Date: 23/05/2025
Subject: Official Statement on IVDR extended transitional period

To whom it may concern,

This letter is to confirm that:

1. Obelis s.a. established at Bd Général Wahis 53, 1030 Brussels, Belgium, is acting as European Authorised Representative of the manufacturer Osang Healthcare Co., Ltd, based in 132, Anyangcheondong-ro, Dongan-gu, Anyang-si, Gyeonggi-do, 14040, Republic of Korea.
2. The Regulation (EU) 2024/1860 amends the provisions included in Art.110 of the Regulation (EU) 2017/746 (IVDR).
3. The amendments to the aforementioned provisions allow the placing on the European market of certain legacy devices after the 26 May 2025, if the specific conditions mentioned in the Regulation are met;
4. According to Question 5 of the *European Commission's Q&A on the Extension of the IVDR Transitional Periods* (July 2024), the extension of transitional periods and certificate validity occurs **automatically by law**, provided the conditions of Article 110(3c) IVDR are met.
5. Manufacturers are expected to issue a **self-declaration** confirming that the conditions for the extension are fulfilled, and it should include the **end date of the transition period**, identify the **devices covered**, and refer to **any certificates concerned**.
6. Other supporting documents may be used to demonstrate compliance, such as **copies of the application or agreement** with the notified body.
7. **"Up-classified devices"** are in vitro diagnostic medical devices that, due to the application of the new classification rules under the IVDR, have moved from a lower risk class under the IVDD to a higher risk class, thereby requiring conformity assessment by a Notified Body.
8. **The deadlines for signing the Written Agreement with the Notified Body foreseen are the following (Art. 110(3c)(f) IVDR)**:
   - **By 26 September 2025**: For devices with an IVDD CE certificate or up-classified to Class D under IVDR.
   - **By 26 September 2026**: For devices up-classified to Class C.
   - **By 26 September 2027**: For devices up-classified to Class B or Class A sterile.

9. Pursuant to Article 110 IVDR and the clarifications issued by the European Commission, it is confirmed that as of 26 May 2025, devices complying with the conditions set out in Article 110(3c) IVDR may continue to be placed on the EU

Obelis SA Registered Address: Boulevard General Wahis 53, Brussels 1030, Belgium | **Registered Office Address**: Boulevard Brand Whitlock 30, Brussels 1200, Belgium | **T: +322725954** | **E: sales@obelis.net** | **W: www.obelis.net**

market without a confirmation letter from a notified body. A self-declaration issued by the manufacturer shall be deemed sufficient evidence of compliance.

10. Provided the other requirements of Articles 110(3c) and 110(3d) are fulfilled, legacy devices may continue to be placed on the market beyond 26 May 2025 even in the absence of a signed agreement with a notified body, until the relevant deadlines specified in Article 110(3c)(f). Osang Healthcare Co., Ltd has submitted self-declarations to Obelis s.a., confirming compliance with Article 110(3c) IVDR. These self-declarations, identifying the affected devices, are attached to this statement for reference.
11. Accordingly, the validity of the IVDR mandate between Osang Healthcare Co., Ltd and Obelis s.a. is considered extended for the relevant devices, in line with the transitional periods set out in Article 110 IVDR. The mandate is also attached for reference.

Sincerely,

G.ELKAIAM C.E.O.

OBELIS s.a. - O.E.A.R.C
Registered address :
Bd Général Wahis 53
1030 Bruxelles
Tél. +32 2 732 59 54 - Fax +32 2 732 60 03

Obelis SA Registered Address: Boulevard General Wahis 53, Brussels 1030, Belgium | **Registered Office Address**: Boulevard Brand Whitlock 30, Brussels 1200, Belgium | **T: +322725954** | **E: sales@obelis.net** | **W: www.obelis.net**

OHC
OSANG HEALTHCARE

Manufacturer's Declaration

in relation to Regulation (EU) 2024/1860 amending Regulation (EU) 2017/746 (IVDR) as regards the transitional provisions for certain *in vitro* diagnostic medical devices, in particular with respect to

- the extended transitional periods for devices for which the conformity assessment procedure pursuant to Directive 98/79/EC (IVDD) did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2022 and for which the conformity assessment procedure pursuant to Regulation (EU) 2017/746 (IVDR) requires the involvement of a notified body *and/or*
- the validity of certificates issued under Directive 98/79/EC (IVDD) (Directive Certificate) *and/or*
- 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	Osang Healthcare Co., Ltd.
Manufacturer address and contact details	132, Anyangcheondong-ro, Dongan-gu, Anyang-si, Gyeonggi-do 14040 Republic of Korea
Single Registration Number (SRN) (if available)	KR-MF-000032605

Authorised Representative name (if applicable)	Obelis s.a.
Authorised Representative address and contact details	Boulevard Général Wahis, 53 1030 Brussels Belgium regulatory@obelis.net
Single Registration Number (SRN) (if available)	BE-AR-000000106

Notified body name (if applicable)	TÜV SÜD Product Service GmbH	☒ See attached schedule ☐ Not applicable
Notified body number (if applicable)	0123	☒ See attached schedule ☐ Not applicable
Directive Certificate number(s) to which this confirmation is made (if applicable)	V1 001395 0018 Rev. 04	☒ See attached schedule ☐ Not applicable
Original expiry date as indicated on the Directive Certificate(s) prior to the extension of the validity (if applicable)	26 May 2025	☒ See attached schedule ☐ Not applicable
End date of extended validity/transition period	31 December 2027	☒ See attached schedule

