporation

6-10-1 Nishi-shinjuku, Shinjuku-ku, Tokyo

160-0023, Japan

declare under our sole responsibility that PENTAX or PENTAX Medical brand product:

Product Category : Endoscopes, video processors and accessories

Model Name : See attached

Meets;

- 1) the conformity assessment procedure in Annex II in accordance with the provisions of Medical Devices Directive 93/42/EEC. The classification and rules applied to each model are described in the attachment.

This declaration is based on EC quality system approved by

TÜV SÜD Product Service GmbH (No.0123), Ridlerstraße 65, 80339 München, Germany

- 2) the provisions of RoHS Directive 2011/65/EU.

Tokyo, May 25, 2021

A handwritten signature in black ink, reading "Kazunori Shimada".

Kazunori Shimada

Manager

Regulatory Affairs Department

PENTAX Lifecare Division

HOYA Corporation

Authorized Representative in the European Union :

PENTAX Europe GmbH, Julius Vosseler Straße 104, 22527 Hamburg, Germany

List of products labeled with CE marking

Category : Endoscopes, video processors and accessories

MDD Class II a& II b / RoHS

Model Name	General Name	MDD Class	Rule	Initial date of declaration of conformity	Remarks
DN-D2718B	Electro-Surgical Knife	II b	9	2016.06.01	
DN-D2722B	Electro-Surgical Knife	II b	9	2016.06.01	
DO-D2618	Snare	II b	9	2016.08.29	
DO-D2622	Snare	II b	9	2016.08.29	
DP-D2518	Electro-Surgical Knife	II b	9	2016.08.29	
DP-D2622	Electro-Surgical Knife	II b	9	2016.08.29	
EB-1170K	Video Bronchoscope	II a	5	2017.12.25	
EB15-J10	Video Bronchoscope	II a	5	2016.06.01	
EB-1970TK	Video Bronchoscope	II a	5	2017.12.25	
EB-1990i	Video Bronchoscope	II a	5	2017.12.25	
EB19-J10	Video Bronchoscope	II a	5	2016.06.01	
EB11-J10	Video Bronchoscope	II a	5	2019.04.05	
EB11-S01	Video Bronchoscope	II a	5	2021.05.25	20210525 added
EB15-S01	Video Bronchoscope	II a	5	2021.05.25	20210525 added
EC-2990Li	Video Colonoscope	II a	5	2017.12.25	
EC-3490FK	Video Colonoscope	II a	5	2017.12.25	
EC-3490LK	Video Colonoscope	II a	5	2017.12.25	
EC-3490MK	Video Colonoscope	II a	5	2017.12.25	
EC-3490TFi	Video Colonoscope	II a	5	2017.12.25	
EC-3490TLi	Video Colonoscope	II a	5	2017.12.25	
EC-3490TMi	Video Colonoscope	II a	5	2017.12.25	
EC34-i10F	Video Colonoscope	II a	5	2017.12.25	
EC34-i10L	Video Colonoscope	II a	5	2017.12.25	
EC34-i10M	Video Colonoscope	II a	5	2017.12.25	
EC34-i10NL	Video Colonoscope	II a	5	2019.07.05	
EC34-i10NF	Video Colonoscope	II a	5	2019.07.05	
EC34-i10TF	Video Colonoscope	II a	5	2017.09.15	
EC34-i10TL	Video Colonoscope	II a	5	2017.09.15	
EC34-i10TM	Video Colonoscope	II a	5	2017.09.15	
EC38-i10cL	Video Colonoscope	II a	5	2018.07.19	
EC38-i10cF	Video Colonoscope	II a	5	2018.07.19	
EC38-i10cF2	Video Colonoscope	II a	5	2018.10.25	
EC38-i10cM	Video Colonoscope	II a	5	2018.07.19	
EC34-i10cL	Video Colonoscope	II a	5	2018.07.19	
EC34-i10cF	Video Colonoscope	II a	5	2018.07.19	
EC34-i10cM	Video Colonoscope	II a	5	2018.07.19	
EC-3890Fi	Video Colonoscope	II a	5	2017.12.25	
EC-3890Fi2	Video Colonoscope	II a	5	2017.12.25	
EC-3890FK	Video Colonoscope	II a	5	2017.12.25	
EC-3890FK2	Video Colonoscope	II a	5	2017.12.25	
EC-3890FZi	Video Colonoscope	II a	5	2017.12.25	
EC-3890Li	Video Colonoscope	II a	5	2017.12.25	
EC-3890LK	Video Colonoscope	II a	5	2017.12.25	
EC-3890LZi	Video Colonoscope	II a	5	2017.12.25	
EC-3890MK	Video Colonoscope	II a	5	2017.12.25	
EC-3890MZi	Video Colonoscope	II a	5	2017.12.25	
EC-3890TLK	Video Colonoscope	II a	5	2017.12.25	
EC38-i10F	Video Colonoscope	II a	5	2017.12.25	
EC38-i10F2	Video Colonoscope	II a	5	2017.12.25	
EC38-i10L	Video Colonoscope	II a	5	2019.07.02	
EC38-i10L	Video Colonoscope	II a	5	2017.12.25	
EC38-i10M	Video Colonoscope	II a	5	2017.12.25	
EC38-i10M2	Video Colonoscope	II a	5	2017.12.25	
EC38-i10NF	Video Colonoscope	II a	5	2016.06.01	
EC38-i10NL	Video Colonoscope	II a	5	2016.06.01	
ECY-1575K	Video Cystoscope	II a	5	2017.12.25	
ED-3490TK	Video Duodenoscope	II a	5	2017.12.25	
ED34-i10T	Video Duodenoscope	II a	5	2017.12.25	
ED34-i10T2	Video Duodenoscope	II a	5	2017.06.23	
OE-A63	Single Use Sterile Distal End Cap with Elevator	II a	5	2020.03.24	
ED32-i10	Video Duodenoscope	II a	5	2019.08.23	
OE-A65	Single Use Sterile Distal End Cap with Elevator	II a	5	2020.03.24	
EE17-J10	Video Esophagoscope	II a	5	2019.06.12	
EG16-K10	Video Upper GI Scope	II a	5	2017.12.25	
EG17-J10	Video Upper GI Scope	II a	5	2019.06.12	
EG-1690K	Video Upper GI Scope	II a	5	2018.02.16	
EG-2490K	Video Upper GI Scope	II a	5	2017.12.25	
EG-2790K	Video Upper GI Scope	II a	5	2017.12.25	
EG27-i10	Video Upper GI Scope	II a	5	2017.12.25	

