



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, October 25, 2018

Fujimaro Takahashi

RA Manager
Quality Assurance and
Regulatory Affairs, Japan
PENTAX Lifecare Division
HOYA Corporation

Authorized Representative in the European Union :

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PENTAX Life Care Division

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 | Serial/Lot Number | Remarks |
|-------------|------------------------|-----------|------|---|-------------------|--------------------|
| DC-D2618 | Electro-Surgical Knife | II b | 9 | 2016.08.29 | B605459- | |
| DL-D2618 | Electro-Surgical Knife | II b | 9 | 2016.06.01 | B501390- | |
| DL-D2622 | Electro-Surgical Knife | II b | 9 | 2016.06.01 | — | |
| DN-D2718A | Electro-Surgical Knife | II b | 9 | 2016.06.01 | B602186- | |
| DN-D2718B | Electro-Surgical Knife | II b | 9 | 2016.06.01 | B502150- | |
| DN-D2722A | Electro-Surgical Knife | II b | 9 | 2016.06.01 | B601655- | |
| DN-D2722B | Electro-Surgical Knife | II b | 9 | 2016.06.01 | B601380- | |
| DO-D2618 | Snare | II b | 9 | 2016.08.29 | B601086- | |
| DO-D2622 | Snare | II b | 9 | 2016.08.29 | B501131- | |
| DP-D2518 | Electro-Surgical Knife | II b | 9 | 2016.08.29 | B604468- | |
| DP-D2622 | Electro-Surgical Knife | II b | 9 | 2016.08.29 | B604440- | |
| EB-1170K | Video Bronchoscope | II a | 5 | 2017.12.25 | K120001- | |
| EB15-J10 | Video Bronchoscope | II a | 5 | 2016.06.01 | A120008- | |
| EB-1970TK | Video Bronchoscope | II a | 5 | 2017.12.25 | K120001- | |
| EB-1990i | Video Bronchoscope | II a | 5 | 2017.12.25 | K120001- | |
| EB19-J10 | Video Bronchoscope | II a | 5 | 2016.06.01 | A120008- | |
| EC-2990Li | Video Colonoscope | II a | 5 | 2017.12.25 | K110001- | |
| EC-3490FK | Video Colonoscope | II a | 5 | 2017.12.25 | K120001- | |
| EC-3490LK | Video Colonoscope | II a | 5 | 2017.12.25 | K120001- | |
| EC-3490MK | Video Colonoscope | II a | 5 | 2017.12.25 | K120001- | |
| EC-3490TFi | Video Colonoscope | II a | 5 | 2017.12.25 | K110001- | |
| EC-3490TLi | Video Colonoscope | II a | 5 | 2017.12.25 | K110001- | |
| EC-3490TMI | Video Colonoscope | II a | 5 | 2017.12.25 | K110001- | |
| EC34-i10F | Video Colonoscope | II a | 5 | 2017.12.25 | K110001- | |
| EC34-i10L | Video Colonoscope | II a | 5 | 2017.12.25 | K110001- | |
| EC34-i10M | Video Colonoscope | II a | 5 | 2017.12.25 | K110001- | |
| EC34-i10TF | Video Colonoscope | II a | 5 | 2017.09.15 | A110001- | |
| EC34-i10TL | Video Colonoscope | II a | 5 | 2017.09.15 | A110001- | |
| EC34-i10TM | Video Colonoscope | II a | 5 | 2017.09.15 | A110001- | |
| EC38-i10cL | Video Colonoscope | II a | 5 | 2018.07.19 | A0002Z0001- | |
| EC38-i10cF | Video Colonoscope | II a | 5 | 2018.07.19 | A0003Z0001- | |
| EC38-i10cF2 | Video Colonoscope | II a | 5 | 2018.10.25 | A001FZ0001- | 2018.10.25 revised |
| EC38-i10cM | Video Colonoscope | II a | 5 | 2018.07.19 | A0004Z0001- | |
