



# CERTIFICATE OF IVDR NOTIFICATION

Reference No.: RDP 0151-2026

Date: 18/03/2026

Order No.: EU AL 0044-2026

EXPIRATION Date: 18/09/2028

This is to certify that, according to the Regulation (EU) 2017/746, we, here at Obelis s.a. performed all notification duties and responsibilities as the European Authorized Representative (EC REP) of:

Name:

Address:

AS STIPULATED AND DEMANDED BY THE AFOREMENTIONED REGULATION.

The manufacturer declares that the Class (A/B/C/D) device(s) comply(ies) with the Regulation including all general safety and performance requirements.

The Manufacturer has provided Obelis s.a. (EC REP) with all the appropriate declarations as per the Regulation (EU) 2017/746 article 48 requirements, including the EC Declaration of Conformity (according to annex IV) confirming that their Class (A/B/C/D) in vitro diagnostic medical device(s), as stipulated here below, is/are fulfilling the applicable requirements of the Regulation (EU) 2017/746.

The notification of the following in vitro diagnostic medical device(s) has been completed by Obelis s.a. (EC REP) in compliance with the Regulation (EU) 2017/746 on the 16/03/2026

CLASS OF IVD DEVICE(S): Please See Annex A - List of Devices (11 Page, Devices from #35 to #40)

As of the 17/03/2026, and provided that the Manufacturer will continue complying with the hereabove mentioned requirements\*, he therefore:

- Is required to affix the CE marking on this(ese) device(s);
- May place this(ese) device(s) in the European Union and EEA territory.



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Mr. G. Elkayam CEO  
Obelis sa



Obelis European Authorized Representative Center is a member of the European Association of Authorized Representatives (E.A.A.R.).  
Obelis s.a. is ISO 9001 : 2015 and ISO 13485 : 2016 certified.

## ANNEX to IVDR Certificates

**Manufacturer: RBC Bioscience Corp.**

**Country: Taiwan**

#	Name of device	Intended use	Class and Rule under IVDR	EMDN Code	GMDN Code	Basic UDI-DI	Mandated (Y/N)	Mandate starting date	Mandated Vigilance (Y/N)
1	MagCore® HF16 Automated Nucleic Acid Extractor	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	A, 5(b)	W02050106	60736	471989067M0000A9	Y	01/06/2022	Y
2	MagCore® Compact Automated Nucleic Acid Extractor	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 Extraction Kit is for use with the MagCore® Nucleic Acid Extraction System	A, 5(b)	W02050106	60736	471989067M0000A9	Y	01/06/2022	Y
3	MagCore® Super Automated Nucleic Acid Extractor	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	A, 5(b)	W02050106	60736	471989067M0000A9	Y	01/06/2022	Y

		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.							
4	MagCore® HF16 Plus Automated Nucleic Acid Extractor	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.	A, 5(b)	W02050106	60736	471989067M0000A9	Y	01/06/2022	Y
5	MagCore® HF48 Automated Nucleic Acid Extractor	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.	A, 5(b)	W02050106	60736	471989067M0000A9	Y	01/06/2022	Y
6	MagCore® Plus II Automated Nucleic Acid Extractor	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.	A, 5(b)	W02050106	60736	471989067M0000A9	Y	01/06/2022	Y
7	MagCore® EDA Automated Nucleic Acid Extractor and Assay Setup	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	A, 5(b)	W02050106	60736	471989067M0000A9	Y	01/06/2022	Y

		reagents). The MagCore® Nucleic Acid Extraction System and Essay Setupis 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.							
8	MagCore® Genomic DNA Whole Blood Kit (Speedy installation) Cartridge code 101	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.	A, 5(a)	W0105900 101	52521	471989067M00 00A9	Y	01/06/2022	Y
9	MagCore® Genomic DNA Whole Blood Kit Cartridge code 102	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	A, 5(a)	W0105900 101	52521	471989067M00 00A9	Y	01/06/2022	Y
10	MagCore® Genomic DNA Large Volume Whole Blood Kit Cartridge Code 104	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.	A, 5(a)	W0105900 101	52521	471989067M00 00A9	Y	01/06/2022	Y

11	MagCore® Plasma DNA Extraction Kit Cartridge Code 105	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.	A, 5(a)	W0105900101	52521	471989067M0000A9	Y	01/06/2022	Y
12	MagCore® Genomic DNA Whole Blood Kit (For Genotyping ) Cartridge Code 106	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	A, 5(a)	W0105900101	52521	471989067M0000A9	Y	01/06/2022	Y
13	MagCore® Cultured Cells DNA Kit Cartridge Code 110	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.	A, 5(a)	W0105900101	52521	471989067M0000A9	Y	01/06/2022	Y
14	MagCore® Genomic DNA large volume whole blood kit (3ml) Cartridge Code: 114	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	A, 5(a)	W0105900101	52521	471989067M0000A9	Y	01/06/2022	Y

		MagCore® Nucleic Acid Extraction Kit is for use with the MagCore® Nucleic Acid Extraction System							
15	MagCore® Circulating DNA large volume kit (3-4 ml) Cartridge Code: 115	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	A, 5(a)	W0105900 101	52521	471989067M00 00A9	Y	01/06/2022	Y
16	MagCore® Viral Nucleic Acid Extraction Kit Cartridge Code 201	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	A, 5(a)	W0105900 101	52521	471989067M00 00A9	Y	01/06/2022	Y
17	MagCore® Viral Nucleic Acid Extraction Kit (Low PCR Inhibition) Cartridge Code 202	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.	A, 5(a)	W0105900 101	52521	471989067M00 00A9	Y	01/06/2022	Y
18	MagCore® Viral nucleic acid extraction kit (high sensitivity) Cartridge Code: 203	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	A, 5(a)	W0105900 101	52521	471989067M00 00A9	Y	01/06/2022	Y