List of products labeled with CE marking

Category : Endoscopes, video processors and accessories

MDD Class II a& II b / RoHS

Model Name	General Name	MDD Class	Rule	Initial date of declaration of conformity	Remarks
EG-2990i	Video Upper GI Scope	IIa	5	2017.12.25	
EG-2990K	Video Upper GI Scope	IIa	5	2017.12.25	
EG-2990Zi	Video Upper GI Scope	IIa	5	2017.12.25	
EG29-i10	Video Upper GI Scope	IIa	5	2017.12.25	
EG29-i10N	Video Upper GI Scope	IIa	5	2018.02.16	
EG29-i10c	Video Upper GI Scope	IIa	5	2018.07.19	
EG-3490K	Video Upper GI Scope	IIa	5	2017.12.25	
EG34-i10	Video Upper GI Scope	IIa	5	2017.09.08	
EG-3890TK	Video Upper GI Scope	IIa	5	2017.12.25	
EPK-3000	Video Processor	IIa	2	2016.06.01	
EPK-i5000	Video Processor	IIa	2	2017.12.25	
EPK-i5500c	Video Processor	IIa	2	2018.07.19	
EPK-i7010	Video Processor	IIa	2	2016.06.01	
FB-10V	Broncho Fiberscope	IIa	5	2017.12.25	
FB-15RBS	Broncho Fiberscope	IIa	5	2017.12.25	
FB-15V	Broncho Fiberscope	IIa	5	2017.12.25	
FB-18RBS	Broncho Fiberscope	IIa	5	2017.12.25	
FB-18V	Broncho Fiberscope	IIa	5	2017.12.25	
FB-19TV	Broncho Fiberscope	IIa	5	2017.12.25	
FB-8V	Broncho Fiberscope	IIa	5	2017.12.25	
FC-38FV	GI Fiberscope	IIa	5	2017.12.25	
FC-38LV	GI Fiberscope	IIa	5	2017.12.25	
FCN-15X	Choledoch-Nephro Fiberscope	IIa	5	2017.12.25	
FCP-9P	Peroral Choledoch Fiberscope	IIa	5	2017.12.25	
FCY-15RBS	Portable Cystoscope	IIa	5	2017.12.25	
FD-34V2	GI Fiberscope	IIa	5	2017.12.25	
FG-16V	GI Fiberscope	IIa	5	2017.12.25	
FG-24V	GI Fiberscope	IIa	5	2017.12.25	
FG-29V	GI Fiberscope	IIa	5	2017.12.25	
FHY-10RBS	Portable Hysteroscope	IIa	5	2017.12.25	
FHY-15RBS	Portable Hysteroscope	IIa	5	2017.12.25	
FI-10RBS	Portable Intubation Scope	IIa	5	2017.12.25	
FI-13RBS	Portable Intubation Scope	IIa	5	2017.12.25	
FI-16RBS	Portable Intubation Scope	IIa	5	2017.12.25	
FI-7RBS	Portable Intubation Scope	IIa	5	2017.12.25	
FI-9RBS	Portable Intubation Scope	IIa	5	2017.12.25	
FNL-10RBS	Naso-Pharyngo-Laryngoscope	IIa	5	2017.12.25	
FNL-10RP3	Naso-Pharyngo-Laryngoscope	IIa	5	2017.12.25	
FNL-15RP3	Naso-Pharyngo-Laryngoscope	IIa	5	2017.12.25	
FNL-7RP3	Naso-Pharyngo-Laryngoscope	IIa	5	2017.12.25	
FS-34V	GI Fiberscope	IIa	5	2017.12.25	
FUR-9RBS	Portable Ureterorenoscopy	IIa	5	2017.12.25	
HS-D2618	Hot Hemostasis Forceps	IIb	9	2016.06.01	
HS-D2622	Hot Hemostasis Forceps	IIb	9	2016.06.01	
LH-150PC	Halogen Light Source	IIa	2	2017.12.25	
OF-B130	Single Use Suction Control Valve	IIa	5	2020.04.06	
OF-B194	Single Use Suction Control Valve	IIa	5	2020.04.06	
OF-B205	Single Use Suction Control Valve	IIa	5	2016.06.01	
OF-G11	Single Use Suction Control Valve	IIa	5	2020.04.06	
OS-H4	Water Bottle Assembly	IIa	2	2016.06.01	
OS-H5	Water Bottle Assembly	IIa	2	2016.06.01	
VNL-1190STK	Video Naso-Pharyngo-Laryngoscope	IIa	5	2017.12.25	
VNL-1070STK	Video Naso-Pharyngo-Laryngoscope	IIa	5	2018.02.15	
VNL-1570STK	Video Naso-Pharyngo-Laryngoscope	IIa	5	2018.02.15	
VNL11-J10	Video Naso-Pharyngo-Laryngoscope	IIa	5	2016.06.01	
VNL-1590STi	Video Naso-Pharyngo-Laryngoscope	IIa	5	2017.12.25	
VNL15-J10	Video Naso-Pharyngo-Laryngoscope	IIa	5	2016.06.01	
VNL8-J10	Video Naso-Pharyngo-Laryngoscope	IIa	5	2016.06.01	
VSB-2990i	Video Small Bowel Enteroscope	IIa	5	2017.12.25	

TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD
ZERTIFIKAT ♦ CERTIFICATE ♦ 認證證書 ♦ CERTIFICADO ♦ CERTIFICAT



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www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 068357 0028 Rev. 00

Manufacturer: HOYA Corporation
6-10-1 Nishi-shinjuku
Shinjuku-ku
Tokyo
160-0023 JAPAN

EC-Representative: PENTAX Europe GmbH
Julius-Vosseler-Str. 104,
22527 Hamburg,
GERMANY

Product Category(ies): Endoscopes, Ultrasound Endoscopes,
their Related Equipment and Accessories (IIa, IIb)

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: JAQ235034630

Valid from: 2019-02-01
Valid until: 2024-01-31

Date, 2018-12-12

Stefan Preiß



嘱託人 長谷川 勇人 が提出した別紙編綴の書類の謄本は、
その原本と対照し、符合することを認めた。

よって、これを認証する。

令和元年 8 月 21 日、本公証人役場において
東京都立川市柴崎町3丁目9番21号
東京法務局所属

公 証 人
Notary

佐 藤 道 明



Michiaki Sato

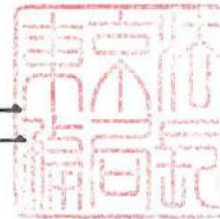
証 明

上記署名は、東京法務局所属公証人の署名に相違ないものであり、かつ、その押印は、
真実のものであることを証明する。

令和元年 8 月 21 日

東京法務局長

岩 山 伸 二



APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: JAPAN
This public document
2. has been signed by Michiaki Sato
3. acting in the capacity of Notary of the Tokyo Legal Affairs Bureau
4. bears the seal/stamp of Michiaki Sato, Notary
Certified
5. at Tokyo
6. AUG. 21. 2019
7. by the Ministry of Foreign Affairs
8. 19- **Nº 065483**
9. Seal/stamp:
10. Signature



T. TANAKA

Toshie TANAKA

For the Minister for Foreign Affairs

NOTARIAL CERTIFICATE

This is to certify that the attached copy of the document exactly corresponds with the seen original.

Dated this 21st day of August, 2019.

Michiaki Sato

Michiaki Sato



NOTARY

9 - 21, 3 - CHOME, SHIBAZAKICHO

TACHIKAWA, TOKYO, JAPAN

TOKYO LEGAL AFFAIRS BUREAU

Логотип: [ZLG] Уполномочено
Центральным ведомством земель по охране
здоровья в области лекарственных средств и
медицинской продукции
ZLG-BS-244.10.08
www.zlg.de

Логотип:
TÜV
SÜD
Product Service]

СЕРТИФИКАТ ЕС

Комплексная система менеджмента качества продукции
Директива 93/42/ЕЕС о медицинских изделиях (MDD), Приложение II, исключая (4)
(Изделия Класса Па, Пб или П)

№: G1 068357 0028 Верс. 00

**Производственный(е)
объект(ы)**

ХОЯ Корпорейшн Фабрика ПЕНТАКС Мяги
30-2 Окада, Аза-Шимомияно, Цукидате, Курихара-Ши,
Мяги, 987-2203, ЯПОНИЯ

ХОЯ Корпорейшн Фабрика ПЕНТАКС Ямагата
4 – 1 Хиноде-чо, Нагаи-ши, Ямагата, 993-0012 ЯПОНИЯ

