AUTHORISED REPRESENTATIVE MANDATE

According to the Regulation (EU) 2017/746

I. Address /Contact

OSANG HEALTHCARE CO., LTD.
Registered Address:
132 Anyangcheondong-ro, Dongan-gu,
Anyang-si, 14040, Gyeonggi-do,
Republic of Korea

(*) Address of registered place of business as to be mentioned on all certificates & official documents

Tel: +82.31.460.0300
Fax: +82.31.460.0401
E-mail: hkcho1@osanghc.com
Web: www.osanghc.com
Company registration #229-81-022-91

Hereinafter "The Manufacturer"

OBELIS S.A.
Registered Address:
Bd. General Wahis 53,
1030 Brussels
Belgium

Tel: +32.2.732.59.54
Fax: +32.2.732.60.03
E-mail: mail@obelis.net
Web: www.obelis.net

Hereinafter "Obelis"

This Authorised Representative Mandate (hereinafter the "Mandate") between the Manufacturer and Obelis, first issued on December 20th, 2022 in accordance with the terms and conditions specified in the Authorised Representative Services Agreement ("hereinafter the "Agreement"), concluded between the parties.

II. Designation and tasks

1. Upon signing this Mandate, the Manufacturer hereby designates Obelis to act as the sole Authorised Representative in the European Union as defined by the Regulation (EU) 2017/746 ("hereinafter the "Regulation") for,at least, all in vitro diagnostic medical devices of the same generic device group listed according to the date stated for each specific device in the approved and signed Annex M, and notwithstanding the Manufacturer's obligations as per the Regulation and the terms of the Agreement. The Annex M shall be an integral part of this Mandate.

2. Upon signing this Mandate, Obelis hereby accepts to act as Authorised Representative in the European Union for the in vitro diagnostic medical devices listed in the approved Annex M, in accordance with the terms of this Mandate.

The validity of this Mandate is related only to the devices listed in the Annex M to the Mandate.
Any modification of the Mandate need to be fully approved by the Authorised Representative and the Manufacturer upon signature of the respective PRRC.
This Mandate was issued electronically and is bound by the conditions of the contract and the IVDR Agreement.
For any device that received a CE Certificate under the REGULATION (EU) 2017/746, there will be just one entry in the Mandate still covering any remaining legacy and/or extended variant present on the EU Market.

3. Any modification of the Annex M to the Mandate shall be approved by Obelis and the Manufacturer. The latest updated version of the Mandate is the only one bearing full validity.

4. Obelis shall fulfil the tasks specified in this Mandate as per Article 11.3 of the Regulation and according to the specified terms of the Agreement. Obelis shall, therefore:

   4.1. Verify that the EU Declaration of Conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the Manufacturer;

   4.2. Keep available a copy of the technical documentation, the EU Declaration of Conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements, issued in accordance with Article 51 of the Regulation, at the disposal of the competent authorities for a period of at least 10 years after the last device covered by the EU Declaration of Conformity has been placed on the market.

   4.3. Comply with the registration obligations laid down in Article 28 of the Regulation and verify that the Manufacturer has complied with the registration obligations laid down in Articles 26 and 28 of the Regulation;

   4.4. In response to a request from the competent authorities, provide the competent authorities with all the information and documentation necessary to demonstrate the conformity of a device, in an official Union language determined by the Member State concerned;

   4.5. Forward to the Manufacturer any request by the competent authorities of the Member State in which Obelis has its registered place of business for samples, or access to a device and verify that the competent authorities receive the samples or is given access to the device;

   4.6. Cooperate with the competent authorities on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices;

   4.7. Immediately inform the Manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device for which they have been designated;

   4.8. Terminate the Mandate if the Manufacturer acts contrary to its obligations under the Regulation and immediately inform the competent authorities of the Member State in which it is established and, where applicable, the Notified Body that was involved in the conformity assessment for the device of the termination of the mandate and the reasons therefor.

   4.9. Inform Manufacturer immediately of significant changes affecting Obelis regulatory compliance .

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5. The Manufacturer has granted Obelis access to the vigilance module of EUDAMED to enable it to access to vigilance reports of the Manufacturer.
6. On a case by case basis, Manufacturer may request Obelis to notify serious incidents/FSCA/trend reports to the concerned competent authorities.

7. Obelis shall provide a copy of this Mandate to the competent authorities upon request.

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For: **The Manufacturer**
Person Responsible for Regulatory Compliance (PRRC)

Name: …… YoungGyun Kim …….

Position: …. PRRC ……..

Date: ……22/10/2025…..

Signature: ……..

YoungGyun Kim
YoungGyun Kim (Nov 7, 2025 13:47:11 GMT+9)

Company stamp:

For: **Obelis**
Person Responsible for Regulatory Compliance (PRRC)

Name: … Doram Elkayam …….

Position: …COO……..

Date: ……22/10/2025…..

Signature: ……..

