

PENTAX
MEDICAL

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

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