ХОЯ Корпорейшн
6-10-1 Ниси-синдзюку, Синдзюку-ку, Токио, 160-0023,
Япония

ХОЯ Корпорейшн Подразделение ПЕНТАКС Лайф Кеар
Технологический центр Шованомори
1-1-110 Цуцуджигаока, Акишима-ши, Токио, 196-0012
ЯПОНИЯ

ХОЯ Корпорейшн Подразделение ПЕНТАКС Лайф Кеар
Производственно-технологический центр/Фабрика Огава
395 Оаза-Какуяма, Огава-мачи, Хики-гун, Сайтама 355-
0316 ЯПОНИЯ

Логотип: [ZLG] Уполномочено
Центральным ведомством земель по охране
здоровья в области лекарственных средств и
медицинской продукции
ZLG-BS-244.10.08
www.zlg.de

[штрих-код]

Логотип:
TÜV
SÜD
Product Service]

СЕРТИФИКАТ ЕС

Комплексная система менеджмента качества продукции
Директива 93/42/ЕЕС о медицинских изделиях (MDD), Приложение II, исключая (4)
(Изделия Класса IIa, IIb или III)
№: G1 068357 0028 Верс. 00

Производитель: ХОЯ Корпорейшн
(HOYA Corporation)
6-10-1 Ниси-синдзюку
Синдзюку-ку
Токио
160-0023 ЯПОНИЯ

**Представитель
в ЕС:** ПЕНТАКС Европа ГмбХ
(PENTAX Europe GmbH)
Юлиус-Фосселер-Штрассе 104,
22527 г. Гамбург
ГЕРМАНИЯ

**Категория
изделия(й):** Эндоскопы, ультразвуковые эндоскопы, их сопутствующее
оборудование и принадлежности к ним (IIa, IIb)

Орган сертификации TÜV SÜD Product Service GmbH заявляет, что вышеуказанный производитель внедрил систему менеджмента качества в отношении проектирования, производства и контроля соответствующих изделий/категорий изделий согласно Приложению II к MDD. Данная система менеджмента качества соответствует положениям указанной Директивы и подлежит периодической проверке. Для реализации на рынке продукции класса III обязателен дополнительный сертификат – по Приложению II (4). См. также примечания на обороте.

Номер отчета: JAQ235034630

Действителен с: 01.02.2019

Действителен до: 31.01.2024

Дата, 12.12.2018

[Подпись]
Штефан Прайс

Страница 1 из 2

TÜV SÜD Product Service GmbH является уполномоченным органом, имеющим
идентификационный номер 0123.

TÜV SÜD Product Service GmbH-Сертификационный орган - Ридлерштрассе 65 - 80339 г.Мюнхен-Германия
TÜV®

Печать: Нотариус Митиаки Сато.

Документ зарегистрирован за номером: № «175» за «2019» год

Подтверждение

Настоящим подтверждаю тот факт, что прилагаемая копия документа в точности соответствует представленному оригиналу. На основании чего я подтверждаю изложенные факты.

21 августа 2019 года

Документ составлен в офисе нотариуса,

г. Токио, Татикава, Сибасаки-тё, 3-тёме, 9-21

Нотариус, подведомственный Токийскому бюро по юридическим вопросам

Печать: Нотариус Митиаки Сато.

Нотариус

Митиаки Сато

Свидетельство

Вышеприведенная подпись является подлинной подписью нотариуса, подведомственного Токийскому бюро по юридическим вопросам, кроме того, я подтверждаю подлинность приложенной личной печати упомянутого лица.

21 августа 2019 года

Директор Токийского бюро по юридическим вопросам ИВАЯМА СИНДЗИ

Печать: Директор Токийского бюро по юридическим вопросам.

АПОСТИЛЬ

(Гаагская конвенция от 5 октября 1961 года)

1. Страна: ЯПОНИЯ
Данный официальный документ
2. подписан **Митиаки Сато**
3. выступающим в качестве **нотариуса Токийского бюро по юридическим вопросам**
4. заверен печатью/штампом **Митиаки Сато, нотариуса**

Удостоверено

5. в г. Токио

6. 21 АВГУСТА 2019 Г.

7. Министерством иностранных дел

8. 19-№ 065483

9. Печать/штамп

Гербовая печать: ЯПОНИЯ. МИНИСТЕРСТВО ИНОСТРАННЫХ ДЕЛ.

10. Подпись

[Подпись]

Тоси ТАНАКА

От имени Министра иностранных дел

НОТАРИАЛЬНОЕ СВИДЕТЕЛЬСТВО

Настоящим свидетельствуется, что прилагаемая копия документа в точности соответствует представленному оригиналу.

Датировано 21 августа 2019 года.

