

# AUTHORISED REPRESENTATIVE MANDATE

According to the Regulation (EU) 2017/745

## I. Address /Contact

### RBC BIOSCIENCE CORP.

**Registered Address:**

15F., No. 15,  
Qiaohu Rd., Zhonghe Dist.,  
New Taipei City, 235029,  
Taiwan.

Tel: +886.2891.21200  
E-mail: [vicky.lin@rbcbioscience.com](mailto:vicky.lin@rbcbioscience.com)  
Web: [www.rbcbioscience.com](http://www.rbcbioscience.com)  
Company registration: #28089461

Hereinafter "The Manufacturer"

This Authorised Representative Mandate (hereinafter the "Mandate") between the Manufacturer and Obelis first issued on 1st June 2022, will be in force in accordance with the terms and conditions specified in the Authorised Representative Services Agreement ("hereinafter the "Agreement"), concluded between the parties.

### 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](mailto:mail@obelis.net)  
Web: [www.obelis.net](http://www.obelis.net)

Hereinafter "Obelis"

## 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 for, at least, all medical devices of the same generic device group listed 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 medical devices listed according to the date stated for each specific device in the approved Annex M, as defined in the Regulation, the current Mandate and in accordance with the terms of the Agreement.

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 MDR Agreement.

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 of the 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 56 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. In the case of implantable devices, the period shall be at least 15 years after the last device has been placed on the market.
  - 4.3. Comply with the registration obligations laid down in Article 31 of the regulation and verify that the Manufacturer has complied with the registration obligations laid down in Articles 27 and 29 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 .
5. The Manufacturer has granted Obelis access to the vigilance module of EUDAMED to enable it to access to vigilance reports of the Manufacturer.

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 MDR Agreement.

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.

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

Name: Lee YiLing

Position: Senior Specialist

Date: 06/03/2026

Signature: Lee YiLing  
 Lee YiLing (Mar 18, 2026 09:19:58 GMT+8)

Company stamp:



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

Name: Doram Elkayam

Position: C.O.O.

Date: 06/03/2026

Signature: [Handwritten Signature]

**Mandate History**

Mandate issued	Revision Number	Action	Expiration Date
01/06/2022	1	First Issue	N/A
24/01/2024	2	Second Issue	N/A
22/04/2024	3	Third Issue	N/A
02/03/2026	4	Fourth Issue	02/09/2028

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 MDR Agreement.

## ANNEX M – Annex to IVDR Authorised Representative Mandate

**Manufacturer: RBC Bioscience Corp.**

**Country: Taiwan**

#	Name of device	Legacy (Y/N)	Intended use	Class under IVDD	Risk Class and Classification Rule IVDR	EMDN Code	GMDN Code	Basic UDI-DI	Validity start date	End date
1	MagCore® HF16 Automated Nucleic Acid Extractor	N	The MagCore® Nucleic Acid Extraction System is an automated nucleic acid purification system consisting of the MagCore® instrument, software, Kit (consumables and reagents). The MagCore® Nucleic Acid Extraction System is intended for use by professional users for the purification of nucleic acids from biological samples for in vitro diagnostic purposes. The MagCore® Nucleic Acid Extraction Kit is for use with the MagCore® Nucleic Acid Extraction System	All Others	A, 5(b)	W02050106	60736	471989067M0000A9	01/06/2022	N/A
2	MagCore® Compact Automated Nucleic Acid Extractor	N	MagCore® Compact Automated Nucleic Acid Extractor purification system consisting of the MagCore® instrument, software, Kit (consumables and reagents). The MagCore® Nucleic Acid Extraction System is intended for use by professional users for the purification of nucleic acids from biological samples for in vitro diagnostic purposes. The MagCore® Nucleic Acid	All Others	A, 5(b)	W02050106	60736	471989067M0000A9	01/06/2022	N/A

