



## 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 : Ultrasound Endoscopes

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 26, 2018

  
Fujimaro Takahashi

RA Manager  
Quality Assurance and  
Regulatory Affairs, Japan  
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**

Product Category: Ultrasound Endoscopes

MDD Class II a / RoHS

Model Name	General Name	MDD Class	Rule	Initial date of declaration of conformity	Serial/Lot Number	Remarks
EB-1970UK	Ultrasound Endoscope	II a	5	2017.12.25	K120001-	
EB19-J10U	Ultrasound Endoscope	II a	5	2017.04.06	A120007-	
EG-3270UK	Ultrasound Endoscope	II a	5	2017.12.25	K120001-	
EG-3670URK	Ultrasound Endoscope	II a	5	2017.12.25	K120001-	
EG-3870UTK	Ultrasound Endoscope	II a	5	2017.12.25	K120001-	
EG34-J10U	Ultrasound Endoscope	II a	5	2018.05.31	K120001-	
EG36-J10UR	Ultrasound Endoscope	II a	5	2018.05.31	K120001-	
EG38-J10UT	Ultrasound Endoscope	II a	5	2018.07.13	K120001-	