[Подпись]

Митиаки Сато

НОТАРИУС

9-21, 3-ТЁМЕ, СИБАЗАКИТЁ

ТАТИКАВА, ТОКИО, ЯПОНИЯ

ТОКИЙСКОЕ БЮРО ПО ЮРИДИЧЕСКИМ
ВОПРОСАМ

Печать: ТОКИЙСКОЕ БЮРО ПО ЮРИДИЧЕСКИМ ВОПРОСАМ. **НОТАРИУС.**
9-21, 3-ТЁМЕ, СИБАЗАКИТЁ
ТАТИКАВА, ТОКИО, ЯПОНИЯ.

Перевод данного текста сделан мной, переводчиком Алексеевым Алексеем Александровичем.

h

Российская Федерация

Город Москва

Двадцать восьмого августа две тысячи девятнадцатого года

Я, Ребрина Елена Дмитриевна, временно исполняющая обязанности нотариуса города Москвы Акимов Глеба Борисовича, свидетельствую подлинность подписи переводчика Алексеева Алексея Александровича.

Подпись сделана в моем присутствии.

Личность подписавшего документ установлена.

Зарегистрировано в реестре: № 77/09-н/77-2019-73-1426

Взыскано государственной пошлины(по тарифу): 100 руб.

Уплачено за оказание услуг правового и технического характера: 200 руб.

*Всего прошнуровано, пронумеровано
и скреплено печатью 7 лист(а)(ов)*

ВРИО нотариуса



h





F-60.00 / F-90.00

W 48cm L 46cm H 42cm

GB SUCTION PUMP

Mobile suction machine for professional use, with powerful double piston motor. ABS anti-shock case. Four antistatic castors, two of which with brakes. Vacuum gauge for the control of vacuum. Vacuum regulation. Two jars, 2 lt. capacity made of Makrolon autoclavable. Each jar with double security valve. Independent use of each jar. Supplied with disposable filter and set of tubes.

F ASPIRATEUR DE MUCOSITES

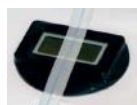
Aspirateur mobile avec puissant moteur à double piston. Boîtier en ABS antichoc avec quatre roulettes antistatiques, dont 2 avec freins. Livré avec 2 bocaux Makrolon autoclavables de 2 litres indépendants et double valve de reflux. Régulateur de dépression avec vacuomètre. Fourni avec filtre jetable et un jeu de tubes.

AVAILABLE CONFIGURATIONS / CONFIGURATIONS DISPONIBLES

Jar / Bocaux	230V 50-60Hz	110V 60Hz
	code	code
2 x 2 lt.	F-60	F-60.20
2 x 2 lt. with footswitch / avec pédale	F-60/F	F-60/F.20
2 x 4 lt.	F-60/4	F-60/4.20
2 x 4 lt. with footswitch / avec pédale	F-60/F4	F-60/F4.20
Jar / Bocaux	230V 50/60Hz	110V 60Hz
	code	code
2 x 2 lt.	F-90	F-90.20
2 x 2 lt. with footswitch / avec pédale	F-90/F	F-90/F.20
2 x 4 lt.	F-90/4	F-90/4.20
2 x 4 lt. with footswitch / avec pédale	F-90/F4	F-90/F4.20

TECHNICAL SPECIFICATIONS / SPECIFICATIONS TECHNIQUES

	F-60	F-90
Motor / Moteur	Maintenance-free Oil free piston pump	Maintenance-free Oil free piston pump
Weight / Poids	12 kg	14,5 kg
Power supply / Alimentation	230V/50-60Hz (0,260A)	230V/50-60Hz 120VA (0,93A)
Power consumption / Puissance absorbée	60 W	200W
Suction power / Débit	70 l/min	90 l/min
Max vacuum / Vide maximum	0,80 bar - 600 mmHg / -75 kPa	0,80 bar - 675 mmHg
Operating cycle / Cycle d'opération	60min ON / 30 min OFF	Continuous
Noisiness / Niveau sonore	61,2 dB	62,3 dB



SUCTION PUMP DIGITAL

Available digital display / Disponibles avec affichage digital
F-60 D / F-90 D / FX50 D / F100D

APPLICATIONS

Operating theatre, general surgery /
Bloc opératoire, chirurgie générale

Auto Leakage Tester SHA-P6

Better care for your scopes



By alerting you to existing leaks in your flexible endoscopes, the SHA-P6 Automatic Leakage Tester helps to avoid costly repairs.

Intuitively Simple



The SHA-P6 Auto Leakage Tester is specifically designed for use with PENTAX Medical flexible endoscopes to avoid costly service interventions.

Improved operational efficiency

Default pressure setting, automated pressurization cycle, and air release reduce the risk for human error and potential risky variability within the reprocessing process.

Space saving and mobile

No need to have large space available in the reprocessing room, due to the handy format of SHA-P6. With the re-chargeable battery, the automatic leakage tester is usable in several stations without power connection need.

Optimized economic outcomes

Lowers overall repair costs, improves scope utilization and prevents downtime as a result of the optimized, automated process capability.