OSANG Healthcare Co., Ltd. Address: 132, Anyangcheondong-ro, Dongan-gu, Anyang-si, Gyeonggi-do, 14040, Republic of Korea
Tel.: 82 031 460 9901 Fax: 82 031 460 0401 Website: www.osanghc.com

We, as the manufacturer declare under our sole responsibility:

- for the **Directive Certificate(s)** listed in the attached schedule the conditions for the legal extension of validity as required in Article 110.2 of the IVDR are met *and/or*
- the **device(s)** listed in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 110.3c of the IVDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

- **Directive Certificate(s)** as listed above

  ☒ Original expiry date *after 9 July 2024 - Expired on 26 May 2025*

  ☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII IVDR for conformity assessment has/have been lodged or will be lodged by us to a notified body no later than 26 May 2025 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII IVDR before 26 September 2025.

- **Quality Management System (QMS)**

  Applicable statement is checked.

  ☐ QMS in accordance with Article 10(8) IVDR will be put in place by no later than 26 May 2025.

  ☐ QMS in accordance with Article 10(8) IVDR is in place.

  ☒ Notified body has issued the attached certificate for the IVDR-compliant QMS.

- **Device(s) listed in the attached schedule (apart from the device indicated to be withdrawn)**
  - The device(s) continue(s) to comply with the IVDD.
  - There are no significant changes in the design and intended purpose.
  - 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:

Osang Healthcare Co., Ltd.

132, Anyangcheondong-ro, Dongan-gu, Anyangsi, Gyeonggi-do 144040 Republic of Korea

YoungGyun Kim, Person Responsible for Regulatory Compliance

ygkim@osnaghc.com

OSANG Healthcare Co., Ltd. Address: 132, Anyangcheondong-ro, Dongan-gu, Anyang-si, Gyeonggi-do, 14040, Republic of Korea
Tel.: 82 031 460 9901 Fax: 82 031 460 0401 Website: www.osanghc.com

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OSANG HEALTHCARE

Schedule of Devices

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

Identification of the device(s) [1] ***IVDD certified legacy devices**	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable) ***New device under IVDR intended to substitute IVDD legacy devices**	**Directive Certificate number to which this declaration is issued**	**Original expiry date as indicated on the Directive Certificate prior to the extension of the validity**	**Notified Body name and number that issued the Directive Certificate**	**Notified Body name and number where the IVDR application was lodged/contract signed**
GluNEO (IGM-1001C)*1)	31 Dec 2027	GluNEO Lite S (OG-SH01-GL)	V1 001395 0018 Rev. 04 (with individual confirmation statement VCQ 001395 0020 Rev.00)	26 May 2025	TÜV SÜD Product Service GmbH (0123)	BSI Group The Netherlands (2797)
GluNEO Lite, Oh'Care Lite, EXAMEDIN Fast (IGM-1003A) *1)	31 Dec 2027	GluNEO Lite (OG-SH11-GL), Oh'Care Lite (OG-SH21-GL), EXAMEDIN Fast (OG-SH31-GL)				
GluNEO Plus (IGM-1003B) *1)	31 Dec 2027	GluNEO Plus Blood Glucose Monitoring System (OG-SH11-GP)				
Healthpro X-1 (IGM-0028B) *1)	31 Dec 2027	Healthpro X-1 (OG-SX11-HE)				
ELEMENT (IGM-0021)*1)	31 Dec 2027	GlucoLAB Autocoding S (OG-SX01-LB)				
GlucoLAB Auto-coding (IGM-0022) *1)	31 Dec 2027	GlucoLAB Autocoding (OG-SX01-LB)				
Finetest Lite (IGM-1003B)	31 Dec 2027	Finetest Lite (OG-SH01-FL)				
EASYGLUCO Auto-Coding (IGM-0016B) *1)	31 Dec 2027	EasyGluco AutoCoding (OG-SX01-EG)				
FINETEST Auto-coding premium (IGM-0017B) *1)	31 Dec 2027	Finetest AutoCoding Premium (OG-SX01-FP)				
adia (IGM-1003A) *1)	31 Dec 2027	adia (OG-SH03-AD)				
Gluco Check Excellent (IGM-0028C) *1)	31 Dec 2027	Gluco Check Excellent (OG-SX03-EX)				
Finetest Lite Smart (IGM-1003G) *2)	31 Dec 2027	Finetest Lite Smart (OG-SH01-FS)				

*1) The case indicated as 1) is that the device(s) stated on "Substitute Device(s)" are intended to substitute the IVDD legacy devices. Since the IVDR application for the substitute devices has been already lodged to the BSI Group The Netherlands (2797).

*2) The case indicated as 2) is that the device(s) stated on "Substitute Device(s)" are intended to substitute the IVDD legacy devices, but IVDR application for the substitute devices has not been lodged to the BSI Group Netherlands (2797). The IVDR application of the substitute devices will be lodged within 26 May 2025 to BSI Group The Netherlands (2797).

** Written agreement with BSI Group The Netherlands (2797) addressing the transition of all IVDD certified legacy devices including surveillance transfer and extended period will be concluded before 26 Sep 2025. All cases need the tripartite party agreement between outgoing NB (TÜV SÜD Product Service GmbH, 0123), incoming NB (BSI Group The Netherlands, 2797) and the manufacturer (Osang Healthcare Co., Ltd.). It will be concluded within 26 Sep 2025 as well.

All devices indicated as 1) and 2) are classified as Class C under IVDR, as per the rule 4(a) since they are intended for self-testing.