			Extraction Kit is for use with the MagCore® Nucleic Acid Extraction System							
3	MagCore® Super Automated Nucleic Acid Extractor	N	The MagCore® Nucleic Acid Extraction System is an automated nucleic acid purification system consisting of the MagCore® instrument, software, Kit (consumables and reagents). The MagCore® Nucleic Acid Extraction System is intended for use by professional users for the purification of nucleic acids from biological samples for in vitro diagnostic purposes. The MagCore® Nucleic Acid Extraction Kit is for use with the MagCore® Nucleic Acid Extraction System.	All Others	A, 5(b)	W02050106	60736	471989067M0000A9	01/06/2022	N/A
4	MagCore® HF16 Plus Automated Nucleic Acid Extractor	N	The MagCore® Nucleic Acid Extraction System is an automated nucleic acid purification system consisting of the MagCore® instrument, software, Kit (consumables and reagents). The MagCore® Nucleic Acid Extraction System is intended for use by professional users for the purification of nucleic acids from biological samples for in vitro diagnostic purposes. The MagCore® Nucleic Acid Extraction Kit is for use with the MagCore® Nucleic Acid Extraction System.	All Others	A, 5(b)	W02050106	60736	471989067M0000A9	01/06/2022	N/A
5	MagCore® HF48 Automated Nucleic Acid Extractor	N	The MagCore® Nucleic Acid Extraction System is an automated nucleic acid purification system consisting of the MagCore® instrument, software, Kit	All Others	A, 5(b)	W02050106	60736	471989067M0000A9	01/06/2022	N/A

			(consumables and reagents). The MagCore® Nucleic Acid Extraction System is intended for use by professional users for the purification of nucleic acids from biological samples for in vitro diagnostic purposes. The MagCore® Nucleic Acid Extraction Kit is for use with the MagCore® Nucleic Acid Extraction System.							
6	MagCore® Plus II Automated Nucleic Acid Extractor	N	The MagCore® Nucleic Acid Extraction System is an automated nucleic acid purification system consisting of the MagCore® instrument, software, Kit (consumables and reagents). The MagCore® Nucleic Acid Extraction System is intended for use by professional users for the purification of nucleic acids from biological samples for in vitro diagnostic purposes. The MagCore® Nucleic Acid Extraction Kit is for use with the MagCore® Nucleic Acid Extraction System	All Others	A, 5(b)	W02050106	60736	471989067M0000A9	01/06/2022	N/A
7	MagCore® EDA Automated Nucleic Acid Extractor and Assay Setup	N	The MagCore® Nucleic Acid Extraction System and Assay Setup is an automated nucleic acid purification system consisting of the MagCore® instrument, software, Kit (consumables and reagents). The MagCore® Nucleic Acid Extraction System and Assay Setup is intended for use by professional users for the purification of nucleic acids from biological samples for in vitro diagnostic purposes. The	All Others	A, 5(b)	W02050106	60736	471989067M0000A9	01/06/2022	N/A

			MagCore® Nucleic Acid Extraction Kit is for use with the MagCore® Nucleic Acid Extraction System.							
8	MagCore® Genomic DNA Whole Blood Kit (Speedy installation) Cartridge code 101	N	The MagCore® Nucleic Acid Extraction System is an automated nucleic acid purification system consisting of the MagCore® instrument, software, Kit (consumables and reagents). The MagCore® Nucleic Acid Extraction System is intended for use by professional users for the purification of nucleic acids from biological samples for in vitro diagnostic purposes. The MagCore® Nucleic Acid Extraction Kit is for use with the MagCore® Nucleic Acid Extraction System.	All Others	A, 5(a)	W0105900101	52521	471989067M0000A9	01/06/2022	N/A
9	MagCore® Genomic DNA Whole Blood Kit Cartridge code 102	N	The MagCore® Nucleic Acid Extraction System is an automated nucleic acid purification system consisting of the MagCore® instrument, software, Kit (consumables and reagents). The MagCore® Nucleic Acid Extraction System is intended for use by professional users for the purification of nucleic acids from biological samples for in vitro diagnostic purposes. The MagCore® Nucleic Acid Extraction Kit is for use with the MagCore® Nucleic Acid Extraction System.	All Others	A, 5(a)	W0105900101	52521	471989067M0000A9	01/06/2022	N/A
10	MagCore® Genomic DNA Large Volume Whole Blood Kit Cartridge Code 104	N	The MagCore® Nucleic Acid Extraction System is an automated nucleic acid purification system consisting of the MagCore®	All Others	A, 5(a)	W0105900101	52521	471989067M0000A9	01/06/2022	N/A