Mandate History

Mandate issued	Revision Number	Action
20/12/2022	1	First Issue
02/05/2023	2	Addition of devices to Annex M
20/06/2024	3	Addition of devices to Annex M
29/08/2024	4	Addition of devices to Annex M
31/10/2024	5	Addition of devices to Annex M
22/11/2024	6	Addition of devices to Annex M

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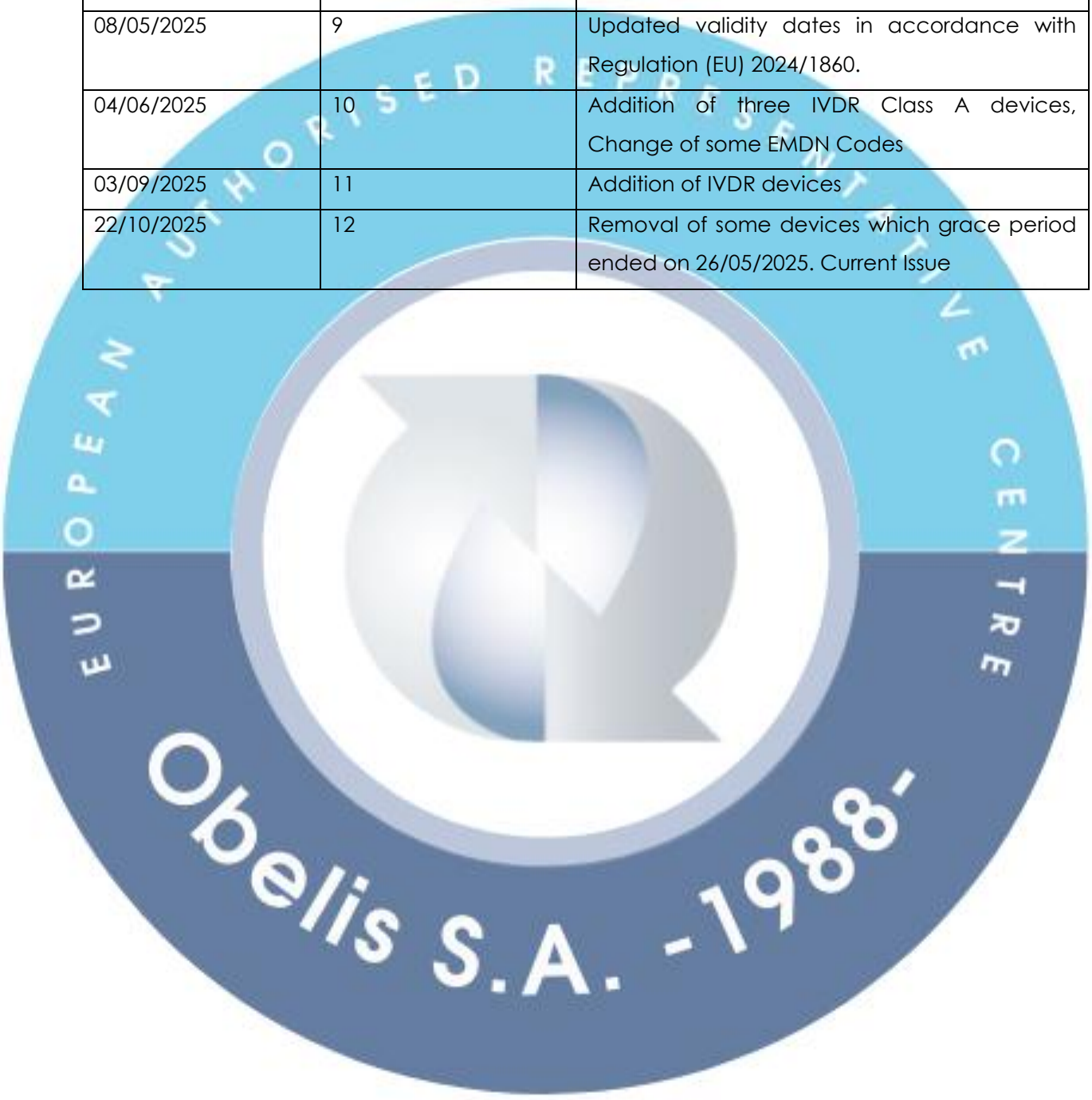
04/12/2024	7	Manufacturer's PRRC change
07/03/2025	8	Addition of device.
08/05/2025	9	Updated validity dates in accordance with Regulation (EU) 2024/1860.
04/06/2025	10	Addition of three IVDR Class A devices, Change of some EMDN Codes
03/09/2025	11	Addition of IVDR devices
22/10/2025	12	Removal of some devices which grace period ended on 26/05/2025. Current Issue



The validity of this Mandate is related only to the devices listed in the Annex M to the Mandate.
Any modification of the Mandate need to be fully approved by the Authorised Representative and the Manufacturer upon signature of the respective PRRC.
This Mandate was issued electronically and is bound by the conditions of the contract and the IVDR Agreement.
For any device that received a CE Certificate under the REGULATION (EU) 2017/746, there will be just one entry in the Mandate still covering any remaining legacy and/or extended variant present on the EU Market.

