PENTAX MEDICAL

令和７年４月１日

関係各位

宣 言 書

私どもＨＯＹＡ株式会社、東京都新宿区西新宿６－１０－１は、添付の下記文書が書類原本の写しであることを証明致します。

「EC Certificate」
「Manufacturer's Declaration」
「TÜV SÜD Product Service GmbH Confirmation Letter CL 068357 0033 Rev. 00」

HOYA 株式会社
PENTAX ライフケア事業部
開発統括部長代理
兼 カスタマーソリューション開発部　部長
坂井 康弘

Digitally signed by Beşirik Inga
Date: 2026.03.03 10:04:38 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

April 1, 2025

To whom it may concern,

STATEMENT

We, HOYA Corporation (6-10-1 Nishi-shinjuku Shinjuku-ku, Tokyo 160-0023 Japan), hereby certify that attached documents listed in above are the copies of the original document.

SAKAI Yasuhiro
Senior General Manager
Customer Solution Development
Japan Research & Development Department
PENTAX Lifecare Division
HOYA Corporation

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 068357 0028 Rev. 01

Manufacturer:

HOYA Corporation
6-10-1 Nishi-shinjuku
Shinjuku-ku
Tokyo
160-0023 JAPAN

Product Category(ies): **Endoscopes, Ultrasound Endoscopes, their Related Equipment and Accessories (IIa, IIb)**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: **JAQ235039944**

Valid from: **2020-01-08**
Valid until: **2024-05-26**

Date, **2020-01-08**

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 068357 0028 Rev. 01

Facility(ies):

HOYA Corporation
6-10-1 Nishi-shinjuku, Shinjuku-ku, Tokyo, 160-0023 JAPAN

HOYA Corporation PENTAX Lifecare Division Showanomori Technology Center
1-1-110 Tsutsujigaoka, Akishima-shi, Tokyo, 196-0012 JAPAN

HOYA Corporation PENTAX Lifecare Division Production Technology Center / Ogawa Factory
395 Oaza-kakuyama, Ogawa-machi, Hiki-gun, Saitama, 355-0316 JAPAN

HOYA Corporation PENTAX Miyagi Factory
30-2 Okada, Aza-Shimomiyano, Tsukidate, Kurihara-shi, Miyagi, 987-2203 JAPAN

HOYA Corporation PENTAX Yamagata Factory
4-1 Hinode-cho, Nagai-shi, Yamagata, 993-0012 JAPAN

-/-

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

Manufacturer's Declaration

in relation to Regulation 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	HOYA Corporation
Manufacturer address and contact details	6-10-1 Nishi-shinjuku, Shinjuku-ku, Tokyo, Japan 160-0023 Contact Person incl. Function: Hiroaki Takahashi(QA) Contact E-Mail: Hiroaki.takahashi@pentaxmedical.com
Single Registration Number (SRN) (if available)	JP-MF-000005227

Authorised Representative name (if applicable)	PENTAX Europe GmbH
Authorised Representative address and contact details	Julius-Vosseler-Straße 104, 22527 Hamburg, Germany Contact Person incl. Function: Mr. Frank Wilmerstaedt, General (Manager QARA EMEA) Contact E-Mail: ra.emea@pentaxmedical.com
Single Registration Number (SRN) (if available)	DE-AR-000000006

Notified body name (if applicable)	TÜV SÜD Product Service GmbH □ See attached schedule

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

Notified body number (if applicable)	NB0123 □ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	G1 068357 0028 Rev. 01 G2S 068357 0029 Rev. 01 □ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	2024-05-26 □ See attached schedule
End date of extended validity/transition period	2028-12-31 □ See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021, was/were not withdrawn by 20 March 2023
- *Choose applicable statements:*

☐ Expired *before* 20 March 2023:

☐ Before the original date of expiry as indicated on the Directive Certificate, we and the notified body have signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment in respect of the device covered by the expired certificate or in respect of a device intended to substitute that device

☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request)

☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

☑ Expired/expires *after* 20 March 2023:

- ☑ A formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its substitute and a signed written agreement is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

- ☐ A formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its substitute and a signed written agreement is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

- *Choose one applicable statement:*
  - ☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
  - ☐ A QMS in accordance with Article 10(9) MDR is in place.
  - ☑ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

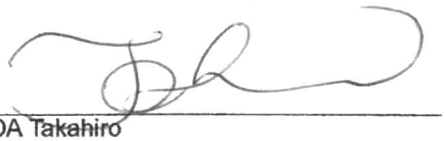
- The device(s) continue to comply with the AIMDD or MDD.
- The device(s) has/have not been significantly changed in its/their design and intended purpose since 26 May 2021.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Full Company Name: HOYA Corporation

Location & Date: Tokyo, Japan, April 5th, 2024

Signature:



Name: IKEDA Takahiro

Title: Chief Quality Officer

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate prior to the extension of the validity** (if applicable)	**Notified Body name and number**	**End date of extended validity/transition period**	**Substitute Device** (if applicable)
OE-A51 OE-A52 OE-A56 OE-A60 OE-A61 OF-A67 OF-B205 OF-B215 OF-B220	G2S 068357 0029	2024-05-26	TÜV SÜD Product Service GmbH NB0123	2028-12-31	OE-A61 (applied in March 2024) **Class:** Is **Device Group:** G0380 **MDR Certificate to be covered**: G11 068357 0031
EB11-S01 EB15-S01 EB15-J10 EB19-J10 FB-15RBS FB-8V FB-15V FB-18RBS FB-18V FB-19TV EB19-J10U	G1 068357 0028	2024-05-26	TÜV SÜD Product Service GmbH NB0123	2028-12-31	EB11-J10 **Class:** IIa **Device Group:** Z120208 **MDR Certificate**: G10 068357 0031
FNL-10RBS FNL-10RP3 FNL-7RP3 VNL11-J10 VNL15-J10 VNL8-J10	G1 068357 0028	2024-05-26	TÜV SÜD Product Service GmbH NB0123	2028-12-31	VNL11-J10 (applied in May 2023) **Class:** IIa **Device Group:** Z120210 **MDR Certificate to be covered**: G10 068357 0031

Identification of the device (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate prior to the extension of the validity** (if applicable)	**Notified Body name and number**	**End date of extended validity/transition period**	**Substitute Device** (if applicable)
EPK-i5500c EPK-3000 EPK-i7010 LH-150PC	G1 068357 0028	2024-05-26	TÜV SÜD Product Service GmbH NB0123	2028-12-31	EPK-i8020c **Class:** IIa **Device Group:** Z120204 **MDR Certificate**: G10 068357 0031
EE17-J10 EG17-J10 EG29-i10c EG-2990Zi EG29-i10 EG34-i10 EG-2490K EG-2790K EG27-i10 EG-2990K EG-2990i EG-3890TK EG34-J10U EG36-J10UR EG38-J10UT FG-24V FG-29V ED32-i10 ED34-i10T2 ED34-i10T	G1 068357 0028	2024-05-26	TÜV SÜD Product Service GmbH NB0123	2028-12-31	EG29-i20c **Class:** IIa **Device Group:** Z120205 **MDR Certificate**: G10 068357 0031
ECY-1575K FCY-15RBS	G1 068357 0028	2024-05-26	TÜV SÜD Product Service GmbH NB0123	2028-12-31	ECY-1575K (applied in March 2024) **Class:** IIa **Device Group:** Z120207 **MDR Certificate to be covered**: G10 068357 0031

Identification of the device (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate prior to the extension of the validity** (if applicable)	**Notified Body name and number**	**End date of extended validity/transition period**	**Substitute Device** (if applicable)
EC38-i10cF	G1 068357 0028	2024-05-26	TÜV SÜD Product Service GmbH NB0123	2028-12-31	EC38-i20c series **Class:** IIa **Device Group:** Z120206 **MDR Certificate**: G10 068357 0031
EC38-i10cF2					
EC38-i10cL					
EC38-i10cM					
EC34-i10F					
EC34-i10L					
EC34-i10M					
EC34-i10TM					
EC-3890FZi					
EC-3890LZi					
EC38-i10F					
EC38-i10L					
EC34-i10NF					
EC34-i10NL					
FC-38LV					
EC-3490FK					
EC-3490LK					
EC34-i10TF					
EC34-i10TL					
EC-3890Fi					
EC-3890Fi2					
EC-3890FK					
EC-3890FK2					
EC-3890Li					
EC-3890LK					
EC-3890TLK					
EC38-i10F2					
EC38-i10M					
EC38-i10M2					

Identification of the device (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate prior to the extension of the validity** (if applicable)	**Notified Body name and number**	**End date of extended validity/transition period**	**Substitute Device** (if applicable)
FI-13RBS	G1 068357 0028	2024-05-26	TÜV SÜD Product Service GmbH NB0123	2028-12-31	FI-7RBS (applied in March 2024) **Class:** IIa **Device Group:** Z120290 **MDR Certificate to be covered**: G10 068357 0031
FI-7RBS					
FI-16RBS					
FI-10RBS					
FI-9RBS					
OE-A65	G1 068357 0028	2024-05-26	TÜV SÜD Product Service GmbH NB0123	2028-12-31	OE-A63 **Class:** IIa **Device Group:** G0380 **MDR Certificate**: G10 068357 0031
OF-B130	G1 068357 0028	2024-05-26	TÜV SÜD Product Service GmbH NB0123	2028-12-31	OF-B194 **Class:** IIa **Device Group:** G0380 **MDR Certificate**: G10 068357 0031
OF-G11					
OS-H5					
DN-D2718B	G1 068357 0028	2024-05-26	TÜV SÜD Product Service GmbH NB0123	2028-12-31	N/A (All model applied in March 2024) **Class:** IIb **GMDN:** 58039 **MDR Certificate to be covered**: G10 068357 0031
DN-D2722B					
HS-D2618	G1 068357 0028	2024-05-26	TÜV SÜD Product Service GmbH NB0123	2028-12-31	N/A (All model applied in March 2024) **Class:** IIb **GMDN:** 61872 **MDR Certificate to be covered**: G10 068357 0031
HS-D2622					