The substitute device (new device under IVDR) intended to replace the IVDD certified legacy device will be IVDR certified by December 31, 2027. Once the substitute device is certified and replacement in the sales field is completed, the corresponding IVDD legacy device will be discontinued, even if this occurs before December 31, 2027.

[1] for devices with IVDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above

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Manufacturer's Declaration

in relation to Regulation (EU) 2024/1860 amending Regulation (EU) 2017/746 (IVDR) as regards the transitional provisions for certain *in vitro* diagnostic medical devices, in particular with respect to

- the extended transitional periods for devices for which the conformity assessment procedure pursuant to Directive 98/79/EC (IVDD) did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2022 and for which the conformity assessment procedure pursuant to Regulation (EU) 2017/746 (IVDR) requires the involvement of a notified body *and/or*
- the validity of certificates issued under Directive 98/79/EC (IVDD) (Directive Certificate) *and/or*
- 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	Osang Healthcare Co., Ltd.
Manufacturer address and contact details	132, Anyangcheondong-ro, Dongan-gu, Anyang-si, Gyeonggi-do 14040 Republic of Korea
Single Registration Number (SRN) (if available)	KR-MF-000032605

Authorised Representative name (if applicable)	Obelis s.a.
Authorised Representative address and contact details	Boulevard Général Wahis, 53 1030 Brussels Belgium regulatory@obelis.net
Single Registration Number (SRN) (if available)	BE-AR-000000106

Notified body name (if applicable)	TÜV SÜD Product Service GmbH	☒ See attached schedule ☐ Not applicable
Notified body number (if applicable)	0123	☒ See attached schedule ☐ Not applicable
Directive Certificate number(s) to which this confirmation is made (if applicable)	V1 001395 0018 Rev. 04	☒ See attached schedule ☐ Not applicable
Original expiry date as indicated on the Directive Certificate(s) prior to the extension of the validity (if applicable)	26 May 2025	☒ See attached schedule ☐ Not applicable
End date of extended validity/transition period	31 December 2027	☒ See attached schedule

OSANG Healthcare Co., Ltd. Address: 132, Anyangcheondong-ro, Dongan-gu, Anyang-si, Gyeonggi-do, 14040, Republic of Korea
Tel.: 82 031 460 9901 Fax: 82 031 460 0401 Website: www.osanghc.com

We, as the manufacturer declare under our sole responsibility:

- for the **Directive Certificate(s)** listed in the attached schedule the conditions for the legal extension of validity as required in Article 110.2 of the IVDR are met *and/or*
- the **device(s)** listed in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 110.3c of the IVDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

- **Directive Certificate(s)** as listed above

  ☒ Original expiry date *after 9 July 2024 - Expired on 26 May 2025*

  ☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII IVDR for conformity assessment has/have been lodged or will be lodged by us to a notified body no later than 26 May 2025 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII IVDR before 26 September 2025.

- **Quality Management System (QMS)**

  Applicable statement is checked.

  ☐ QMS in accordance with Article 10(8) IVDR will be put in place by no later than 26 May 2025.

  ☐ QMS in accordance with Article 10(8) IVDR is in place.

  ☒ Notified body has issued the attached certificate for the IVDR-compliant QMS.

- **Device(s) listed in the attached schedule (apart from the device indicated to be withdrawn)**
  - The device(s) continue(s) to comply with the IVDD.
  - There are no significant changes in the design and intended purpose.
  - 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:

Osang Healthcare Co., Ltd.

132, Anyangcheondong-ro, Dongan-gu, Anyangsi, Gyeonggi-do 144040 Republic of Korea

YoungGyun Kim, Person Responsible for Regulatory Compliance

ygkim@osnaghc.com

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Schedule of Devices

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

Identification of the device(s)[1] ***IVDD certified legacy devices**	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable) ***New device intended to substitute IVDD legacy devices**	**Directive Certificate number to which this declaration is issued**	**Original expiry date as indicated on the Directive Certificate prior to the extension of the validity**	**Notified Body name and number that issued the Directive Certificate**	**Notified Body name and number where the IVDR application was lodged/contract signed**
Multiplex Real-time PCR kit For CT(Chlamydia trachomatis) NG(Neisseria gonorrhoeae) And UU (Ureaplasma urealyticum)**	31 Dec 2027	N/A	V1 001395 0018 Rev. 04 (with individually confirmation statement VCQ 001395 0020 Rev.00)	26 May 2025	TÜV SÜD Product Service GmbH (0123)	BSI Group The Netherlands (2797)
GeneFinder HLA-B*51 RealAmp Kit**	31 Dec 2027	N/A				
GeneFinder HLA-ABCDRB1DQ RealAmp kit**	31 Dec 2027	N/A				
GeneFinder HLA-ABDR RealAmp kit**	31 Dec 2027	N/A				
GeneFinder HLA-B*57:01 RealAmp kit**	31 Dec 2027	N/A				

* Written agreement with BSI Group The Netherlands (2797) addressing the transition of all IVDD certified legacy devices and extended period will be concluded before 26 Sep 2025. All cases need the three party agreement between outgoing NB (TÜV SÜD Product Service GmbH, 0123), incoming NB (BSI Group The Netherlands, 2797) and the manufacturer (Osang Healthcare Co., Ltd.). It will be concluded within 26 Sep 2025 as well.