ANNEX M – Annex to IVDR Authorised Representative Mandate

Manufacturer: Osang Healthcare Co., Ltd

Country: Republic of Korea

#	Name of device	Legacy or IVDR compliant	Intended use	Class under IVDD	Risk Class and Classification Rule IVDR	Basic UDI	EMDN code	Validity Start Date	Validity End Date
1.	GluNEO Lite Blood Glucose Monitoring System for self-testing	Legacy	Blood Glucose Monitoring System for self-testing	Annex II, List B	Class C, Rule 4(a)	N/A	W0201060102	20/12/2022	31/12/2027*
2.	GluNEO Lite Blood Glucose Test Strip	Legacy	Biosensor for determining concentration of glucose in the blood	Annex II, List B	Class C, Rule 4(a)	N/A	W0101060101	20/12/2022	31/12/2027*

3.	GluNEO Lite Blood Glucose Control Solution	Legacy	Control solution is required to ensure glucose in the blood	Annex II, List B	Class C, Rule 4(a)	N/A	W0101060108 01	20/12/2022	31/12/2027*
4.	Clover A1c Plus Test Cartridge	Legacy	HbA1c Test Cartridge	All others	Class C, Rule 3(k), 4(b)	N/A	W01010214	20/12/2022	31/12/2028*
5.	Healthpro-X1 Blood Glucose Monitoring System for self-testing List of components: 1. Test meter 2. Sterile lancet 3. Lancing device 4. Battery	Legacy	Blood Glucose Monitoring System for self-testing	Annex II, List B	Class C, Rule 4(a)	N/A	W0201060102	20/12/2022	31/12/2027*
6.	Healthpro-X1 Blood Glucose Test Strip	Legacy	Biosensor for determining concentration of glucose in the blood	Annex II, List B	Class C, Rule 4(a)	N/A	W0101060101	20/12/2022	31/12/2027*
7.	Healthpro-X1 Blood Glucose Control Solution	Legacy	Control solution is required to ensure glucose in the blood	Annex II, List B	Class C, Rule 4(a)	N/A	W0101060108 01	20/12/2022	31/12/2027*

8.	GeneFinder COVID-19 Ag Self-Test List of components: 1. Test cassette 2. Extraction buffer tube & Tube filter cap	Legacy	Immuno Diagnosis Measuring Test strip for self-testing	Self-testing	Class C, Rule 4(a)	N/A	W0105040619	20/12/2022	31/12/2027*
9.	GeneFinder COVID-19 Ag Plus Rapid Test List of components: 1. Test cassette 2. Extraction buffer tube 3. Tube filter cap 4. Positive control swab 5. Negative control swab	Legacy	Immuno Diagnosis Measuring Test strip of Professional use	All others	Class B, Rule 6	N/A	W0105040619	20/12/2022	31/12/2029*
10.	ELEMENT Blood Glucose Monitoring System for self-testing List of components: 1.Test meter 2.Sterile lancet 3.Lancing device 4.Battery	Legacy	Blood Glucose Monitoring System for self-testing	Annex II, List B	Class C, Rule 4(a)	N/A	W0201060102	20/12/2022	31/12/2027*
11.	ELEMENT Blood Glucose Test Strip	Legacy	Biosensor for determining concentration of glucose in the blood	Annex II, List B	Class C, Rule 4(a)	N/A	W0101060101	20/12/2022	31/12/2027*

12.	ELEMENT Blood Glucose Control Solution	Legacy	Control solution is required to ensure glucose in the blood	Annex II, List B	Class C, Rule 4(a)	N/A	W0101060108 01	20/12/2022	31/12/2027*
13.	GLUCOLAB Auto-coding Blood Glucose Monitoring System for self-testing List of components: 1. Test meter 2. Sterile lancet 3. Lancing device 4. Battery	Legacy	Blood Glucose Monitoring System for self-testing	Annex II, List B	Class C, Rule 4(a)	N/A	W0201060102	20/12/2022	31/12/2027*
14.	GLUCOLAB Auto-coding Blood Glucose Test Strip	Legacy	Biosensor for determining concentration of glucose in the blood	Annex II, List B	Class C, Rule 4(a)	N/A	W0101060101	20/12/2022	31/12/2027*
15.	GLUCOLAB Auto-coding Blood Glucose Control Solution	Legacy	Control solution is required to ensure glucose in the blood	Annex II, List B	Class C, Rule 4(a)	N/A	W0101060108 01	20/12/2022	31/12/2027*
16.	GluNEO Blood Glucose Monitoring System for self-testing List of components: 1. Test meter 2. Sterile lancet	Legacy	Blood Glucose Monitoring System for self-testing	Annex II, List B	Class C, Rule 4(a)	N/A	W0201060102	20/12/2022	31/12/2027*

	3. Lancing device 4. Battery								
17.	GluNEO Blood Glucose Test Strip	Legacy	Biosensor for determining concentration of glucose in the blood	Annex II, List B	Class C, Rule 4(a)	N/A	W0101060101	20/12/2022	31/12/2027*
18.	GluNEO Blood Glucose Control Solution	Legacy	Control solution is required to ensure glucose in the blood	Annex II, List B	Class C, Rule 4(a)	N/A	W0101060108 01	20/12/2022	31/12/2027*
19.	Adia Blood Glucose Monitoring System for self-testing List of components: 1.Test meter 2.Sterile lancet 3.Lancing device 4.Battery	Legacy	Blood Glucose Monitoring System for self-testing	Annex II, List B	Class C, Rule 4(a)	N/A	W0201060102	20/12/2022	31/12/2027*
20.	Adia Blood Glucose Test Strip	Legacy	Biosensor for determining concentration of glucose in the blood	Annex II, List B	Class C, Rule 4(a)	N/A	W0101060101	20/12/2022	31/12/2027*

