



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-0000000006),

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

Product Category	: Endoscopes, video processors and accessories
Model Name	: See Attached
General Name	: See Attached
Basic UDI-DI	: See Attached
Risk Classification	: I

conform(s) to;

- 1) the conformity assessment procedure in Annex II and III in accordance with the provisions of Regulation (EU) 2017/745 (**EU-MDR**).
- 2) applicable common Specification(s): Not available as it has not been issued

Place:
Tokyo Japan

Signature:

Date:
December 27, 2022


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

PENTAX Life Care Division

No	Model Name	General name	Basic UDI-DI	Initial DoC date	Note
1	AL-SF2	Adapter for Other's Fiber to P-Light	4961333010501XY	May 20, 2021	
2	AL-SL	Light Source Adapter	4961333010501XY	May 20, 2021	
3	BS-B1	SOAKING CAP	4961333010502Y2	May 20, 2021	
4	CS2010A	PENTAX Medical PROFILE Single Use Endoscope Cleaning Brush Kits	4961333010507YC	May 20, 2021	
5	CS2022A	PENTAX Medical PROFILE Single Use Endoscope Cleaning Brush Kits	4961333010507YC	May 20, 2021	
6	CS2037A	PENTAX Medical PROFILE Single Use Endoscope Cleaning Brush Kits	4961333010507YC	May 20, 2021	
7	CS3010S	Cleaning Brush	4961333010507YC	May 20, 2021	
8	CS3022A	PENTAX Medical PROFILE Single Use Endoscope Cleaning Brush Kits	4961333010507YC	May 20, 2021	
9	CS3025S	Cleaning Brush	4961333010507YC	May 20, 2021	
10	CS4010A	PENTAX Medical PROFILE Single Use Endoscope Cleaning Brush Kits	4961333010507YC	May 20, 2021	
11	CS5503A	PENTAX Medical PROFILE Single Use Endoscope Cleaning Brush Kits	4961333010507YC	May 20, 2021	
12	CS5522A	PENTAX Medical PROFILE Single Use Endoscope Cleaning Brush Kits	4961333010507YC	May 20, 2021	
13	CS5530A	PENTAX Medical PROFILE Single Use Endoscope Cleaning Brush Kits	4961333010507YC	May 20, 2021	
14	CS6002SN	Cleaning Brush	4961333010507YC	May 20, 2021	
15	CS6015ST	Cleaning Brush	4961333010507YC	May 20, 2021	
16	CS6021SN	Cleaning Brush	4961333010507YC	May 20, 2021	
17	CS6021T	Cleaning Brush	4961333010507YC	May 20, 2021	
18	CS6030SN	Cleaning Brush	4961333010507YC	May 20, 2021	
19	CS-C11A	PENTAX Medical PROFILE Single Use Endoscope Cleaning Brush Kits	4961333010507YC	May 20, 2021	
20	CS-C12A	PENTAX Medical PROFILE Single Use Endoscope Cleaning Brush Kits	4961333010507YC	May 20, 2021	
21	CS-C13A	PENTAX Medical PROFILE Single Use Endoscope Cleaning Brush Kits	4961333010507YC	May 20, 2021	
22	CS-C3S	Cleaning Brush	4961333010507YC	May 20, 2021	
23	CS-C5S	Cleaning Brush	4961333010507YC	May 20, 2021	
24	CS-C9S	Cleaning Brush	4961333010507YC	May 20, 2021	
25	SHA-P5	PENTAX LEAKAGE TESTER	4961333010508YE	May 20, 2021	
26	OE-B10	PENTAX Medical Cleaning Adapter	4961333010509YG	May 20, 2021	
27	OE-B11	PENTAX Medical Cleaning Adapter	4961333010509YG	May 20, 2021	
28	OE-B5	PENTAX Adapter For Ultrasound Endoscope	4961333010509YG	May 20, 2021	
29	OE-C20	Water Jet Channel Cleaning Adapter	4961333010509YG	May 20, 2021	
30	OE-C23	LIGHT GUIDE PLUG CAP	4961333010502Y2	May 20, 2021	
31	OE-C27	Soaking Cap	4961333010502Y2	May 20, 2021	
32	OE-C29	PENTAX Medical Ventilating Connector Adapter	4961333010510XZ	May 20, 2021	
33	OE-G1	PENTAX Medical Cleaning Adapter	4961333010509YG	May 20, 2021	
34	OE-C5	AIR/WATER, SUCTION CHANNEL & DISINFECTION ADAPTER	4961333010509YG	May 20, 2021	
35	OE-C8	Suction Nipple Cleaning Adapter	4961333010509YG	May 20, 2021	
36	OE-C9	PVE Soaking Cap	4961333010502Y2	May 20, 2021	
37	OE-U1	Soaking Cap for US Connector	4961333010502Y2	May 20, 2021	
38	OE-U4	Scanning Unit Connector Soaking Cap	4961333010502Y2	May 20, 2021	
39	OF-B103	Suction Channel Cleaning & Disinfection Adapter	4961333010509YG	May 20, 2021	

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40	OF-B115	A/W, Suction Channel Cleaning Adapter	4961333010509YG	May 20, 2021	
41	OF-B153	A/W, Suction Channel Cleaning Adapter	4961333010509YG	May 20, 2021	
42	OF-B155	Cleaning Adapter	4961333010509YG	May 20, 2021	
43	OF-B162	Cleaning Adapter	4961333010509YG	May 20, 2021	
44	OF-B166	A/W, Suction Channel Cleaning Adapter	4961333010509YG	May 20, 2021	
45	OF-B212	PENTAX Medical Cleaning Adapter	4961333010509YG	May 20, 2021	
46	OF-B218	Cleaning Cap for Instrument Channel inlet	4961333010503Y4	May 20, 2021	
47	OF-B75	Channel Cleaning Adapter	4961333010509YG	May 20, 2021	
48	OF-C5	ETO VENTING CAP	4961333010504Y6	May 20, 2021	
49	OF-D3	EYESHIELD	4961333010505Y8	May 20, 2021	
50	OF-G17	Air/Water Channel Cleaning & Disinfection Adapter	4961333010509YG	May 20, 2021	
51	OF-Z5	Bite Block	4961333010506YA	May 20, 2021	
52	OS-A63	Water bottle Cleaning adapter for Water bottle OS-H5	4961333010509YG	May 20, 2021	
53	OE-B15	PENTAX Medical Air/Water Channel Cleaning Adapter	4961333010509YG	Dec.27, 2022	20221227 added
54	OE-B16	PENTAX Medical Cylinder Cleaning Adapter	4961333010509YG	Dec.27, 2022	20221227 added
55	OE-C31	PENTAX Medical Water Jet Channel Cleaning Adapter	4961333010509YG	Dec.27, 2022	20221227 added

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