** All devices indicated are classified as Class C under IVDR, as per Rule 3 and Rule 2.
- The GeneFinder HLA-B51 and HLA-B57:01 RealAmp Kits are classified under Rule 3(i) as Class C devices intended for human genetic testing (Molecular genetic tests (or gene tests) study single genes or short lengths of DNA to identify its constitution, or variations or mutations that lead to a genetic disorder.)
- The GeneFinder HLA-ABCDRB1DQ RealAmp Kit and GeneFinder HLA-ABDR RealAmp Kit is classified under Rule 2 as a Class C device intended for tissue typing to ensure the immunological compatibility of blood, blood components, cells, tissues, or organs for transfusion, transplantation, or cell administration.
- The Multiplex Real-time PCR Kit for CT, NG, and UU is classified under Rule 3(a) as a Class C device intended for detecting the presence of, or exposure to, a sexually transmitted agent (Chlamydia trachomatis, Neisseria gonorrhoeae, and Ureaplasma urealyticum).

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Manufacturer's Declaration

in relation to Regulation (EU) 2024/1860 amending Regulation (EU) 2017/746 (IVDR) as regards the transitional provisions for certain *in vitro* diagnostic medical devices, in particular with respect to

- the extended transitional periods for devices for which the conformity assessment procedure pursuant to Directive 98/79/EC (IVDD) did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2022 and for which the conformity assessment procedure pursuant to Regulation (EU) 2017/746 (IVDR) requires the involvement of a notified body *and/or*
- the validity of certificates issued under Directive 98/79/EC (IVDD) (Directive Certificate) *and/or*
- 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	Osang Healthcare Co., Ltd.
Manufacturer address and contact details	132, Anyangcheondong-ro, Dongan-gu, Anyang-si, Gyeonggi-do 14040 Republic of Korea
Single Registration Number (SRN) (if available)	KR-MF-000032605

Authorised Representative name (if applicable)	Obelis s.a.
Authorised Representative address and contact details	Boulevard Général Wahis, 53 1030 Brussels Belgium regulatory@obelis.net
Single Registration Number (SRN) (if available)	BE-AR-000000106

Notified body name (if applicable)	-	☐ See attached schedule ☒ Not applicable
Notified body number (if applicable)	-	☐ See attached schedule ☒ Not applicable
Directive Certificate number(s) to which this confirmation is made (if applicable)	-	☐ See attached schedule ☒ Not applicable
Original expiry date as indicated on the Directive Certificate(s) prior to the extension of the validity (if applicable)	-	☐ See attached schedule ☒ Not applicable
End date of extended validity/transition period	31 December 2028 31 December 2029	☒ See attached schedule

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Tel.: 82 031 460 9901 Fax: 82 031 460 0401 Website: www.osanghc.com

We, as the manufacturer declare under our sole responsibility:

- for the **device(s)** listed in the attached schedule the conditions for the legal extension of transitional periods as required in Article 110.3b of the IVDR are met *and/or*
- the **device(s)** listed in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 110.3c of the IVDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

- **Devices which were self-declared under the IVDD and require notified body involvement under the IVDR**

  In case of devices for which the conformity assessment procedure pursuant to IVDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2022 and for which the conformity assessment procedure pursuant to IVDR requires the involvement of a notified body:

  ☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII IVDR for conformity assessment has/have been lodged or will be lodged by us to a notified body for the device(s) listed in the attached schedule or its/their substitutes no later than:

  ☐ 26 May 2025 for class D devices

  ☒ 26 May 2026 for class C devices

  ☒ 27 May 2027 for class B and class A (sterile) devices

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

  ☐ Original expiry date *before 9 July 2024* – Expired on 26 May 2025

  ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII IVDR for conformity assessment has/have been lodged or will be lodged by us to a notified body no later than 26 May 2025 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII IVDR before 26 September 2025.

- **Quality Management System (QMS)**

  ☒ Notified body has issued the attached certificate for the IVDR-compliant QMS.

- **Device(s) listed in the attached schedule (apart from the device indicated to be withdrawn)**

  - The device(s) continue(s) to comply with the IVDD.
  - There are no significant changes in the design and intended purpose.
  - 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.

OSANG Healthcare Co., Ltd. Address: 132, Anyangcheondong-ro, Dongan-gu, Anyang-si, Gyeonggi-do, 14040, Republic of Korea
Tel.: 82 031 460 9901 Fax: 82 031 460 0401 Website: www.osanghc.com

Signed for and on behalf of the manufacturer:

OSANG HealthCare Co., Ltd.

132, Anyangcheondong-ro, Dongan-gu, Anyang-si, Gyeonggi-do 14040 Republic of Korea

Date: 21st March 2025

YoungGyun Kim,
Person Responsible for Regulatory Compliance

ygkim@osanghc.com

OSANG Healthcare Co., Ltd. Address: 132, Anyangcheondong-ro, Dongan-gu, Anyang-si, Gyeonggi-do, 14040, Republic of Korea
Tel.: 82 031 460 9901 Fax: 82 031 460 0401 Website: www.osanghc.com

