PENTAX MEDICAL

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Date: 2025.08.08 13:50:00 EEST
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Location: Moldova
MOLDOVA EUROPEANĂ

EU DECLARATION OF CONFORMITY

We ; HOYA Corporation
6-10-1 Nishi-shinjuku, Shinjuku-ku, Tokyo
160-0023, Japan (SRN: JP-MF-000005227),

whose Authorized Representative in the European Union is :
PENTAX Europe GmbH, Julius-Vosseler-Straße 104, 22527 Hamburg, Germany
(SRN: DE-AR-000000006),

declare under our sole responsibility that PENTAX or PENTAX Medical brand product(s) below:

Product Category	:	Endoscopes, Video Processors and its accessories
Model Name	:	See Attached
General Name	:	See Attached
Basic UDI-DI	:	See Attached
Risk Classification	:	IIa

conform(s) to;

1) the conformity assessment procedure in Annex IX in accordance with the provisions of Regulation (EU) 2017/745 on Medical Devices (**EU-MDR**) which is based on EU QMS Certificate (MDR) issued by TÜV SÜD Product Service GmbH (No.0123), Ridlerstrasse 65, 80339 Muenchen, Germany (Certificate No.: G10 068357 0031) and the provisions of RoHS Directive 2011/65/EU amended by Directive (EU) 2015/863.

2) applicable common Specification(s): Not available as it has not been issued

Place:
Tokyo Japan

Signature:

IKEDA Takahiro
Vice President
Global Quality Assurance &
Regulatory Affairs
PENTAX Lifecare Division
HOYA Corporation

Date:
January 13, 2023

No	Model Name	General name	Basic UDI-DI	Initial DoC date	Note
1	EB11-J10	PENTAX Medical Video Bronchoscope	4961333010101XC	Feb.2, 2022	
2	EPK-i8020c	PENTAX Medical Video Processor	4961333010301XN	Dec.14, 2022	20221214 added
3	EC38-i20cL	PENTAX Medical Video Colonoscope	4961333010102XE	Dec.27. 2022	20221227 added
4	EC38-i20cF	PENTAX Medical Video Colonoscope	4961333010102XE	Dec.27, 2022	20221227 added
5	EC38-i20cM	PENTAX Medical Video Colonoscope	4961333010102XE	Dec.27, 2022	20221227 added
6	EG29-i20c	PENTAX Medical Video Upper GI Scope	4961333010104XJ	Dec.27, 2022	20221227 added
7	ED34-i10cT	PENTAX Medical Video Duodenoscope	4961333010103XG	Jan.13, 2023	20230113 added
8	ED34-i10cT2	PENTAX Medical Video Duodenoscope	4961333010103XG	Jan.13, 2023	20230113 added