| EC34-i10cL | Video Colonoscope | II a | 5 | 2018.07.19 | A0005Z0001- | |
| EC34-i10cF | Video Colonoscope | II a | 5 | 2018.07.19 | A0006Z0001- | |
| EC34-i10cM | Video Colonoscope | II a | 5 | 2018.07.19 | A0007Z0001- | |
| EC-3890Fi | Video Colonoscope | II a | 5 | 2017.12.25 | K110001- | |
| EC-3890Fi2 | Video Colonoscope | II a | 5 | 2017.12.25 | K110001- | |
| EC-3890FK | Video Colonoscope | II a | 5 | 2017.12.25 | K120001- | |
| EC-3890FK2 | Video Colonoscope | II a | 5 | 2017.12.25 | K120001- | |
| EC-3890FZi | Video Colonoscope | II a | 5 | 2017.12.25 | K110001- | |
| EC-3890Li | Video Colonoscope | II a | 5 | 2017.12.25 | K110001- | |
| EC-3890LK | Video Colonoscope | II a | 5 | 2017.12.25 | K120001- | |
| EC-3890LZi | Video Colonoscope | II a | 5 | 2017.12.25 | K110001- | |
| EC-3890MK | Video Colonoscope | II a | 5 | 2017.12.25 | K120001- | |
| EC-3890MZi | Video Colonoscope | II a | 5 | 2017.12.25 | K110001- | |
| EC-3890TLK | Video Colonoscope | II a | 5 | 2017.12.25 | K120001- | |
| EC38-i10F | Video Colonoscope | II a | 5 | 2017.12.25 | K110001- | |
| EC38-i10F2 | Video Colonoscope | II a | 5 | 2017.12.25 | K110001- | |
| EC38-i10L | Video Colonoscope | II a | 5 | 2017.12.25 | K110001- | |
| EC38-i10M | Video Colonoscope | II a | 5 | 2017.12.25 | K110001- | |
| EC38-i10M2 | Video Colonoscope | II a | 5 | 2017.12.25 | K110001- | |
| EC38-i10NF | Video Colonoscope | II a | 5 | 2016.06.01 | A110045- | |
| EC38-i10NL | Video Colonoscope | II a | 5 | 2016.06.01 | A110036- | |
| ECY-1575K | Video Cystoscope | II a | 5 | 2017.12.25 | K120001- | |
| ED-3490TK | Video Duodenoscope | II a | 5 | 2017.12.25 | K120001- | |
| ED34-i10T | Video Duodenoscope | II a | 5 | 2017.12.25 | K110001- | |
| ED34-i10T2 | Video Duodenoscope | II a | 5 | 2017.06.23 | A110004- | |
| EG16-K10 | Video Upper GI Scope | II a | 5 | 2017.12.25 | K120001- | |
| EG-1690K | Video Upper GI Scope | II a | 5 | 2018.02.16 | K120001- | |
| EG-2490K | Video Upper GI Scope | II a | 5 | 2017.12.25 | K120001- | |
| EG-2790K | Video Upper GI Scope | II a | 5 | 2017.12.25 | K120001- | |
| EG27-i10 | Video Upper GI Scope | II a | 5 | 2017.12.25 | K110001- | |
| EG-2990i | Video Upper GI Scope | II a | 5 | 2017.12.25 | K110001- | |
| EG-2990K | Video Upper GI Scope | II a | 5 | 2017.12.25 | K120001- | |
| EG-2990Zi | Video Upper GI Scope | II a | 5 | 2017.12.25 | K110001- | |
| EG29-i10 | Video Upper GI Scope | II a | 5 | 2017.12.25 | K110001- | |
| EG29-i10N | Video Upper GI Scope | II a | 5 | 2018.02.16 | K110001- | |
| EG29-i10c | Video Upper GI Scope | II a | 5 | 2018.07.19 | A0008Z0001- | |
| EG-3490K | Video Upper GI Scope | II a | 5 | 2017.12.25 | K120001- | |
| EG34-i10 | Video Upper GI Scope | II a | 5 | 2017.09.08 | A110001- | |
| EG-3890TK | Video Upper GI Scope | II a | 5 | 2017.12.25 | K120001- | |
| EPK-3000 | Video Processor | II a | 2 | 2016.06.01 | A020033- | |
| | | | | 2018.07.31 | A620006- | |
| | | | | 2018.07.31 | M620006- | |