Schedule of Devices

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

Identification of the device(s)[1] (e.g., device name, family/group name device model or catalogue number)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)	**Directive Certificate number to which this declaration is issued** (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 that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the IVDR application was lodged/contract signed** (if applicable)
GeneFinder HPV-HR RealAmp Kit*	31 Dec 2028	N/A	This product has completed DOC declaration under IVDD Annex IV without section 4 and 6 of IVDD 98/79/EC. It is neither listed in Annex II, IVDD 98/79/EC, nor a self-testing device. The respective DOC numbers are listed below.	N/A	This product has completed DOC declaration under IVDD Annex IV without section 4 and 6 of IVDD 98/79/EC. It is neither listed in Annex II, IVDD 98/79/EC, nor a self-testing device.	BSI Group The Netherlands (2797) (Contracted in 2023, currently undergoing IVDR technical review)
GeneFinder STD II (MG/MH/TV) Multiplex Real-time PCR kit*	31 Dec 2028	N/A		N/A		BSI Group The Netherlands (2797) (Contract planned for 2026)
GeneFinder TB&NTM Multiplex Real-time PCR kit*	31 Dec 2028	N/A		N/A		
GeneFinder HSV 1&2 Real*Amp* kit*	31 Dec 2028	N/A		N/A		
High Risk HPV ELITe Panel *	31 Dec 2028	N/A		N/A		
GeneFinder COVID-19/Flu A&B Real*Amp* Kit**	31 Dec 2029	N/A		N/A		BSI Group The Netherlands (2797) (Contract planned for 2027)

* All devices indicated are classified as Class C under IVDR, as per Rule 3.
- The GeneFinder HPV-HR RealAmp Kit is classified under Rule 3(a) as a device intended for detecting the presence of, or exposure to, a sexually transmitted agent. DOC Number: EUDC-MRR26-0
- The GeneFinder STD II (MG/MH/TV) Multiplex Real-time PCR Kit is classified under Rule 3(a) as a device intended for detecting the presence of, or exposure to, a sexually transmitted agent (*Mycoplasma genitalium, Mycoplasma hominis, and Trichomonas vaginalis*). DOC Number: EUDC-MR04-0

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Manufacturer's Declaration

in relation to Regulation (EU) 2024/1860 amending Regulation (EU) 2017/746 (IVDR) as regards the transitional provisions for certain *in vitro* diagnostic medical devices, in particular with respect to

- the extended transitional periods for devices for which the conformity assessment procedure pursuant to Directive 98/79/EC (IVDD) did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2022 and for which the conformity assessment procedure pursuant to Regulation (EU) 2017/746 (IVDR) requires the involvement of a notified body *and/or*
- the validity of certificates issued under Directive 98/79/EC (IVDD) (Directive Certificate) *and/or*
- 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	Osang Healthcare Co., Ltd.
Manufacturer address and contact details	132, Anyangcheondong-ro, Dongan-gu, Anyang-si, Gyeonggi-do 14040 Republic of Korea
Single Registration Number (SRN) (if available)	KR-MF-000032605

Authorised Representative name (if applicable)	Obelis s.a.
Authorised Representative address and contact details	Boulevard Général Wahis, 53 1030 Brussels Belgium regulatory@obelis.net
Single Registration Number (SRN) (if available)	BE-AR-000000106

Notified body name (if applicable)	POLISH CENTRE FOR TETING AND CETIFICATION	☒ See attached schedule ☐ Not applicable
Notified body number (if applicable)	1434	☒ See attached schedule ☐ Not applicable
Directive Certificate number(s) to which this confirmation is made (if applicable)	1434-IVDD-247/2022	☒ See attached schedule ☐ Not applicable
Original expiry date as indicated on the Directive Certificate(s) prior to the extension of the validity (if applicable)	26 May 2025	☒ See attached schedule ☐ Not applicable
End date of extended validity/transition period	31 Dec 2027	☒ See attached schedule

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Tel.: 82 031 460 9901 Fax: 82 031 460 0401 Website: www.osanghc.com

We, as the manufacturer declare under our sole responsibility:

- for the **device(s)** listed in the attached schedule the conditions for the legal extension of transitional periods as required in Article 110.3b of the IVDR are met *and/or*
- the **device(s)** listed in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 110.3c of the IVDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

- **Devices which were self-declared under the IVDD and require notified body involvement under the IVDR**

  In case of devices for which the conformity assessment procedure pursuant to IVDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2022 and for which the conformity assessment procedure pursuant to IVDR requires the involvement of a notified body:

  ☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII IVDR for conformity assessment has/have been lodged or will be lodged by us to a notified body for the device(s) listed in the attached schedule or its/their substitutes no later than:

  ☐ 26 May 2025 for class D devices

  ☒ 26 May 2026 for class C devices

  ☐ 27 May 2027 for class B and class A (sterile) devices

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

  ☒ Original expiry date *before 9 July 2024* – Expired on 26 May 2025

  ☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII IVDR for conformity assessment has/have been lodged or will be lodged by us to a notified body no later than 26 May 2025 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII IVDR before 26 September 2025.

- **Quality Management System (QMS)**

  ☒ Notified body has issued the attached certificate for the IVDR-compliant QMS.

- **Device(s) listed in the attached schedule (apart from the device indicated to be withdrawn)**

  - The device(s) continue(s) to comply with the IVDD.
  - There are no significant changes in the design and intended purpose.
  - 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:

OSANG Healthcare Co., Ltd. Address: 132, Anyangcheondong-ro, Dongan-gu, Anyang-si, Gyeonggi-do, 14040, Republic of Korea
Tel.: 82 031 460 9901 Fax: 82 031 460 0401 Website: www.osanghc.com

OSANG HealthCare Co., Ltd.