			instrument, software, Kit (consumables and reagents). The MagCore® Nucleic Acid Extraction System is intended for use by professional users for the purification of nucleic acids from biological samples for in vitro diagnostic purposes. The MagCore® Nucleic Acid Extraction Kit is for use with the MagCore® Nucleic Acid Extraction System.							
11	MagCore® Plasma DNA Extraction Kit Cartridge Code 105	N	The MagCore® Nucleic Acid Extraction System is an automated nucleic acid purification system consisting of the MagCore® instrument, software, Kit (consumables and reagents). The MagCore® Nucleic Acid Extraction System is intended for use by professional users for the purification of nucleic acids from biological samples for in vitro diagnostic purposes. The MagCore® Nucleic Acid Extraction Kit is for use with the MagCore® Nucleic Acid Extraction System.	All Others	A, 5(a)	W0105900101	52521	471989067M0000A9	01/06/2022	N/A
12	MagCore® Genomic DNA Whole Blood Kit (For Genotyping) Cartridge Code 106	N	The MagCore® Nucleic Acid Extraction System is an automated nucleic acid purification system consisting of the MagCore® instrument, software, Kit (consumables and reagents). The MagCore® Nucleic Acid Extraction System is intended for use by professional users for the purification of nucleic acids from biological samples for in vitro diagnostic purposes. The	All Others	A, 5(a)	W0105900101	52521	471989067M0000A9	01/06/2022	N/A

			MagCore® Nucleic Acid Extraction Kit is for use with the MagCore® Nucleic Acid Extraction System							
13	MagCore® Cultured Cells DNA Kit Cartridge Code 110	N	The MagCore® Nucleic Acid Extraction System is an automated nucleic acid purification system consisting of the MagCore® instrument, software, Kit (consumables and reagents). The MagCore® Nucleic Acid Extraction System is intended for use by professional users for the purification of nucleic acids from biological samples for in vitro diagnostic purposes. The MagCore® Nucleic Acid Extraction Kit is for use with the MagCore® Nucleic Acid Extraction System.	All Others	A, 5(a)	W0105900101	52521	471989067M0000A9	01/06/2022	N/A
14	MagCore® Genomic DNA large volume whole blood kit (3ml) Cartridge Code: 114	N	The MagCore® Nucleic Acid Extraction System is an automated nucleic acid purification system consisting of the MagCore® instrument, software, Kit (consumables and reagents). The MagCore® Nucleic Acid Extraction System is intended for use by professional users for the purification of nucleic acids from biological samples for in vitro diagnostic purposes. The MagCore® Nucleic Acid Extraction Kit is for use with the MagCore® Nucleic Acid Extraction System.	All Others	A, 5(a)	W0105900101	52521	471989067M0000A9	01/06/2022	N/A
15	MagCore® Circulating DNA large volume kit (3-4 ml) Cartridge Code: 115	N	The MagCore® Nucleic Acid Extraction System is an automated nucleic acid purification system consisting of the MagCore®	All Others	A, 5(a)	W0105900101	52521	471989067M0000A9	01/06/2022	N/A

			instrument, software, Kit (consumables and reagents). The MagCore® Nucleic Acid Extraction System is intended for use by professional users for the purification of nucleic acids from biological samples for in vitro diagnostic purposes. The MagCore® Nucleic Acid Extraction Kit is for use with the MagCore® Nucleic Acid Extraction System							
16	MagCore® Viral Nucleic Acid Extraction Kit Cartridge Code 201	N	The MagCore® Nucleic Acid Extraction System is an automated nucleic acid purification system consisting of the MagCore® instrument, software, Kit (consumables and reagents). The MagCore® Nucleic Acid Extraction System is intended for use by professional users for the purification of nucleic acids from biological samples for in vitro diagnostic purposes. The MagCore® Nucleic Acid Extraction Kit is for use with the MagCore® Nucleic Acid Extraction System	All Others	A, 5(a)	W0105900101	52521	471989067M0000A9	01/06/2022	N/A
17	MagCore® Viral Nucleic Acid Extraction Kit (Low PCR Inhibition) Cartridge Code 202	N	The MagCore® Nucleic Acid Extraction System is an automated nucleic acid purification system consisting of the MagCore® instrument, software, Kit (consumables and reagents). The MagCore® Nucleic Acid Extraction System is intended for use by professional users for the purification of nucleic acids from biological samples for in vitro	All Others	A, 5(a)	W0105900101	52521	471989067M0000A9	01/06/2022	N/A