PENTAX Medical Auto Leakage Tester SHA-P6 Specifications

AC adapter	DC output voltage / current AC input frequency AC input voltage	7.5V, 1.6A 50 to 60Hz AC100 - 240V
Built - in packaged lithium battery	Battery capacity	2,600 mAh
Mode of Operation		Continuous Operation
Operating Environment	Ambient temperature Relative humidity Air pressure	10 to 40 °C (50 to 104°F) 30 to 85% RH 700 to 1,060 hPa (10.2 to 15.4 psi)
Storage Environment	Ambient temperature Relative humidity Air pressure	-20 to 60 °C (-4 to 140°F) 10 to 85% RH 700 to 1,060 hPa (10.2 to 15.4 psi)
Pressurization		Automatic (air pump)
Air release		Automatic rapid air release valve
Displayed pressure range		0 to 40 kPa (0 to 5.80 psi)
Pressurization setting range		20 to 30 kPa (in increments of 1kPa) (2.90 to 4.35 psi)
Size		154mm (W) x 63.2mm (H) x 95.6mm (D) (6.06in (W) x 2.49in (H) x 3.76in (D))
Weight		380g (0.84lb) (main unit only)
Electric shock protection		Internal power supply equipment and Class II
Degree of Electric shock protection		Equipment Type BF (Body Floating)
Electro Magnetic Compatibility		IEC60601 - 1 - 2 : 2007
Electrical Safety		IEC60601 - 1 : 2005 + A1 : 2012
IP Classification		IP22

EC REP EMEA Headquarter
Germany
PENTAX Europe GmbH
Julius-Vosseler-Straße 104 . 22527 Hamburg
Tel.: +49 40 / 5 61 92 - 0 . Fax: +49 40 / 5 60 42 13
E-mail: info.emea@pentaxmedical.com . www.pentaxmedical.com

Medical device class: I • This product must be used only by healthcare professionals.
Before use and for detailed product specifications, please refer to the instructions
for use. In the interest of technical process, specifications may change without notice.

PENTAX
MEDICAL
Excellence in Focus

令和4年3月2日

関係各位

宣 言 書

私どもHOYA株式会社、東京都新宿区西新宿6-10-1は、添付の下記文書が
書類原本の写しであることを証明致します。

「Certificate No. Q5 068357 0027 Rev. 01」

HOYA 株式会社
PENTAX ライフケア事業部
開発統括部長代理
兼 カスタマーソリューション開発部 部長
坂井 康弘

March 2, 2022

To whom it may concern,

STATEMENT

We, HOYA Corporation (6-10-1 Nishi-shinjuku Shinjuku-ku, Tokyo 160-0023 Japan),
hereby certify that attached document listed in above is the copy of the original
document.



SAKAI Yasuhiro
Senior General Manager
Customer Solution Development
Japan Research & Development Department
PENTAX Lifecare Division
HOYA Corporation



Product Service

Certificate

No. Q5 068357 0027 Rev. 01**Holder of Certificate:****PENTAX**
MEDICAL**HOYA Corporation**
6-10-1 Nishi-shinjuku
Shinjuku-ku
Tokyo
160-0023 JAPAN**Certification Mark:****Scope of Certificate:****Design and Development, Production,
Distribution and Servicing of
Medical Endoscopes and Related Products**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 068357 0027 Rev. 01

Report No.:**JA1768298****Valid from:****2022-02-27****Valid until:****2025-02-26****Date,****2022-02-24****Christoph Dicks****Head of Certification/Notified Body**

Certificate

No. Q5 068357 0027 Rev. 01

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

HOYA Corporation PENTAX Miyagi Factory
30-2 Okada, Aza-Shimomiyano, Tsukidate, Kurihara-shi,
Miyagi, 987-2203 JAPAN

Production and Distribution of Medical Endoscopes and Related
Products

HOYA Corporation PENTAX Yamagata Factory
4-1 Hinode-cho, Nagai-shi, Yamagata, 993-0012 JAPAN

Production of Medical Endoscopes and Related Products

HOYA Corporation
6-10-1 Nishi-shinjuku, Shinjuku-ku, Tokyo, 160-0023 JAPAN

Regulatory Affairs

**HOYA Corporation PENTAX Lifecare Division Medical
Instrument SBU Japan Sales Headquarters**
3-35-1 Shimo-renjaku, Mitaka-shi, Tokyo, 181-0013 JAPAN

Distribution of Medical Endoscopes and Related Products

**HOYA Corporation PENTAX Lifecare Division Showanomori
Technology Center**
1-1-110 Tsutsujigaoka, Akishima-shi, Tokyo, 196-0012 JAPAN

Design and Development and Distribution of Medical Endoscopes
and Related Products

**HOYA Corporation PENTAX Lifecare Division Production
Technology Center / Ogawa Factory**
395 Oaza-kakuyama, Ogawa-machi, Hiki-gun, Saitama,
355-0316 JAPAN

Production, Distribution and Servicing of Medical Endoscopes and
Related Products

-/-



認 証

囑託人 HOYA 株式会社 PENTAX ライフケア事業部 開発統括部 開発統括
部長代理 兼 カスタマーソリューション開発部 部長 坂井康弘 の代理人
長谷川 勇人 は、本公証人に対し坂井康弘が別紙証書の署名につき、自ら
したものであることを承認している旨陳述した。