132, Anyangcheondong-ro, Dongan-gu, Anyang-si, Gyeonggi-do 14040 Republic of Korea

YoungGyun Kim,
Person Responsible for Regulatory Compliance

ygkim@osanghc.com

Date: 7th April 2025

Schedule of Devices

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

Identification of the device(s)[1] (e.g., device name, family/group name device model or catalogue number)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)	**Directive Certificate number to which this declaration is issued** (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 that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the IVDR application was lodged/contract signed** (if applicable)
GeneFinder COVID-19 Ag Self Test*	31 Dec 2027	N/A	1434-IVDD-247/2022	26 May 2025	POLISH CENTRE FOR TETING AND CETIFICATION (1434)	BSI Group The Netherlands (2797) (Contract planned for 2025)

* The devices indicated are classified as Class C under IVDR, as per Rule 4(a).
- The GeneFinder COVID-19 Ag Self Test is classified C under Rule 4(a) as a self-testing device intended for the detection of SARS-CoV-2.

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- The GeneFinder TB&NTM Multiplex Real-time PCR Kit is classified under Rule 3(b) as a device intended for detecting transmissible agents (*Mycobacterium tuberculosis* and *Nontuberculous mycobacteria*) in clinical specimens. DOC Number: EUDC-MRR7-0
- The GeneFinder HSV 1&2 RealAmp Kit is classified under Rule 3(a) as a device intended for detecting the presence of, or exposure to, a sexually transmitted agent (*Herpes Simplex Virus 1 & 2*). DOC Number: EUDC-MR19-0
- The High Risk HPV ELITe Panel is classified under Rule 3(a) as a device intended for detecting the presence of, or exposure to, a sexually transmitted agent. DOC Number: EUDC-MR26A-0

** All devices indicated are classified as Class B under IVDR, as per Rule 6.
- The GeneFinder COVID-19/Flu A&B RealAmp Kit is classified under Rule 6, which applies to devices not covered by the above classification rules and, therefore, are classified as Class B. DOC Number: EUDC-MRR57-0

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Manufacturer's Declaration

in relation to Regulation (EU) 2024/1860 amending Regulation (EU) 2017/746 (IVDR) as regards the transitional provisions for certain *in vitro* diagnostic medical devices, in particular with respect to

- the extended transitional periods for devices for which the conformity assessment procedure pursuant to Directive 98/79/EC (IVDD) did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2022 and for which the conformity assessment procedure pursuant to Regulation (EU) 2017/746 (IVDR) requires the involvement of a notified body *and/or*
- the validity of certificates issued under Directive 98/79/EC (IVDD) (Directive Certificate) *and/or*
- 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	Osang Healthcare Co., Ltd.
Manufacturer address and contact details	132, Anyangcheondong-ro, Dongan-gu, Anyang-si, Gyeonggi-do 14040 Republic of Korea
Single Registration Number (SRN) (if available)	KR-MF-000032605

Authorised Representative name (if applicable)	Obelis s.a.
Authorised Representative address and contact details	Boulevard Général Wahis, 53 1030 Brussels Belgium regulatory@obelis.net
Single Registration Number (SRN) (if available)	BE-AR-000000106

Notified body name (if applicable)	-	☐ See attached schedule ☒ Not applicable
Notified body number (if applicable)	-	☐ See attached schedule ☒ Not applicable
Directive Certificate number(s) to which this confirmation is made (if applicable)	-	☐ See attached schedule ☒ Not applicable
Original expiry date as indicated on the Directive Certificate(s) prior to the extension of the validity (if applicable)		☐ See attached schedule ☒ Not applicable
End date of extended validity/transition period	31 Dec 2029	☒ See attached schedule

OSANG Healthcare Co., Ltd. Address: 132, Anyangcheondong-ro, Dongan-gu, Anyang-si, Gyeonggi-do, 14040, Republic of Korea
Tel.: 82 031 460 9901 Fax: 82 031 460 0401 Website: www.osanghc.com

We, as the manufacturer declare under our sole responsibility:

- for the **device(s)** listed in the attached schedule the conditions for the legal extension of transitional periods as required in Article 110.3b of the IVDR are met *and/or*
- the **device(s)** listed in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 110.3c of the IVDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

- **Devices which were self-declared under the IVDD and require notified body involvement under the IVDR**

  In case of devices for which the conformity assessment procedure pursuant to IVDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2022 and for which the conformity assessment procedure pursuant to IVDR requires the involvement of a notified body:

  ☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII IVDR for conformity assessment has/have been lodged or will be lodged by us to a notified body for the device(s) listed in the attached schedule or its/their substitutes no later than:

  ☐ 26 May 2025 for class D devices

  ☐ 26 May 2026 for class C devices

  ☒ 27 May 2027 for class B and class A (sterile) devices

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

  ☐ Original expiry date *before 9 July 2024* – Expired on 26 May 2025

  ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII IVDR for conformity assessment has/have been lodged or will be lodged by us to a notified body no later than 26 May 2025 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII IVDR before 26 September 2025.

- **Quality Management System (QMS)**

  ☒ Notified body has issued the attached certificate for the IVDR-compliant QMS.

- **Device(s) listed in the attached schedule (apart from the device indicated to be withdrawn)**

  - The device(s) continue(s) to comply with the IVDD.
  - There are no significant changes in the design and intended purpose.
  - 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:

OSANG Healthcare Co., Ltd. Address: 132, Anyangcheondong-ro, Dongan-gu, Anyang-si, Gyeonggi-do, 14040, Republic of Korea
Tel.: 82 031 460 9901 Fax: 82 031 460 0401 Website: www.osanghc.com

OSANG HealthCare Co., Ltd.