21.	Adia Blood Glucose Control Solution	Legacy	Control solution is required to ensure glucose in the blood	Annex II, List B	Class C, Rule 4(a)	N/A	W0101060108 01	20/12/2022	31/12/2027*
22.	Oh'Care Lite Blood Glucose Monitoring System for self-testing List of components: 1. Test meter 2. Sterile lancet 3. Lancing device 4. Battery	Legacy	Blood Glucose Monitoring System for self-testing	Annex II, List B	Class C, Rule 4(a)	N/A	W0201060102	20/12/2022	31/12/2027*
23.	Oh'Care Lite Blood Glucose Test Strip	Legacy	Biosensor for determining concentration of glucose in the blood	Annex II, List B	Class C, Rule 4(a)	N/A	W0101060101	20/12/2022	31/12/2027*
24.	Oh'Care Lite Blood Glucose Control Solution	Legacy	Control solution is required to ensure glucose in the blood	Annex II, List B	Class C, Rule 4(a)	N/A	W0101060108 01	20/12/2022	31/12/2027*
25.	Examedin® FAST Blood Glucose Monitoring System for self-testing List of components: 1. Test meter 2. Sterile lancet 3. Lancing device 4. Battery	Legacy	Blood Glucose Monitoring System for self-testing	Annex II, List B	Class C, Rule 4(a)	N/A	W0201060102	20/12/2022	31/12/2027*

26.	Finetest Lite Blood Glucose Monitoring System for self-testing List of components: 1. Test meter 2. Sterile lancet 3. Lancing device 4. Battery	Legacy	Blood Glucose Monitoring System for self-testing	Annex II, List B	Class C, Rule 4(a)	N/A	W0201060102	20/12/2022	31/12/2027*
27.	Finetest Lite Blood Glucose Test Strip	Legacy	Biosensor for determining concentration of glucose in the blood	Annex II, List B	Class C, Rule 4(a)	N/A	W0101060101	20/12/2022	31/12/2027*
28.	Finetest Lite Blood Glucose Control Solution	Legacy	Control solution is required to ensure glucose in the blood	Annex II, List B	Class C, Rule 4(a)	N/A	W0101060108 01	20/12/2022	31/12/2027*
29.	GluNEO Plus Blood Glucose Monitoring System for self-testing List of components: 1. Test meter 2. Sterile lancet 3. Lancing device 4. Battery	Legacy	Blood Glucose Monitoring System for self-testing	Annex II, List B	Class C, Rule 4(a)	N/A	W0201060102	20/12/2022	31/12/2027*
30.	GluNEO Plus Blood Glucose Test Strip	Legacy	Biosensor for determining concentration of glucose in the blood	Annex II, List B	Class C, Rule 4(a)	N/A	W0101060101	20/12/2022	31/12/2027*

31.	HemoCue HbA1c 501 Test Cartridge	Legacy	HbA1c Test Cartridge	All others	Class C, Rule 3(k), 4(b)	N/A	W01010214	20/12/2022	31/12/2028*
32.	Clover A1c Test Cartridge	Legacy	HbA1c Test Cartridge	All others	Class C, Rule 3(k), 4(b)	N/A	W01010214	20/12/2022	31/12/2028*
33.	Clover A1c Self-Test Analyzer List of components: 1. Analyzer 2. Daily Check cartridge 3. Monthly Check cartridge 4. Fan Filter 5. Adapter & AC/DC cable	Legacy	Self HbA1c measuring system	Annex II, List B	Class C, Rule 3(k) and 4(a)	N/A	W0201060101	20/12/2022	31/12/2027*
34.	CLOVER A1c Self Test Cartridge	Legacy	HbA1c Test Cartridge	Annex II, List B	Class C, Rule 3(k) and 4(a)	N/A	W01010214	20/12/2022	31/12/2027*
35.	GeneFinder™ STD-I(CT/NG/UU) Multiplex Real-time PCR kit List of components: 1. STD I Reaction mixture 2. STD I Probe mixture	Legacy	This product is a qualitative nucleic acids amplification assay for detection of Chlamydia trachomatis(CT), Neisseria gonorrhoeae(NG) and Ureaplasma urealyticum(UU).	Annex II, List B	Class C, Rule 3(a)	N/A	W0105070501	20/12/2022	31/12/2027*

	3. STD I Positive control 4. STD I Negative control								
36.	GeneFinder™ HPV-HR Real*Amp* kit List of components: 1. HPV-HR Reaction Mixture 2. HPV-HR Probe Mixture 3. HPV-HR Positive Control 4. HPV-HR Negative Control	Legacy	In vitro polymerase chain reaction (PCR) assay for HPV high risk group(16, 18 and High-risk 14 types)	All others	Class C, Rule 3(a)	N/A	W0105041003	20/12/2022	31/12/2028*
37.	GeneFinder™ TB&NTM Multiplex Real-time PCR kit List of components: 1. TB & NTM Reaction Mixture 2. TB & NTM Probe Mixture 3. TB & NTM Positive Control 4. TB & NTM Negative Control	Legacy	In vitro polymerase chain reaction (PCR) assay for Mycobacterium tuberculosis and Nontuberculous mycobacteria.	All others	Class C, Rule 3(b)	N/A	W0105010703	20/12/2022	31/12/2028*
38.	GeneFinder™ HSV 1&2 Real*Amp* kit List of components: 1. HSV 1&2 Reaction buffer	Legacy	In vitro polymerase chain reaction (PCR) assay for HSV 1 and HSV 2 from RNA extracted from urogenital swab, urine or blood samples	All others	Class C, Rule 3(a)	N/A	W0105040311	20/12/2022	31/12/2028*

