



## 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", written over a horizontal line.

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                                |                |
|             | 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             | 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     | Choledocho-Nephro Fiberscope     | II a      | 5    | 2017.12.25                                |         |
| FCP-9P      | Peroral Choledocho 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                                |         |