Add value.
Inspire trust.

TÜV SÜD Product Service GmbH· Ridlerstr. 65 · 80339 Munich · Germany

HOYA Corporation
6-10-1 Nishi-shinjuku
Shinjuku-ku
Tokyo
160-0023 JAPAN

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
68357	713202488 | 713202545 | 713348450 | JA1828803_CL	--- medical_devices@tuvsud.com	---	2024-09-26	1 of 7

TÜV SÜD Product Service GmbH
Confirmation Letter
CL 068357 0033 Rev. 00

Reference: 713202488 | 713202545 | 713348450 | JA1828803_CL

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 (in the following referenced as MDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

With this letter TÜV SÜD Product Service GmbH, designated under MDR and identified by the number 0123 on NANDO, confirms that we have received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the above stated manufacturer with the following SRN Number:

SRN Number: JP-MF-000005227

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below.

- Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive.
- Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but TÜV SÜD Product Service GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

If devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that

- the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or
- provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively.

The transition timelines in accordance Article 120 (3) of MDR that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120 (3c) of MDR, are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition, measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

We reserve the right to invoice any issuance, copies, amendments and / or changes of the confirmation letter according to effort.

For confirmation letter validity see www.tuvsud.com/ps-cert?q=cert:CL 068357 0033 Rev. 00

In case of inquiries please contact medical_devices@tuvsud.com.

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-09-26

TÜV SÜD Product Service GmbH
Medical and Health Services

Shunsuke Aoyama
Shunsuke Aoyama (26. September 2024 18:45 GMT+9)

Shunsuke Aoyama
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Christian Ullmann
Christian Ullmann (26. September 2024 11:47 GMT+2)

Dr. Christian Ullmann
Application Reviewer

Table 1: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Balloon for Ultrasound Endoscopes **OE-A61** **4961333010518YH**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☒ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☐ N/A or ☒ Identification of the corresponding device under MDD/AIMDD Individual Article number: OE-A51 OE-A52 OE-A56 OE-A60 OE-A61 OF-A67 OF-B205 OF-B215 OF-B220	☒ Certification as follows: Certificate # G2S 068357 0029 Rev.01; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
PENTAX Medical Video Bronchoscope **EB11-J10** **4961333010101XC**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☐ N/A or ☒ Identification of the corresponding device under MDD/AIMDD Individual Article number: EB11-S01 EB15-S01 EB15-J10 EB19-J10 FB-15RBS FB-8V FB-15V FB-18RBS FB-18V FB-19TV EB19-J10U	☒ Certification as follows: Certificate # G1 068357 0028 Rev.01; NB#0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Video Naso-Pharyngo-Laryngoscope **VNL11-J10** **4961333010111XF**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition	☐ N/A or ☒ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G1 068357 0028 Rev.01; NB#0123 or ☐ Evidence that a competent authority of a Member State had