132, Anyangcheondong-ro, Dongan-gu, Anyang-si, Gyeonggi-do 14040 Republic of Korea

YoungGyun Kim,
Person Responsible for Regulatory Compliance

ygkim@osanghc.com

Date: 7th April 2025

Schedule of Devices

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

Identification of the device(s)[1] (e.g., device name, family/group name device model or catalogue number)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)	**Directive Certificate number to which this declaration is issued** (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 that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the IVDR application was lodged/contract signed** (if applicable)
GeneFinder COVID-19 Ag Plus Rapid Test*	31 Dec 2029	N/A	This product has completed DOC declaration under IVDD Annex IV without section 4 and 6 of IVDD 98/79/EC. It is neither listed in Annex II, IVDD 98/79/EC, nor a self-testing device. The respective DOC numbers are listed below.	N/A	This product has completed DOC declaration under IVDD Annex IV without section 4 and 6 of IVDD 98/79/EC. It is neither listed in Annex II, IVDD 98/79/EC, nor a self-testing device.	BSI Group The Netherlands (2797) (Contract planned for 2025)

* The devices indicated are classified as Class B under IVDR, as per Rule 6.
- The GeneFinder COVID-19 Ag Plus Rapid Test is classified under Rule 6 as a device intended for the detection of SARS-CoV-2. DOC Number: EUDC-ISSP.

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Tel.: 82 031 460 9901 Fax: 82 031 460 0401 Website: www.osanghc.com

Manufacturer's Declaration

in relation to Regulation (EU) 2024/1860 amending Regulation (EU) 2017/746 (IVDR) as regards the transitional provisions for certain *in vitro* diagnostic medical devices, in particular with respect to

- the extended transitional periods for devices for which the conformity assessment procedure pursuant to Directive 98/79/EC (IVDD) did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2022 and for which the conformity assessment procedure pursuant to Regulation (EU) 2017/746 (IVDR) requires the involvement of a notified body *and/or*
- the validity of certificates issued under Directive 98/79/EC (IVDD) (Directive Certificate) *and/or*
- 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	OSANG HealthCare Co., Ltd.
Manufacturer address and contact details	132, Anyangcheondong-ro, Dongan-gu, Anyang-si, Gyeonggi-do 14040 Republic of Korea
Single Registration Number (SRN) (if available)	KR-MF-000032605

Authorised Representative name (if applicable)	Obelis s.a.
Authorised Representative address and contact details	Boulevard Général Wahis, 53 1030 Brussels Belgium regulatory@obelis.net
Single Registration Number (SRN) (if available)	BE-AR-000000106

Notified body name (if applicable)	TÜV SÜD Product Service GmbH	☒ See attached schedule ☐ Not applicable
Notified body number (if applicable)	0123	☒ See attached schedule ☐ Not applicable
Directive Certificate number(s) to which this confirmation is made (if applicable)	V1 001395 0018 Rev. 04	☒ See attached schedule ☐ Not applicable
Original expiry date as indicated on the Directive Certificate(s) prior to the extension of the validity (if applicable)	26 May 2025	☒ See attached schedule ☐ Not applicable
End date of extended validity/transition period	31 December 2027	☒ See attached schedule ☐ Not applicable

OSANG Healthcare Co., Ltd.
Address: 132, Anyangcheondong-ro, Dongan-gu, Anyang-si, Gyeonggi-do, 14040, Republic of Korea
Tel.: 82 031 460 9901 Fax: 82 031 460 0401 Website: www.osanghc.com

We, as the manufacturer declare under our sole responsibility:

- for the **Directive Certificate(s)** listed in the attached schedule the conditions for the legal extension of validity as required in Article 110.2 of the IVDR are met *and/or*
- the **device(s)** listed in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 110.3c of the IVDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

- **Directive Certificate(s)** as listed above

  ☒ Original expiry date *before 9 July 2024 – Expired on 26 May 2025*

  ☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII IVDR for conformity assessment has/have been lodged or will be lodged by us to a notified body no later than 26 May 2025 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII IVDR before 26 September 2025.

➢ **Quality Management System (QMS)**

Choose one applicable statement:

☐ QMS in accordance with Article 10(8) IVDR will be put in place by no later than 26 May 2025.
☐ QMS in accordance with Article 10(8) IVDR is in place.

☒ Notified body has issued the attached certificate for the IVDR-compliant QMS.

➢ **Device(s) listed in the attached schedule (apart from the device indicated to be withdrawn)**

- The device(s) continue(s) to comply with the IVDD.
- There are no significant changes in the design and intended purpose.
- 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:

OSANG HealthCare Co., Ltd.

132, Anyangcheondong-ro, Dongan-gu, Anyangsi, Gyeonggi-do 144040 Republic of Korea / 4th Feb, 2025

YoungGyun Kim, Person Responsible for Regulatory Compliance

ygkim@osanghc.com

OSANG Healthcare Co., Ltd.
Address: 132, Anyangcheondong-ro, Dongan-gu, Anyang-si, Gyeonggi-do, 14040, Republic of Korea
Tel.: 82 031 460 9901 Fax: 82 031 460 0401 Website: www.osanghc.com

Schedule of Devices

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

Identification of the device(s)[1] (e.g., device name, family/group name device model or catalogue number)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)	**Directive Certificate number to which this declaration is issued** (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 that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the IVDR application was lodged/contract signed** (if applicable)
CLOVER A1c Self System (IGM-0023)	31 Dec 2027	N/A	V1 001395 0018 Rev.04 (with individually confirmation statement VCQ 001395 0020 Rev.00)	26 May 2025	TÜV SÜD Product Service GmbH (0123)	BSI Group The Netherlands (2797)

1) The IVDR application for the devices will be lodged within 26 May 2025 for transition to BSI Group The Netherlands (2797).