	2. HSV 1&2 Probe Mixture 3. HSV 1&2 Positive Control 4. HSV 1&2 Negative Control								
39.	GeneFinder™ Flu A&B Real*Amp* kit List of components: 1. Flu A&B Typing Reaction buffer 2. Flu A&B Typing Enzyme Mixture 3. Flu A&B Typing Probe Mixture 4. Flu A&B Typing Positive Control 5. Flu A&B Typing Negative Control	Legacy	In vitro polymerase chain reaction (PCR) assay for Influenza virus(A,B) from RNA extracted from nasopharyngeal swab.	All others	Class B, Rule 6	N/A	W0105040504	20/12/2022	26/05/2027
40.	GeneFinder™ COVID-19 Plus Real*Amp* kit List of components: 1. COVID-19 Plus Reaction buffer 2. COVID-19 Plus Probe Mixture 3. COVID-19 Plus Positive Control 4. COVID-19 Plus Negative Control	Legacy	In vitro polymerase chain reaction (PCR) assay for COVID-19 from RNA extracted from nasopharyngeal & oropharyngeal swab, sputum and bronchoalveolar lavage fluid.	All others	Class B, Rule 6	N/A	W0105040519	20/12/2022	26/05/2027

41.	GeneFinder™ COVID-19 Fast Real*Amp* kit List of components: 1. COVID-19 Fast Reaction buffer 2. COVID-19 Fast Enzyme Mixture 3. COVID-19 Fast Probe Mixture 4. COVID-19 Fast Positive Control 5. COVID-19 Fast Negative Control	Legacy	In vitro polymerase chain reaction (PCR) assay for COVID-19 from RNA extracted from nasopharyngeal &oropharyngeal swab, sputum and bronchoalveolar lavage fluid.	All others	Class B, Rule 6	N/A	W0105040519	20/12/2022	26/05/2027
42.	GeneFinder™ DENV/CHKV Real*Amp* kit List of components: 1. DENV/CHKV Reaction buffer 2. DENV/CHKV Enzyme Mixture 3. DENV/CHKV Probe Mixture 4. DENV/CHKV Positive Control 5. DENV/CHKV Negative Control	Legacy	In vitro polymerase chain reaction (PCR) assay for Dengue and Chikungunya virus from RNA extracted from human blood (EDTA), plasma, serum and cerebrospinal fluid (CSF).	All others	Class C, Rule 3(b)	N/A	W0105070506	20/12/2022	26/05/2026
43.	EASYGLUCO Auto-coding Blood Glucose Monitoring System for self-testing List of components: 1. Test meter 2. Sterile lancet	Legacy	Blood Glucose Monitoring System for self-testing	Annex II, List B	Class C, Rule 4(a)	N/A	W0201060102	20/12/2022	31/12/2027*

	3. Lancing device 4. Battery								
44.	EASYGLUCO Auto-coding Blood Glucose Test Strip	Legacy	Biosensor for determining concentration of glucose in the blood	Annex II, List B	Class C, Rule 4(a)	N/A	W0101060101	20/12/2022	31/12/2027*
45.	EASYGLUCO Auto-coding Blood Glucose Control Solution	Legacy	Control solution is required to ensure glucose in the blood	Annex II, List B	Class C, Rule 4(a)	N/A	W0101060108 01	20/12/2022	31/12/2027*
46.	FINETEST Auto-coding premium Blood Glucose Monitoring System for self-testing List of components: 1.Test meter 2.Sterile lancet 3.Lancing device 4.Battery	Legacy	Blood Glucose Monitoring System for self-testing	Annex II, List B	Class C, Rule 4(a)	N/A	W0201060102	20/12/2022	31/12/2027*
47.	FINETEST Auto-coding premium Blood Glucose Test Strip	Legacy	Biosensor for determining concentration of glucose in the blood	Annex II, List B	Class C, Rule 4(a)	N/A	W0101060101	20/12/2022	31/12/2027*

48.	FINETEST Auto-coding premium Glucose Control Solution	Legacy	Blood Glucose Monitoring System for self-testing	Annex II, List B	Class C, Rule 4(a)	N/A	W0101060108 01	20/12/2022	31/12/2027*
49.	Healthpro Blood Glucose test Control Solution	Legacy	Control solution is required to ensure glucose in the blood	Annex II, List B	Class C, Rule 4(a)	N/A	W0101060108 01	20/12/2022	26/05/2025
50.	Gluco Check Excellent Blood Glucose Monitoring System for self-testing List of components: 1.Test meter 2.Sterile lancet 3.Lancing device 4.Battery	Legacy	Blood Glucose Monitoring System for self-testing	Annex II, List B	Class C, Rule 4(a)	N/A	W0201060102	20/12/2022	31/12/2027*
51.	Gluco Check Excellent Blood Glucose Test Strip	Legacy	Biosensor for determining concentration of glucose in the blood	Annex II, List B	Class C, Rule 4(a)	N/A	W0101060101	20/12/2022	31/12/2027*
52.	Gluco Check Excellent Blood Glucose test Control Solution	Legacy	Control solution is required to ensure glucose in the blood	Annex II, List B	Class C, Rule 4(a)	N/A	W0101060108 01	20/12/2022	31/12/2027*

