

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

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.



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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



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

-/-



## 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*<sup>1</sup>
- 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  <input type="checkbox"/> See attached schedule
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<sup>1</sup> 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 <input type="checkbox"/> 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 <input type="checkbox"/> See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	2024-05-26 <input type="checkbox"/> See attached schedule
End date of extended validity/transition period	2028-12-31 <input type="checkbox"/> 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*<sup>2</sup>
- 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)

<sup>2</sup> 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	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
OE-A52					
OE-A56					
OE-A60					
OE-A61					
OF-B67					
OF-B205					
OF-B215					
OF-B220	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
EB11-S01					
EB15-S01					
EB15-J10					
EB19-J10					
FB-15RBS					
FB-8V					
FB-15V					
FB-18RBS	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
FB-18V					
FB-19TV					
EB19-J10U					
FNL-10RBS					
FNL-10RP3					
FNL-7RP3					
VNL11-J10					
VNL15-J10					
VNL8-J10					

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	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
EPK-3000					
EPK-i7010					
LH-150PC					
EE17-J10	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
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	ECY-1575K (applied in March 2024) Class: IIa Device Group: Z120207 MDR Certificate to be covered: G10 068357 0031
ECY-1575K					
FCY-15RBS					



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 <b>Class:</b> IIa <b>Device Group:</b> Z120206 <b>MDR Certificate:</b> 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.

**Registered Office: Munich**  
Trade Register Munich HRB 85 742  
UniCredit Bank AG · BIC HYVEDEMMXXX  
IBAN DE13 7002 0270 0048 8522 11  
VAT ID No. DE129484267  
Information pursuant to § 2 [1] DL-InfoV  
(Germany) at tuvsud.com/imprint

**Supervisory Board:**  
Holger Lindner (Chairman)  
**Board of Management:**  
Walter Reithmaier (CEO)  
Patrick van Welij

**TÜV SÜD Product Service GmbH**  
Zertifizierstelle für Medizinprodukte /  
Certification Body for Medical Products  
Ridlerstr. 65  
80339 Munich  
Germany

tuvsud.com/ps  
Hotline: +49 89 50084-747





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](http://www.tuvsud.com/ps-cert?q=cert:CL_068357_0033_Rev._00)

In case of inquiries please contact [medical\\_devices@tuvsud.com](mailto: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 <b>OE-A61</b>  <b>4961333010518YH</b>	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input checked="" type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input type="checkbox"/> N/A  or  <input checked="" type="checkbox"/> 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	<input checked="" type="checkbox"/> Certification as follows: Certificate # G2S 068357 0029 Rev.01; NB# 0123  or  <input type="checkbox"/> 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 <b>EB11-J10</b>  <b>4961333010101XC</b>	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input type="checkbox"/> N/A  or  <input checked="" type="checkbox"/> 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	<input checked="" type="checkbox"/> Certification as follows: Certificate # G1 068357 0028 Rev.01; NB#0123  or  <input type="checkbox"/> 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 <b>VNL11-J10</b>  <b>4961333010111XF</b>	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition	<input type="checkbox"/> N/A  or  <input checked="" type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate # G1 068357 0028 Rev.01; NB#0123  or  <input type="checkbox"/> 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
	<input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> 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 IN-SPIRA™ Video Processor <b>EPK-i8020c</b> <b>4961333010301XN</b>	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: EPK-i5500c EPK-3000 EPK-i7010 LH-150PC OS-H5	<input checked="" type="checkbox"/> Certification as follows: Certificate # G1 068357 0028 Rev.01; NB#0123 or <input type="checkbox"/> 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 <b>EG29-i20c</b> <b>4961333010104XJ</b>	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input type="checkbox"/> N/A or <input checked="" type="checkbox"/> 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	<input checked="" type="checkbox"/> Certification as follows: Certificate # G1 068357 0028 Rev.01; NB#0123 or <input type="checkbox"/> 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 <b>ECY-1575K</b>  <b>4961333010107XQ</b>	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input type="checkbox"/> N/A  or  <input checked="" type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: ECY-1575K FCY-15RBS	<input checked="" type="checkbox"/> Certification as follows: Certificate # G1 068357 0028 Rev.01; NB#0123  or  <input type="checkbox"/> 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 <b>EC38-i20c series</b>  <b>4961333010102XE</b>	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input type="checkbox"/> N/A  or  <input checked="" type="checkbox"/> 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	<input checked="" type="checkbox"/> Certification as follows: Certificate # G1 068357 0028 Rev.01; NB#0123  or  <input type="checkbox"/> 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 <b>FI-7RBS</b>  <b>4961333010110XD</b>	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input type="checkbox"/> N/A  or  <input checked="" type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: FI-13RBS FI-7RBS FI-16RBS FI-10RBS FI-9RBS	<input checked="" type="checkbox"/> Certification as follows: Certificate # G1 068357 0028 Rev.01; NB#0123  or  <input type="checkbox"/> 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 <b>OE-A63</b>  <b>4961333010512Y5</b>	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input checked="" type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input type="checkbox"/> N/A  or  <input checked="" type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: OF-B130 OF-B194 OF-G11	<input checked="" type="checkbox"/> Certification as follows: Certificate # G1 068357 0028 Rev.01; NB#0123  or  <input type="checkbox"/> 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 <b>DN-D 2718B/2722B</b>  <b>4961333010601Y5</b>	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input type="checkbox"/> N/A  or  <input checked="" type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: DN-D2718B DN-D2722B	<input checked="" type="checkbox"/> Certification as follows: Certificate # G1 068357 0028 Rev.01; NB#0123  or  <input type="checkbox"/> 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 <b>HS-D2618/2622</b>  <b>4961333010602Y7</b>	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa	<input type="checkbox"/> N/A  or	<input checked="" type="checkbox"/> 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
	<input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number: HS-D2618 HS-D2622	<input type="checkbox"/> 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







囑託人 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



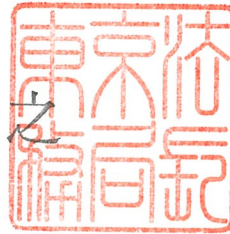
CHIHARA Masahiro  
証 明

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- No 000273
9. Seal/stamp:
10. Signature



松根亮司

TSUGE Ryoji  
For the Minister for Foreign Affairs

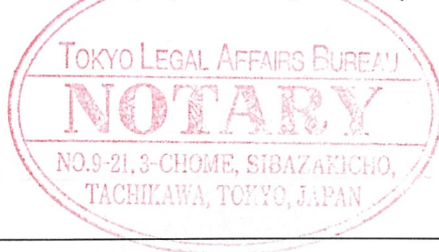


## NOTARIAL CERTIFICATE

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 17<sup>th</sup> day of April, 2025.

CHIHARA Masahiro



CHIHARA Masahiro

NOTARY

9 - 21, 3 - CHOME, SHIBAZAKICHO

TACHIKAWA, TOKYO, JAPAN

TOKYO LEGAL AFFAIRS BUREAU