[1] for devices with IVDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above

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Tel.: 82 031 460 9901 Fax: 82 031 460 0401 Website: www.osanghc.com

Manufacturer's Declaration

in relation to Regulation (EU) 2024/1860 amending Regulation (EU) 2017/746 (IVDR) as regards the transitional provisions for certain *in vitro* diagnostic medical devices, in particular with respect to

- the extended transitional periods for devices for which the conformity assessment procedure pursuant to Directive 98/79/EC (IVDD) did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2022 and for which the conformity assessment procedure pursuant to Regulation (EU) 2017/746 (IVDR) requires the involvement of a notified body *and/or*
- the validity of certificates issued under Directive 98/79/EC (IVDD) (Directive Certificate) *and/or*
- 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	OSANG HealthCare Co., Ltd.
Manufacturer address and contact details	132, Anyangcheondong-ro, Dongan-gu, Anyang-si, Gyeonggi-do 14040 Republic of Korea
Single Registration Number (SRN) (if available)	KR-MF-000032605

Authorised Representative name (if applicable)	Obelis s.a.
Authorised Representative address and contact details	Boulevard Général Wahis, 53 1030 Brussels Belgium regulatory@obelis.net
Single Registration Number (SRN) (if available)	BE-AR-000000106

Notified body name (if applicable)	-	☐ See attached schedule ☒ Not applicable
Notified body number (if applicable)	-	☐ See attached schedule ☒ Not applicable
Directive Certificate number(s) to which this confirmation is made (if applicable)	-	☐ See attached schedule ☒ Not applicable
Original expiry date as indicated on the Directive Certificate(s) prior to the extension of the validity (if applicable)	-	☐ See attached schedule ☒ Not applicable
End date of extended validity/transition period	31 December 2028	☒ See attached schedule ☐ Not applicable

OSANG Healthcare Co., Ltd.
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Tel.: 82 031 460 9901 Fax: 82 031 460 0401 Website: www.osanghc.com

We, as the manufacturer declare under our sole responsibility:

- for the **device(s)** listed in the attached schedule the conditions for the legal extension of transitional periods as required in Article 110.3b of the IVDR are met *and/or*
- the **device(s)** listed in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 110.3c of the IVDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Devices which were self-declared under the IVDD and require notified body involvement under the IVDR**

In case of devices for which the conformity assessment procedure pursuant to IVDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2022 and for which the conformity assessment procedure pursuant to IVDR requires the involvement of a notified body:

Choose applicable statement:

☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII IVDR for conformity assessment has/have been lodged or will be lodged by us to a notified body for the device(s) listed in the attached schedule or its/their substitutes no later than:

☐ 26 May 2025 for class D devices

☒ 26 May 2026 for class C devices

☐ 27 May 2027 for class B and class A (sterile) devices

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

☐ Original expiry date *before 9 July 2024 - Expired on 26 May 2025*

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII IVDR for conformity assessment has/have been lodged or will be lodged by us to a notified body no later than 26 May 2025 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII IVDR before 26 September 2025.

➢ **Quality Management System (QMS)**

Choose one applicable statement:

☐ QMS in accordance with Article 10(8) IVDR will be put in place by no later than 26 May 2025.
☐ QMS in accordance with Article 10(8) IVDR is in place.

☒ Notified body has issued the attached certificate for the IVDR-compliant QMS.

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- **Device(s) listed in the attached schedule (apart from the device indicated to be withdrawn)**
  - The device(s) continue(s) to comply with the IVDD.
  - There are no significant changes in the design and intended purpose.
  - 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:

OSANG HealthCare Co., Ltd.

132, Anyangcheondong-ro, Dongan-gu, Anyangsi, Gyeonggi-do 144040 Republic of Korea / 4th Feb, 2025

YoungGyun Kim, Person Responsible for Regulatory Compliance

ygkim@osanghc.com

OSANG Healthcare Co., Ltd.
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Tel.: 82 031 460 9901 Fax: 82 031 460 0401 Website: www.osanghc.com

Schedule of Devices

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

Identification of the device(s)[1] (e.g., device name, family/group name device model or catalogue number)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)	**Directive Certificate number to which this declaration is issued** (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 that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the IVDR application was lodged/contract signed** (if applicable)
CLOVER A1c Plus Test Cartridge *1)	31 Dec 2028	N/A	N/A	N/A	This product has completed DOC declaration under IVDD Annex IV without section 4 and 6 of IVDD 98/79/EC. It is neither listed in Annex II, IVDD 98/79/EC, nor a self-testing device.	BSI Group The Netherlands (2797) (Contract planned until May, 2026)
HemoCue HbA1c 501 Test Cartridge *2)	31 Dec 2028	N/A	N/A	N/A		
CLOVER A1c Test Cartridge *3)	31 Dec 2028	N/A	N/A	N/A		

**1) CLOVER A1c Plus Analyzer / Daily, Monthly Check Cartridge is not planned to be sold in compliance with IVDR. CLOVER A1c Plus Test Cartridge is scheduled for IVDR transition.*
**2) Since the IVDR application for the devices has been already lodged to the BSI Group The Netherlands (2797). (IVDR application date: August 30, 2023)*
**3) Since the IVDR application for the devices has been already lodged to the BSI Group The Netherlands (2797). (IVDR application date: April 11, 2025)*

Signature:

Email: board@obelis.net

[1] for devices with IVDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above

OSANG Healthcare Co., Ltd. Address: 132, Anyangcheondong-ro, Dongan-gu, Anyang-si, Gyeonggi-do, 14040, Republic of Korea
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