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 | Serial/Lot Number | Remarks |
|-------------|----------------------------------|-----------|------|---|-------------------|---------|
| EPK-i5000 | Video Processor | II a | 2 | 2017.12.25 | K610001 | |
| | | | | 2016.06.22 | A620014- | |
| EPK-i5500c | Video Processor | II a | 2 | 2018.07.19 | A000020001- | |
| | | | | 2016.06.01 | A010107- | |
| EPK-i7010 | Video Processor | II a | 2 | 2018.01.09 | A720002- | |
| FB-10V | Broncho Fiberscope | II a | 5 | 2017.12.25 | K110001- | |
| FB-15RBS | Broncho Fiberscope | II a | 5 | 2017.12.25 | K110001- | |
| FB-15V | Broncho Fiberscope | II a | 5 | 2017.12.25 | K110001- | |
| FB-18RBS | Broncho Fiberscope | II a | 5 | 2017.12.25 | K110001- | |
| FB-18V | Broncho Fiberscope | II a | 5 | 2017.12.25 | K110001- | |
| FB-19TV | Broncho Fiberscope | II a | 5 | 2017.12.25 | K110001- | |
| FB-8V | Broncho Fiberscope | II a | 5 | 2017.12.25 | K110001- | |
| FC-38FV | GI Fiberscope | II a | 5 | 2017.12.25 | K110001- | |
| FC-38LV | GI Fiberscope | II a | 5 | 2017.12.25 | K110001- | |
| FCN-15X | Choledocho-Nephro Fiberscope | II a | 5 | 2017.12.25 | K110001- | |
| FCP-9P | Peroral Choledocho Fiberscope | II a | 5 | 2017.12.25 | K110001- | |
| FCY-15RBS | Portable Cystoscope | II a | 5 | 2017.12.25 | K110001- | |
| FD-34V2 | GI Fiberscope | II a | 5 | 2017.12.25 | K110001- | |
| FG-16V | GI Fiberscope | II a | 5 | 2017.12.25 | K110001- | |
| FG-24V | GI Fiberscope | II a | 5 | 2017.12.25 | K110001- | |
| FG-29V | GI Fiberscope | II a | 5 | 2017.12.25 | K110001- | |
| FHY-10RBS | Portable Hysteroscope | II a | 5 | 2017.12.25 | K110001- | |
| FHY-15RBS | Portable Hysteroscope | II a | 5 | 2017.12.25 | K110001- | |
| FI-10RBS | Portable Intubation Scope | II a | 5 | 2017.12.25 | K110001- | |
| FI-13RBS | Portable Intubation Scope | II a | 5 | 2017.12.25 | K110001- | |
| FI-16RBS | Portable Intubation Scope | II a | 5 | 2017.12.25 | K110001- | |
| FI-7RBS | Portable Intubation Scope | II a | 5 | 2017.12.25 | K110001- | |
| FI-9RBS | Portable Intubation Scope | II a | 5 | 2017.12.25 | K110001- | |
| FNL-10RBS | Naso-Pharyngo-Laryngoscope | II a | 5 | 2017.12.25 | K110001- | |
| FNL-10RP3 | Naso-Pharyngo-Laryngoscope | II a | 5 | 2017.12.25 | K110001- | |
| FNL-15RP3 | Naso-Pharyngo-Laryngoscope | II a | 5 | 2017.12.25 | K110001- | |
| FNL-7RP3 | Naso-Pharyngo-Laryngoscope | II a | 5 | 2017.12.25 | K110001- | |
| FS-34V | GI Fiberscope | II a | 5 | 2017.12.25 | K110001- | |
| FUR-9RBS | Portable Ureterorenoscopy | II a | 5 | 2017.12.25 | K110001- | |
| HDB2418 | Hot Hemostasis Forceps | II b | 9 | 2016.06.01 | — | |
| HDB2418W | Hot Hemostasis Forceps | II b | 9 | 2016.08.29 | G900226- | |
| HDB2422 | Hot Hemostasis Forceps | II b | 9 | 2016.06.01 | — | |
| HDB2422W | Hot Hemostasis Forceps | II b | 9 | 2016.08.29 | J000110- | |
| H-S2518 | Hot Hemostasis Forceps | II b | 9 | 2016.08.29 | D010041- | |
| H-S2522 | Hot Hemostasis Forceps | II b | 9 | 2016.08.29 | D210391- | |
| HS-D2618 | Hot Hemostasis Forceps | II b | 9 | 2016.06.01 | D702751- | |
| HS-D2622 | Hot Hemostasis Forceps | II b | 9 | 2016.06.01 | fixed later | |
| LH-150PC | Halogen Light Source | II a | 2 | 2017.12.25 | K020001- | |
| OF-B205 | Single Use Suction Control Valve | II a | 5 | 2016.06.01 | 0011026- | |
| OS-H3 | Water Bottle Assembly | II a | 2 | 2016.06.01 | 0021046- | |
| OS-H4 | Water Bottle Assembly | II a | 2 | 2016.06.01 | 0051046- | |
| OS-H5 | Water Bottle Assembly | II a | 2 | 2016.06.01 | 0081026- | |
| VNL-1190STK | Video Naso-Pharyngo-Laryngoscope | II a | 5 | 2017.12.25 | K120001- | |
| VNL-1070STK | Video Naso-Pharyngo-Laryngoscope | II a | 5 | 2018.02.15 | K120001- | |
| VNL-1570STK | Video Naso-Pharyngo-Laryngoscope | II a | 5 | 2018.02.15 | K120001- | |
| VNL11-J10 | Video Naso-Pharyngo-Laryngoscope | II a | 5 | 2016.06.01 | A120014- | |
| VNL-1590STi | Video Naso-Pharyngo-Laryngoscope | II a | 5 | 2017.12.25 | K110001- | |
| VNL15-J10 | Video Naso-Pharyngo-Laryngoscope | II a | 5 | 2016.06.01 | A120003- | |
| VNL8-J10 | Video Naso-Pharyngo-Laryngoscope | II a | 5 | 2016.06.01 | A120012- | |
| VSB-2990i | Video Small Bowel Enteroscope | II a | 5 | 2017.12.25 | K110001- | |