よって、これを認証する。

令和4年 3 月 10 日、本公証人役場において
東京都立川市柴崎町3丁目9番21号
東京法務局所属

公 証 人
Notary

綿永 懐
WATAHIKI Yutaka



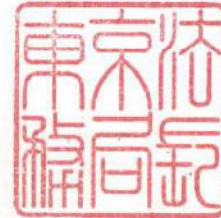
証 明

上記署名は、東京法務局所属公証人の署名に相違ないものであり、かつ、その押印は、
真実のものであることを証明する。

令和4年 3 月 10 日

東京法務局長

坂本佳胤



APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: JAPAN
This public document
2. has been signed by WATAHIKI Yutaka
3. acting in the capacity of Notary of the Tokyo Legal Affairs Bureau
4. bears the seal/stamp of WATAHIKI Yutaka Notary
Certified
5. at Tokyo
6. MAR. 10. 2022
7. by the Ministry of Foreign Affairs
8. 22- No 042117
9. Seal/stamp:
10. Signature



HAMAMOTO Hiroki

For the Minister for Foreign Affairs



認 証

囑託人 HOYA 株式会社 PENTAX ライフケア事業部 開発統括部 開発統括
部長代理 兼 カスタマーソリューション開発部 部長 坂井康弘 の代理人
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よって、これを認証する。

令和4年 3 月 10 日、本公証人役場において
東京都立川市柴崎町3丁目9番21号
東京法務局所属

公 証 人
Notary

綿 糸 懐

WATAHIKI Yutaka

証 明

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真実のものであることを証明する。

令和4年 3 月 10 日

東京法務局長

坂本佳胤



APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: JAPAN
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Certified
5. at Tokyo
6. MAR. 10. 2022
7. by the Ministry of Foreign Affairs
8. 22- NO 042117
9. Seal/stamp:
10. Signature



HAMAMOTO Hiroki

For the Minister for Foreign Affairs

NOTARIAL CERTIFICATE

This is to certify that HASEGAWA Hayato, an agent of SAKAI Yasuhiro, Senior General Manager of HOYA Corporation PENTAX Lifecare Division Japan Research & Development Department Customer Solution Development has stated in my very presence that said SAKAI Yasuhiro acknowledged himself to have signed to the attached document.

Dated this 10th day of March, 2022.



Watahiki Yutaka



WATAHIKI Yutaka

NOTARY

9 - 21, 3 - CHOME, SHIBAZAKICHO

TACHIKAWA, TOKYO, JAPAN

TOKYO LEGAL AFFAIRS BUREAU

PENTAX
MEDICAL

[Сертификат № Q5 068357 0027 Верс. 01]

ХОЯ
ПЕНТАКС

2 марта 2022 года

По месту требования

ПОДТВЕРЖДЕНИЕ

Мы, «ХОЯ Корпорейшн», (6-10-1, Ниси-Синдзюку, Синдзюку-ку, Токио, 160-0023, Япония), настоящим свидетельствуем, что прилагаемый документ, указанный выше, является копией оригинального документа.

[Подпись]

САКАИ Ясухиро

Старший Генеральный менеджер

Отдел разработки клиентских решений

Отдел исследования и развития Японии

Подразделение ПЕНТАКС Лайф Кеар

ХОЯ Корпорейшн

Печать: Нотариус Ютака Ватахики.

Логотип: [DAkkS]
Немецкий орган аккредитации
D-ZM-11321-01-00

[QR код]

Логотип: [TÜV SÜD
Product Service]

СЕРТИФИКАТ

№: Q5 068357 0027 Верс. 01

Держатель сертификата:

**PENTAX
MEDICAL**

ХОЯ Корпорейши (HOYA Corporation)

6-10-1 Ниси-синдзюку

Синдзюку-ку

Токио

160-0023 ЯПОНИЯ

Сертификационный знак:

TÜV SÜD

EN ISO 13485

tuv-sud.com/ps-cert

Область применения
Сертификата:

**Проектирование и разработка, производство,
реализация и обслуживание медицинских
эндоскопов и сопутствующих изделий**

Орган сертификации TÜV SÜD Product Service GmbH свидетельствует, что вышеуказанная компания внедрила и поддерживает систему менеджмента качества, которая соответствует требованиям указанных стандартов. Все применимые требования регламента испытаний и сертификации организации TÜV SÜD Product Service GmbH выполняются. Подробные сведения и информацию о действительности данного сертификата см. по ссылке: www.tuvsud.com/ps-cert?q=cert:Q5_068357_0027_Rev_01

Номер отчета:

JA1768298

Действителен с:

27.02.2022

Действителен до:

26.02.2025

Дата, 24.02.2022

[Подпись]

Кристоф Дикс

Руководитель сертификационного/Нотифицированного органа

Страница 1 из 2

TÜV SÜD Product Service GmbH-Сертификационный орган - Ридлерштрассе 65 - 80339 г.Мюнхен-Германия