			diagnostic purposes. The MagCore® Nucleic Acid Extraction Kit is for use with the MagCore® Nucleic Acid Extraction System.							
18	MagCore® Viral nucleic acid extraction kit (high sensitivity ) Cartridge Code: 203	N	The MagCore® Nucleic Acid Extraction System is an automated nucleic acid purification system consisting of the MagCore® instrument, software, Kit (consumables and reagents). The MagCore® Nucleic Acid Extraction System is intended for use by professional users for the purification of nucleic acids from biological samples for in vitro diagnostic purposes. The MagCore® Nucleic Acid Extraction Kit is for use with the MagCore® Nucleic Acid Extraction System.	All Others	A, 5(a)	W0105900101	52521	471989067M0000A9	01/06/2022	N/A
19	MagCore® Viral Nucleic Acid Large Volume Extraction Kit (2.4 mL) Cartridge Code 210	N	The MagCore® Nucleic Acid Extraction System is an automated nucleic acid purification system consisting of the MagCore® instrument, software, Kit (consumables and reagents). The MagCore® Nucleic Acid Extraction System is intended for use by professional users for the purification of nucleic acids from biological samples for in vitro diagnostic purposes. The MagCore® Nucleic Acid Extraction Kit is for use with the MagCore® Nucleic Acid Extraction System	All Others	A, 5(a)	W0105900101	52521	471989067M0000A9	01/06/2022	N/A
20	MagCore® Viral Nucleic Acid Large Volume Extraction Kit (1.2 mL) Cartridge Code 211	N	The MagCore® Nucleic Acid Extraction System is an automated nucleic acid purification system consisting of the MagCore®	All Others	A, 5(a)	W0105900101	52521	471989067M0000A9	01/06/2022	N/A

			instrument, software, Kit (consumables and reagents). The MagCore® Nucleic Acid Extraction System is intended for use by professional users for the purification of nucleic acids from biological samples for in vitro diagnostic purposes. The MagCore® Nucleic Acid Extraction Kit is for use with the MagCore® Nucleic Acid Extraction System.							
21	MagCore® Viral Nucleic Acid Large Volume Extraction Kit (2.4 mL) High Sensitivity Cartridge Code 220	N	The MagCore® Nucleic Acid Extraction System is an automated nucleic acid purification system consisting of the MagCore® instrument, software, Kit (consumables and reagents). The MagCore® Nucleic Acid Extraction System is intended for use by professional users for the purification of nucleic acids from biological samples for in vitro diagnostic purposes. The MagCore® Nucleic Acid Extraction Kit is for use with the MagCore® Nucleic Acid Extraction System.	All Others	A, 5(a)	W0105900101	52521	471989067M0000A9	01/06/2022	N/A
22	MagCore® Genomic DNA Plant Kit Cartridge Code 301	N	The MagCore® Nucleic Acid Extraction System is an automated nucleic acid purification system consisting of the MagCore® instrument, software, Kit (consumables and reagents). The MagCore® Nucleic Acid Extraction System is intended for use by professional users for the purification of nucleic acids from biological samples for in vitro	All Others	A, 5(a)	W0105900101	52521	471989067M0000A9	01/06/2022	N/A

			diagnostic purposes. The MagCore® Nucleic Acid Extraction Kit is for use with the MagCore® Nucleic Acid Extraction System.							
23	MagCore® Genomic DNA Tissue Kit Cartridge Code 401	N	The MagCore® Nucleic Acid Extraction System is an automated nucleic acid purification system consisting of the MagCore® instrument, software, Kit (consumables and reagents). The MagCore® Nucleic Acid Extraction System is intended for use by professional users for the purification of nucleic acids from biological samples for in vitro diagnostic purposes. The MagCore® Nucleic Acid Extraction Kit is for use with the MagCore® Nucleic Acid Extraction System.	All Others	A, 5(a)	W0105900101	52521	471989067M0000A9	01/06/2022	N/A
24	MagCore® Genomic DNA FFPE One-Step Kit Cartridge Code 405	N	The MagCore® Nucleic Acid Extraction System is an automated nucleic acid purification system consisting of the MagCore® instrument, software, Kit (consumables and reagents). The MagCore® Nucleic Acid Extraction System is intended for use by professional users for the purification of nucleic acids from biological samples for in vitro diagnostic purposes. The MagCore® Nucleic Acid Extraction Kit is for use with the MagCore® Nucleic Acid Extraction System.	All Others	A, 5(a)	W0105900101	52521	471989067M0000A9	01/06/2022	N/A
25	MagCore® Forensic DNA Direct Kit Cartridge Code 406	N	The MagCore® Nucleic Acid Extraction System is an automated nucleic acid purification system consisting of the MagCore®	All Others	A, 5(a)	W0105900101	52521	471989067M0000A9	01/06/2022	N/A