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	FNL-10RBS FNL-10RP3 FNL-7RP3 VNL11-J10 VNL15-J10 VNL8-J10	granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
PENTAX Medical INSPIRA™ Video Processor **EPK-i8020c** **4961333010301XN**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☐ N/A or ☒ Identification of the corresponding device under MDD/AIMDD Individual Article number: EPK-i5500c EPK-3000 EPK-i7010 LH-150PC OS-H5	☒ Certification as follows: Certificate # G1 068357 0028 Rev.01; NB#0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
PENTAX Medical Video Gastroscope EG29-i20c **4961333010104XJ**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☐ N/A or ☒ Identification of the corresponding device under MDD/AIMDD Individual Article number: EE17-J10 EG17-J10 EG29-i10c EG-2990Zi EG29-i10 EG34-i10 EG-2490K EG-2790K EG27-i10 EG-2990K EG-2990i EG-3890TK EG34-J10U EG36-J10UR EG38-J10UT FG-24V FG-29V ED32-i10 ED34-i10T2 ED34-i10T	☒ Certification as follows: Certificate # G1 068357 0028 Rev.01; NB#0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Video Cystoscope **ECY-1575K** **4961333010107XQ**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☐ N/A or ☒ Identification of the corresponding device under MDD/AIMDD Individual Article number: ECY-1575K FCY-15RBS	☒ Certification as follows: Certificate # G1 068357 0028 Rev.01; NB#0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
PENTAX Medical Colonoscope **EC38-i20c series** **4961333010102XE**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☐ N/A or ☒ Identification of the corresponding device under MDD/AIMDD Individual Article number: EC34-i10NF EC34-i10NL EC38-i10cF EC38-i10cF2 EC38-i10cL EC38-i10cM EC34-i10F EC34-i10L EC34-i10M EC34-i10TM EC-3890FZi EC-3890LZi EC38-i10F EC38-i10L EC38-i10NF EC38-i10NL FC-38LV EC-3490FK EC-3490LK EC34-i10TF EC34-i10TL EC-3890Fi EC-3890Fi2 EC-3890FK EC-3890FK2 EC-3890Li EC-3890LK	☒ Certification as follows: Certificate # G1 068357 0028 Rev.01; NB#0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
		EC-3890TLK EC38-i10F2 EC38-i10M EC38-i10M2	
Portable Intubation Scope **FI-7RBS** **4961333010110XD**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☐ N/A or ☒ Identification of the corresponding device under MDD/AIMDD Individual Article number: FI-13RBS FI-7RBS FI-16RBS FI-10RBS FI-9RBS	☒ Certification as follows: Certificate # G1 068357 0028 Rev.01; NB#0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
PENTAX Medical Single Use, Sterile Distal End Cap **OE-A63** **4961333010512Y5**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☐ N/A or ☒ Identification of the corresponding device under MDD/AIMDD Individual Article number: OF-B130 OF-B194 OF-G11	☒ Certification as follows: Certificate # G1 068357 0028 Rev.01; NB#0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Electro-Surgical Knife **DN-D 2718B/2722B** **4961333010601Y5**	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☐ N/A or ☒ Identification of the corresponding device under MDD/AIMDD Individual Article number: DN-D2718B DN-D2722B	☒ Certification as follows: Certificate # G1 068357 0028 Rev.01; NB#0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Hot Hemostasis Forceps **HS-D2618/2622** **4961333010602Y7**	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa	☐ N/A or	☒ Certification as follows: Certificate # G1 068357 0028 Rev.01; NB#0123 or

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ Identification of the corresponding device under MDD/AIMDD Individual Article number: HS-D2618 HS-D2622	☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#

Table 2: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Not Applicable			

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024-09-26	713202488 | 713202545 | 713348450 | JA1828803_CL	Initial issue

令和７年登簿第　37　号

認　証

嘱託人 HOYA株式会社 PENTAXライフケア事業部 開発統括部 開発統括部長代理 兼 カスタマーソリューション開発部 部長 坂井康弘 の代理人 浦井 聡史 は、本公証人に対し坂井康弘が別紙証書の署名につき、自らしたものであることを承認している旨陳述した。

よって、これを認証する。

令和７年　4　月　17　日、本公証人役場において

東京都立川市柴崎町３丁目９番21号
東京法務局所属

公証人
Notary　千原正敬

CHIHARA Masahiro

証　明

上記署名は、東京法務局所属公証人の署名に相違ないものであり、かつ、その押印は、真実のものであることを証明する。

令和７年　4　月　17　日

東京法務局長　山口敬之

APOSTILLE
(Convention de La Haye du 5 octobre 1961)

1. Country: JAPAN
   This public document
2. has been signed by CHIHARA Masahiro
3. acting in the capacity of Notary of the Tokyo Legal Affairs Bureau
4. bears the seal/stamp of CHIHARA Masahiro .Notary
   Certified
5. at Tokyo
6. APR. 17. 2025
7. by the Ministry of Foreign Affairs
8. 25- № 000273
9. Seal/stamp:
10. Signature

TSUGE Ryoji
For the Minister for Foreign Affairs

NOTARIAL CERTIFICATE

This is to certify that URAI Satoshi, an agent of SAKAI Yasuhiro, Senior General Manager of HOYA Corporation PENTAX Lifecare Division Japan Research & Development Department Customer Solution Development has stated in my very presence that said SAKAI Yasuhiro acknowledged himself to have signed to the attached document.

Dated this 17th day of April, 2025.

CHIHARA Masahiro

TOKYO LEGAL AFFAIRS BUREAU
NOTARY
NO.9-21, 3-CHOME, SIBAZAKICHO,
TACHIKAWA, TOKYO, JAPAN

CHIHARA Masahiro

NOTARY

9 - 21, 3 - CHOME, SHIBAZAKICHO

TACHIKAWA, TOKYO, JAPAN

TOKYO LEGAL AFFAIRS BUREAU