TÜV®

СЕРТИФИКАТ

№: Q5 068357 0027 Верс. 01

Применяемый(ые)
стандарт(ы):

EN ISO 13485:2016
Медицинские изделия -- Системы менеджмента качества --
Требования в нормативных целях
(ISO 13485:2016)
DIN EN ISO 13485:2016

Производственное(ые)
предприятие(ия):

ХОЯ Корпорейшн Фабрика ПЕНТАКС Мягги
30-2 Окада, Аза-Шимомияно, Цукидате, Курихара-ши, Мягги,
987-2203, ЯПОНИЯ

Производство и реализация медицинских эндоскопов и
сопутствующих изделий

ХОЯ Корпорейшн Фабрика ПЕНТАКС Ямагата
4 - 1 Хиноде-чо, Нагаи-ши, Ямагата, 993-0012 ЯПОНИЯ

Производство медицинских эндоскопов и сопутствующих изделий

ХОЯ Корпорейшн
6-10-1 Ниси-синдзюку, Синдзюку-ку, Токио, 160-0023,
ЯПОНИЯ

Нормативно-правовое регулирование

ХОЯ Корпорейшн Подразделение ПЕНТАКС Лайф Кеар
СБУ Медицинских инструментов Штаб-квартира продаж в
Японии
3-35-1 Шимо-ренджаку, Митака-ши, Токио, 181-0023 ЯПОНИЯ

Реализация медицинских эндоскопов и сопутствующих изделий

ХОЯ Корпорейшн Подразделение ПЕНТАКС Лайф Кеар
Технологический центр Шованомори
1-1-110 Цуцуджигаока, Акишима-ши, Токио, 196-0012
ЯПОНИЯ

Проектирование и разработка, а также реализация медицинских
эндоскопов и сопутствующих изделий

ХОЯ Корпорейшн Подразделение ПЕНТАКС Лайф Кеар
Производственно-технологический центр/Фабрика Огава
395 Оаза-Какуяма, Огава-мачи, Хики-гун, Сайтама 355-0316
ЯПОНИЯ

Производство, реализация и обслуживание медицинских
эндоскопов и сопутствующих изделий

Печать: Нотариус Ютака Ватахики.

Документ зарегистрирован за номером: № «56» за «2022» год

Подтверждение

Настоящим подтверждаю тот факт, что Хасегава Хаято, представитель Сакаи Ясухиро, Старшего Генерального менеджера, компания «Хоя Корпорейшн», Подразделение ПЕНТАКС Лайф Кеар, отдел исследования и развития Японии, разработки клиентских решений, заявил в моем присутствии о том, что упомянутый Сакаи Ясухиро подтвердил, что он подписал прилагаемый документ. На основании чего я подтверждаю изложенные факты.

10 марта 2022 года

Документ составлен в офисе нотариуса,
г. Токио, Татикава, Сибасаки-тё, 3-тёме, 9-21

Нотариус, подведомственный Токийскому бюро по юридическим вопросам

Печать: Нотариус БАТАХИКИ Ютака.

Нотариус

[Подпись]

БАТАХИКИ Ютака

Свидетельство

Вышеприведенная подпись является подлинной подписью нотариуса, подведомственного Токийскому бюро по юридическим вопросам, кроме того, я подтверждаю подлинность приложенной личной печати упомянутого лица.

10 марта 2022 года

Директор Токийского бюро по юридическим вопросам САКАМОТО ЁСИТАНЭ

Печать: Директор Токийского бюро по юридическим вопросам.

АПОСТИЛЬ

(Гаагская конвенция от 5 октября 1961 года)

1. Страна: ЯПОНИЯ
Данный официальный документ
2. подписан **БАТАХИКИ Ютака**
3. выступающим в качестве **нотариуса Токийского бюро по юридическим вопросам**
4. заверен печатью/штампом **БАТАХИКИ Ютака, нотариуса**

Удостоверено

5. в г. Токио
6. 10 МАРТА 2022 Г.
7. Министерством иностранных дел
8. 22-№ 042117
9. Печать/штамп
- Гербовая печать: ЯПОНИЯ. МИНИСТЕРСТВО ИНОСТРАННЫХ ДЕЛ.
10. Подпись

[Подпись]

ХАМАМОТО Широки

От имени Министра иностранных дел

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НОТАРИУС
9-21, 3-ТЁМЕ, СИБАЗАКИТЁ
ТАТИКАВА, ТОКИО, ЯПОНИЯ

Печать: ТОКИЙСКОЕ БЮРО ПО ЮРИДИЧЕСКИМ ВОПРОСАМ. **НОТАРИУС.**
9-21, 3-ТЁМЕ, СИБАЗАКИТЁ
ТАТИКАВА, ТОКИО, ЯПОНИЯ.

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Российская Федерация

Город Москва

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Зарегистрировано в реестре: № 77/2138-н/77-2022-13-2753

Уплачено за совершение нотариального действия: 400 руб. 00 коп.

Всего прошнуровано, пронумеровано
и скреплено печатью 10 лист(а)(ов)

ВРИО нотариуса