			instrument, software, Kit (consumables and reagents). The MagCore® Nucleic Acid Extraction System is intended for use by professional users for the purification of nucleic acids from biological samples for in vitro diagnostic purposes. The MagCore® Nucleic Acid Extraction Kit is for use with the MagCore® Nucleic Acid Extraction System.							
26	MagCore® Genomic DNA Bacterial Kit Cartridge Code 502	N	The MagCore® Nucleic Acid Extraction System is an automated nucleic acid purification system consisting of the MagCore® instrument, software, Kit (consumables and reagents). The MagCore® Nucleic Acid Extraction System is intended for use by professional users for the purification of nucleic acids from biological samples for in vitro diagnostic purposes. The MagCore® Nucleic Acid Extraction Kit is for use with the MagCore® Nucleic Acid Extraction System	All Others	A, 5(a)	W0105900101	52521	471989067M0000A9	01/06/2022	N/A
27	MagCore® Gut Microbiome DNA kit Cartridge Code: 504	N	The MagCore® Nucleic Acid Extraction System is an automated nucleic acid purification system consisting of the MagCore® instrument, software, Kit (consumables and reagents). The MagCore® Nucleic Acid Extraction System is intended for use by professional users for the purification of nucleic acids from biological samples for in vitro	All Others	A, 5(a)	W0105900101	52521	471989067M0000A9	01/06/2022	N/A

			diagnostic purposes. The MagCore® Nucleic Acid Extraction Kit is for use with the MagCore® Nucleic Acid Extraction System							
28	MagCore® Total RNA Whole Blood Kit Cartridge Code 601	N	The MagCore® Nucleic Acid Extraction System is an automated nucleic acid purification system consisting of the MagCore® instrument, software, Kit (consumables and reagents). The MagCore® Nucleic Acid Extraction System is intended for use by professional users for the purification of nucleic acids from biological samples for in vitro diagnostic purposes. The MagCore® Nucleic Acid Extraction Kit is for use with the MagCore® Nucleic Acid Extraction System.	All Others	A, 5(a)	W0105900101	52521	471989067M0000A9	01/06/2022	N/A
29	MagCore® Total RNA FFPE one-step kit Cartridge Code: 605	N	The MagCore® Nucleic Acid Extraction System is an automated nucleic acid purification system consisting of the MagCore® instrument, software, Kit (consumables and reagents). The MagCore® Nucleic Acid Extraction System is intended for use by professional users for the purification of nucleic acids from biological samples for in vitro diagnostic purposes. The MagCore® Nucleic Acid Extraction Kit is for use with the MagCore® Nucleic Acid Extraction System.	All Others	A, 5(a)	W0105900101	52521	471989067M0000A9	01/06/2022	N/A
30	MagCore® Total RNA Cultured Cells Kit Cartridge Code 610	N	The MagCore® Nucleic Acid Extraction System is an automated nucleic acid purification system consisting of the MagCore®	All Others	A, 5(a)	W0105900101	52521	471989067M0000A9	01/06/2022	N/A

			instrument, software, Kit (consumables and reagents). The MagCore® Nucleic Acid Extraction System is intended for use by professional users for the purification of nucleic acids from biological samples for in vitro diagnostic purposes. The MagCore® Nucleic Acid Extraction Kit is for use with the MagCore® Nucleic Acid Extraction System							
31	Magcore Plasma microRNA Extraction Kit Cartridge Code 620	N	The MagCore® Nucleic Acid Extraction System is an automated nucleic acid purification system consisting of the MagCore® instrument, software, Kit (consumables and reagents). The MagCore® Nucleic Acid Extraction System is intended for use by professional users for the purification of nucleic acids from biological samples for in vitro diagnostic purposes. The MagCore® Nucleic Acid Extraction Kit is for use with the MagCore® Nucleic Acid Extraction System.	All Others	A, 5(a)	W0105900101	52521	471989067M0000A9	01/06/2022	N/A
32	MagCore®triXact RNA Kit Cartridge Code: 631	N	The MagCore® Nucleic Acid Extraction System is an automated nucleic acid purification system consisting of the MagCore® instrument, software, Kit (consumables and reagents). The MagCore® Nucleic Acid Extraction System is intended for use by professional users for the purification of nucleic acids from biological samples for in vitro	All Others	A, 5(a)	W0105900101	52521	471989067M0000A9	01/06/2022	N/A