53.	Examedin® FAST Blood Glucose Test Strip	Legacy	Biosensor for determining concentration of glucose in the blood	Annex II, List B	Class C, Rule 4(a)	N/A	W0101060101	20/12/2022	31/12/2027*
54.	Examedin® FAST Blood Glucose Control Solution	Legacy	Control solution is required to ensure glucose in the blood	Annex II, List B	Class C, Rule 4(a)	N/A	W010106010801	20/12/2022	31/12/2027*
55.	GluNEO Plus Blood Glucose Control Solution	Legacy	Control solution is required to ensure glucose in the blood	Annex II, List B	Class C, Rule 4(a)	N/A	W010106010801	20/12/2022	31/12/2027*
56.	Finetest Lite Smart Blood Glucose Monitoring System for self-testing List of components: 1. Test meter 2. Sterile lancet 3. Lancing device 4. Battery	Legacy	Blood Glucose Monitoring System for self-testing	Annex II, List B	Class C, Rule 4(a)	N/A	W0201060102	20/12/2022	31/12/2027*
57.	Finetest Lite Smart Blood Glucose Test Strip	Legacy	Biosensor for determining concentration of glucose in the blood	Annex II, List B	Class C, Rule 4(a)	N/A	W0101060101	20/12/2022	31/12/2027*

58.	Finetest Lite Smart Blood Glucose Control Solution	Legacy	Control solution is required to ensure glucose in the blood	Annex II, List B	Class C, Rule 4(a)	N/A	W0101060108 01	20/12/2022	31/12/2027*
59.	CLOVER A1c Self Daily Check Cartridge	Legacy	HbA1c Check Cartridge	Annex II, List B	Class C, Rule 3(k) and 4(a)	N/A	W0201060190 85	20/12/2022	31/12/2027*
60.	CLOVER A1c Self Monthly Check Cartridge	Legacy	HbA1c Check Cartridge	Annex II, List B	Class C, Rule 3(k) and 4(a)	N/A	W0201060190 85	20/12/2022	31/12/2027*
61.	GeneFinder™ HLA-B*51 Real*Amp* Kit List of components: 1. B51 2X Rxn 2. B51 DNA pol. 3. B51 PC	Legacy	This product is a qualitative in vitro diagnostic kit by using real-time PCR technology to detect HLA-B*51 genotype.	Annex II, List B	Class C, Rule 3(i)	N/A	W0106010499	20/12/2022	31/12/2027*
62.	GeneFinder™ HLA-ABDR Real*Amp* Kit List of components: 1. HLA-ABDR Rxn 2. HLA-ABDR pol. 3. HLA-ABDR 96 Well plate	Legacy	Real-time polymerase chain reaction (RT-PCR) assay for HLA A, B, DRB1 locus	Annex II, List B	Class C, Rule 2	N/A	W0106010401	20/12/2022	31/12/2027*

63.	GeneFinder™ HLA-ABCDRB1DQ Real*Amp* kit List of components: 1. HLA-ABCDRB1DQ Rxn 2. HLA-ABCDRB1DQ pol. 3. HLA-ABCDRB1DQ 96 Well plate	Legacy	Real-time polymerase chain reaction (RT-PCR) assay for HLA-A, B, C, DRB1, DQA1, DQB1 locus.	Annex II, List B	Class C, Rule 2	N/A	W0106010401	20/12/2022	31/12/2027*
64.	GeneFinder™ STD-II(MG/MH/TV) Multiplex Realtime PCR kit List of components: 1. STD II Reaction Mixture 2. STD II Probe Mixture 3. STD II Positive Control 4. STD II Negative Control	Legacy	In vitro polymerase chain reaction (PCR) assay for Mycoplasma genitalium, Mycoplasma hominis and Trichomonas vaginalis	All others	Class C, Rule 3(a)	N/A	W0105070501	20/12/2022	31/12/2028*
65.	High Risk HPV ELITe panel List of components: 1. HR-HPV Reaction Mixture 2. HR-HPV Probe Mixture 3. HR-HPV Positive Control	Legacy	In vitro polymerase chain reaction (PCR) assay for HPV high risk group (16, 18 and High-risk 14 types)	All others	Class C, Rule 3(a)	N/A	W0105041003	20/12/2022	31/12/2028*

66.	GeneFinder™ HPV Liquid Bead MicroArray Genotype kit List of components: 1. GF Buffer A 2. GF Buffer B 3. GF Bead	Legacy	In vitro Microarray assay for Human papilloma virus (HPV) genotyping.	All others	Class C, Rule 3(a)	N/A	W0105041004	20/12/2022	26/05/2026
67.	GeneFinder™ Malaria Real*Amp* kit List of components: 1. Malaria Reaction Mixture 2. Malaria Probe Mixture 3. Malaria Positive Control 4. Malaria Negative Control	Legacy	In vitro polymerase chain reaction (PCR) assay for Malaria parasites detection (screening for P. falciparum, P. vivax, P. ovale, P. malariae and P. knowlesi, identification for P. falciparum, P. vivax).	All others	Class C, Rule 3(b)	N/A	W0105050209	20/12/2022	26/05/2026
68.	GeneFinder™ DENV Typing Real*Amp* kit List of components: 1. DENV Typing Reaction buffer 2. DENV Typing Enzyme Mixture 3. DENV Typing Probe Mixture 4. DENV Typing Positive Control	Legacy	In vitro polymerase chain reaction (PCR) assay for Dengue and Chikungunya virus from RNA extracted from human blood (EDTA), plasma, serum and cerebrospinal fluid (CSF).	All others	Class C, Rule 3(b)	N/A	W0105040511	20/12/2022	26/05/2026