			diagnostic purposes. The MagCore® Nucleic Acid Extraction Kit is for use with the MagCore® Nucleic Acid Extraction System.							
33	MagCore® NGS Auto Size-Select purification Kit Cartridge Code: 701	N	The MagCore® Nucleic Acid Extraction System is an automated nucleic acid purification system consisting of the MagCore® instrument, software, Kit (consumables and reagents). The MagCore® Nucleic Acid Extraction System is intended for use by professional users for the purification of nucleic acids from biological samples for in vitro diagnostic purposes. The MagCore® Nucleic Acid Extraction Kit is for use with the MagCore® Nucleic Acid Extraction System.	All Others	A, 5(a)	W0105900101	52521	471989067M0000A9	01/06/2022	N/A
34	MagCore mRNA One-Step Kit Cartridge Code: 639	N	The MagCore® Nucleic Acid Extraction System is an automated nucleic acid purification system consisting of the MagCore® instrument, software, Kit (consumables and reagents). The MagCore® Nucleic Acid Extraction System is intended for use by professional users for the purification of nucleic acids from biological samples for in vitro diagnostic purposes. The MagCore® Nucleic Acid Extraction Kit is for use with the MagCore® Nucleic Acid Extraction System.	N/A	A, 5(a)	W0105900101	52521	471989067M0000A9	22/04/2024	n/a
35	MagCore® Giga Automated Nucleic Acid Extractor	N	Automatic Nucleic Acid Purification Instrument/purification of nucleic acids from biological samples for in vitro diagnostic	General	A,5(b)	W02050106	60736	471989067M0000A9	02/03/2026	n/a

			purposes by using MagCore reagent kit							
36	MagCore® Giga Genomic DNA Kit Cartridge Code: 812	N	Nucleic Acid Purification reagent/extraction of genomic DNA from human whole blood sample	General	A,5(a)	W0105900101	52521	471989067M0000A9	02/03/2026	n/a
37	MagCore® Giga Cell Free DNA Kit Cartridge Code: 815	N	Nucleic Acid Purification reagent/extraction of free circulating DNA from human plasma or serum	General	A,5(a)	W0105900101	52521	471989067M0000A9	02/03/2026	n/a
38	MagCore® Giga Total RNA Kit Cartridge Code: 861	N	Nucleic Acid Purification reagent/extraction of total RNA from human whole blood	General	A,5(a)	W0105900101	52521	471989067M0000A9	02/03/2026	n/a
39	MagCore® Giga Viral Nucleic Acid Kit Cartridge Code: 821	N	Nucleic Acid Purification reagent/extraction of viral DNA/RNA from serum, plasma, saliva and cell-free body fluids	General	A,5(a)	W0105900101	52521	471989067M0000A9	02/03/2026	n/a
40	MagCore® Genomic DNA Microbial Library-Ready Kit Cartridge Code: 506	N	Nucleic Acid Purification reagent/extraction of genomic DNA extraction from microbial samples	General	A,5(a)	W0105900101	52521	471989067M0000A9	02/03/2026	n/a

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

Name: Lee YiLing

Position: Senior Specialist

Date:06/03/2026

Signature: Lee YiLing  
Lee YiLing (Mar 18, 2026 09:19:58 GMT+8)

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

Name: Doram Elkayam

Position: COO

Date:06/03/2026

Signature: Doram Elkayam

Company stamp:



\*This document and its content is copyright of OBELIS S.A.- © OBELIS S.A. 2023. All rights reserved.

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

History Log			
Date	Version Number of the Mandate	Action	Expiration Date
01/06/2022	1	First issue	n/a
24/01/2024	2	Addition of UDI-PI on labels and change of device name	n/a
22/04/2024	3	Device #34 added to the Mandate	n/a
02/03/2026	4	Devices #35 to #40 added to the Mandate	02/09/2028