	5. DENV Typing Negative Control								
69.	GeneFinder™ COVID-19/Flu A&B Real*Amp* Kit List of components: 1. COVID-19/Flu A&B Reaction buffer 2. COVID-19/Flu A&B Probe Mixture 3. COVID-19/Flu A&B Positive Control 4. COVID-19/Flu A&B Negative Control	Legacy	In vitro polymerase chain reaction (PCR) assay for COVID-19 and Influenza A&B from RNA extracted from sputum, nasopharyngeal aspirate, Nasopharyngeal swab, Oropharyngeal swab.	All others	Class B, Rule 6	N/A	W0105070503	20/12/2022	31/12/2029*
70.	GeneFinder™ DENV/CHIKV/ZIKV Real*Amp* Kit List of components: 1.DENV/CHIKV/ZIKV Reaction buffer 2.DENV/CHIKV/ZIKV Probe Mixture 3.DENV/CHIKV/ZIKV Positive Control 4.DENV/CHIKV/ZIKV Negative Control	Legacy	In vitro polymerase chain reaction (PCR) assay for Dengue/Chikungunya/Zika virus from RNA extracted from human blood, serum, and plasma.	All others	Class C, Rule 3(b)	N/A	W0105070506	20/12/2022	26/05/2026

71.	GeneFinder™ HPV PCR Kit List of components: 1. HPV Reaction Mixture 2. HPV Primer Mixture I 3. HPV Primer Mixture II 4. HPV Positive Control I 5. HPV Positive Control II 6. HPV Negative Control	Legacy	In polymerase chain reaction (PCR) assay for Human papilloma virus (HPV) genotyping.	All others	Class C, Rule 3(a)	N/A	W0105041002	20/12/2022	26/05/2026
72.	GeneFinder™ HLA-B*57:01 Real*Amp* Kit List of components: 1. B5701 Rxn 2. B5701 DNA pol. 3. B5701 PC	Legacy	This product is a qualitative in vitro diagnostic kit by using real-time PCR technology to detect HLA-B*57:01 genotype	Annex II, List B	Class C, Rule 3(i)	N/A	W0106010499	20/12/2022	31/12/2027*
73.	GluNEO Lite S Blood Glucose Monitoring system	IVDR compliant	Blood Glucose Monitoring System for self-testing	N/A	Class C, Rule 4(a)	880911590OGSH01GL4A	W0201060102	20/06/2024	27/03/2029
74.	GluNEO Lite S Test Strips	IVDR compliant	Biosensor for determining concentration of glucose in the blood	N/A	Class C, Rule 4(a)	880911590OGSH01GL4A	W0101060101	20/06/2024	27/03/2029
75.	GluNEO Lite S Control Solution	IVDR compliant	Control solution is required to ensure glucose in the blood	N/A	Class C, Rule 4(a)	880911590OGSH01GL4A	W010106010801	20/06/2024	27/03/2029
76.	GluNEO Plus S Blood Glucose Monitoring system	IVDR compliant	Blood Glucose Monitoring System for self-testing	N/A	Class C, Rule 4(a)	880911590OGSH01GP4J	W0201060102	20/06/2024	27/03/2029

77.	GluNEO Plus S Test Strips	IVDR compliant	Biosensor for determining concentration of glucose in the blood	N/A	Class C, Rule 4(a)	880911590OGSH01GP4J	W0101060101	20/06/2024	27/03/2029
78.	GluNEO Plus S Control Solution	IVDR compliant	Control solution is required to ensure glucose in the blood	N/A	Class C, Rule 4(a)	880911590OGSH01GP4J	W0101060108 01	20/06/2024	27/03/2029
79.	Hemocue HbA1c 501 Analyzer List of components: 1. Analyzer 2. Daily Check cartridge 3. Monthly Check cartridge 4. Fan Filter 5. Adapter & AC/DC cable	IVDR compliant	HbA1c measuring system	All others	Class A, Rule 5(b)	880911590IGM0026BMUN	W0201060101	29/08/2024	N/A
80.	Hemocue HbA1c 501 Daily Check Cartridge	IVDR compliant	HbA1c Check Cartridge	All others	Class A, Rule 5(b)	880911590IGM0026BMDAZ	W0201060190 85	29/08/2024	N/A
81.	Hemocue HbA1c 501 Monthly Check Cartridge	IVDR compliant	HbA1c Check Cartridge	All others	Class A, Rule 5(b)	880911590IGM0026BMMBK	W0201060190 85	29/08/2024	N/A
82.	Clover A1c Expert Analyzer	IVDR compliant	HbA1c measuring system	N/A	Class A, Rule 5(b)	880911590IHM0005MM5	W0201060101	31/10/2024	N/A

83.	Healthpro S Blood glucose monitoring system	IVDR compliant	Blood Glucose Monitoring System for self-testing	N/A	Class C, Rule 4(a)	880911590OGSX01HE9F	W0201060102; W0101060101; W0101060108 01	22/11/2024	27/03/2029
84.	Healthpro S Test Strips	IVDR compliant	Biosensor for determining concentration of glucose in the blood	N/A	Class C, Rule 4(a)	880911590OGSX01HE9F	W0101060101	22/11/2024	27/03/2029
85.	Healthpro S Control Solution	IVDR compliant	Control solution is required to ensure glucose in the blood	N/A	Class C, Rule 4(a)	880911590OGSX01HE9F	W0101060108 01	22/11/2024	27/03/2029
86.	GLUCOLAB Auto-coding S Blood glucose monitoring system	IVDR compliant	Blood Glucose Monitoring System for self-testing	N/A	Class C, Rule 4(a)	880911590OGSX01LB9M	W0201060102; W0101060101; W0101060108 01	22/11/2024	27/03/2029
87.	GLUCOLAB Auto-coding S Test Strips	IVDR compliant	Biosensor for determining concentration of glucose in the blood	N/A	Class C, Rule 4(a)	880911590OGSX01LB9M	W0101060101	22/11/2024	27/03/2029
88.	GLUCOLAB Auto-coding S Control Solution	IVDR compliant	Control solution is required to ensure glucose in the blood	N/A	Class C, Rule 4(a)	880911590OGSX01LB9M	W0101060108 01	22/11/2024	27/03/2029

89.	GeneFinder™ HLA-B*27 Real*Amp* Kit	IVDR compliant	This product is a qualitative in vitro diagnostic kit by using real-time PCR technology to detect HLA-B*27 genotype.	Annex II, List B	Class C, Rule 3(i)	880911590IF MR08GB	W01 06010499	20/12/2022 (Legacy) 22/11/2024 (IVDR)	27/03/2029 **
90.	CLOVER A1c Expert Test Cartridge	IVDR compliant	Near-patient testing (NPT) in-vitro diagnostics (IVD) automated test assay intended for quantitative determination of glycated hemoglobin in human capillary whole blood and anticoagulated venous whole blood samples to monitor long term glycemic control in adults previously diagnosed with diabetes mellitus.	N/A	Class C, Rule 3(k), 4(b)	880911590I HM0005CLH	W01010214	20/12/2022 (Legacy) 07/03/2025 (IVDR)	27/03/2029 **

91.	CLOVER A1c Analyzer List of components: 1. Analyzer 2. Daily Check cartridge 3. Monthly Check cartridge 4. Fan Filter 5. Adapter & AC/DC cable	IVDR compliant	The CLOVER A1c Analyzer is a near-patient testing (NPT) in vitro diagnostic (IVD) automated medical device intended for quantitative measurement of hemoglobin A1c (HbA1c). This device is intended for healthcare professionals at hospitals, clinics, and clinical/medical laboratories and must only be used with CLOVER A1c Test Cartridge.	All others	Class A, Rule5(b)	880911590IGM0023MLQ	W0201060101	04/06/2025	N/A
92.	CLOVER A1c Daily Check Cartridge	IVDR compliant	The CLOVER A1c Daily Check Cartridge is intended to evaluate the optical performance of the analyzer. This cartridge does not contain any reagents and does not require any additional sample collection. The CLOVER A1c Daily Check Cartridge must only be used with the CLOVER A1c Analyzer.	All others	Class A, Rule 5(b)	880911590IGM0023MDUN	W020106019085	04/06/2025	N/A

93.	CLOVER A1c Monthly Check Cartridge	IVDR compliant	The CLOVER A1c Monthly Check Cartridge is intended to evaluate the optical performance of the analyzer and calibrate the analyzer to maintain the specified performance. This cartridge does not require any additional sample collection. The CLOVER A1c Monthly Check Cartridge must only be used with the CLOVER A1c Analyzer.	All others	Class A, Rule 5(b)	880911590IGM0023MMV8	W020106019085	04/06/2025	N/A

***The manufacturer declares that they comply with all the requirements as per Regulation (EU) 2024/1860.**

**** The device is placed on the EU market both as IVDR compliant device per IVDR EC Certification, and as a Legacy Device as per IVDR Art. 110 as amended by the Regulation (EU) 2024/1860. The validity date of the device with the legacy status is the one set in the Regulation (EU) 2023/607 depending on the device risk class.**

Disclaimers:

1. For any device that received a CE Certificate under the REGULATION (EU) 2017/746, there will be just one entry in the Mandate still covering any remaining legacy and/or extended variant present on the EU Market.

2. At the moment of EC Certificate expiration/withdrawal/suspension date, the Mandate is automatically suspended and terminated for the specific device.

For: **The Manufacturer**
PERSON Responsible for Regulatory Compliance (PRRC)

Name: … YoungGyun Kim.....

Position: .....PRRC.....

Date: …….22/10/2025….....

Signature: YoungGyun Kim
YoungGyun Kim (Nov 7, 2025 13:47:11 GMT+9)
……..

For: **Obelis PRRC**
PERSON Responsible for Regulatory Compliance (PRRC)

Name: …Doram Elkayam…….....

Position: ……COO……..…..

Date: ……22/10/2025….....

Signature: ……..

Company stamp:

Disclaimer: At the moment of EC Certificate expiration/withdrawal/suspension date, the Mandate is automatically suspended and terminated for the specific device.

History Log		
Date	Version Number of the Mandate	Action
20/12/2022	1	First Issue
02/05/2023	2	Addition of devices to Annex M
20/06/2024	3	Addition of devices to Annex M
29/08/2024	4	Addition of devices to Annex M
31/10/2024	5	Addition of devices to Annex M
22/11/2024	6	Addition of devices to Annex M
04/12/2024	7	Manufacturer's PRRC change
07/03/2025	8	Addition of device.
08/05/2025	9	Updated validity dates in accordance with Regulation (EU) 2024/1860.
04/06/2025	10	Addition of three IVDR Class A devices, Change of some EMDN Codes
03/09/2025	11	Addition of IVDR devices
22/10/2025	12	Removal of some devices which grace period ended on 26/05/2025. Current Issue