		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.							
19	MagCore® Viral Nucleic Acid Large Volume Extraction Kit (2.4 mL) Cartridge Code 210	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	A, 5(a)	W0105900101	52521	471989067M0000A9	Y	01/06/2022	Y
20	MagCore® Viral Nucleic Acid Large Volume Extraction Kit (1.2 mL) Cartridge Code 211	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.	A, 5(a)	W0105900101	52521	471989067M0000A9	Y	01/06/2022	Y
21	MagCore® Viral Nucleic Acid Large Volume Extraction Kit (2.4 mL) High Sensitivity Cartridge Code 220	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.	A, 5(a)	W0105900101	52521	471989067M0000A9	Y	01/06/2022	Y
22	MagCore® Genomic DNA Plant Kit Cartridge Code 301	The MagCore® Nucleic Acid Extraction System is an automated nucleic acid purification system consisting of the MagCore® instrument, software, Kit	A, 5(a)	W0105900101	52521	471989067M0000A9	Y	01/06/2022	Y

		(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.							
23	MagCore® Genomic DNA Tissue Kit Cartridge Code 401	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.	A, 5(a)	W0105900101	52521	471989067M0000A9	Y	01/06/2022	Y
24	MagCore® Genomic DNA FPPE One-Step Kit Cartridge Code 405	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.	A, 5(a)	W0105900101	52521	471989067M0000A9	Y	01/06/2022	Y
25	MagCore® Forensic DNA Direct Kit Cartridge Code 406	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.	A, 5(a)	W0105900101	52521	471989067M0000A9	Y	01/06/2022	Y

26	MagCore® Genomic DNA Bacterial Kit Cartridge Code 502	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	A, 5(a)	W0105900101	52521	471989067M0000A9	Y	01/06/2022	Y
27	MagCore® Gut Microbiome DNA kit Cartridge Code: 504	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	A, 5(a)	W0105900101	52521	471989067M0000A9	Y	01/06/2022	Y
28	MagCore® Total RNA Whole Blood Kit Cartridge Code 601	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.	A, 5(a)	W0105900101	52521	471989067M0000A9	Y	01/06/2022	Y
29	MagCore® Total RNA FFPE one-step kit Cartridge Code: 605	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	A, 5(a)	W0105900101	52521	471989067M0000A9	Y	01/06/2022	Y

		MagCore® Nucleic Acid Extraction Kit is for use with the MagCore® Nucleic Acid Extraction System.							
30	MagCore® Total RNA Cultured Cells Kit Cartridge Code 610	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.	A, 5(a)	W0105900 101	52521	471989067M00 00A9	Y	01/06/2022	Y
31	Magcore Plasma microRNA Extraction Kit Cartridge Code 620	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.	A, 5(a)	W0105900 101	52521	471989067M00 00A9	Y	01/06/2022	Y
32	MagCore®tr iXact RNA Kit Cartridge Code: 631	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.	A, 5(a)	W0105900 101	52521	471989067M00 00A9	Y	01/06/2022	Y
33	MagCore® NGS Auto Size-Select purification Kit Cartridge Code: 701	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	A, 5(a)	W0105900 101	52521	471989067M00 00A9	Y	01/06/2022	Y

		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.							
34	MagCore mRNA One-Step Kit Cartridge Code: 639	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.	A, 5(a)	W0105900101	52521	471989067M0000A9	Y	22/04/2024	Y
35	MagCore® Giga Automated Nucleic Acid Extractor	Automatic Nucleic Acid Purification Instrument/purification of nucleic acids from biological samples for in vitro diagnostic purposes by using MagCore reagent kit	A,5(b)	W02050106	60736	471989067M0000A9	Y	02/03/2026	Y
36	MagCore® Giga Genomic DNA Kit Cartridge Code: 812	Nucleic Acid Purification reagent/extraction of genomic DNA from human whole blood sample	A,5(a)	W0105900101	52521	471989067M0000A9	Y	02/03/2026	Y
37	MagCore® Giga Cell Free DNA Kit Cartridge Code: 815	Nucleic Acid Purification reagent/extraction of free circulating DNA from human plasma or serum	A,5(a)	W0105900101	52521	471989067M0000A9	Y	02/03/2026	Y
38	MagCore® Giga Total RNA Kit Cartridge Code: 861	Nucleic Acid Purification reagent/extraction of total RNA from human whole blood	A,5(a)	W0105900101	52521	471989067M0000A9	Y	02/03/2026	Y
39	MagCore® Giga Viral Nucleic Acid Kit Cartridge Code: 821	Nucleic Acid Purification reagent/extraction of viral DNA/RNA from serum, plasma, saliva and cell-free body fluids	A,5(a)	W0105900101	52521	471989067M0000A9	Y	02/03/2026	Y
40	MagCore® Genomic DNA Microbial Library-Ready Kit Cartridge Code: 506	Nucleic Acid Purification reagent/extraction of genomic DNA extraction from microbial samples	A,5(a)	W0105900101	52521	471989067M0000A9	Y	02/03/2026	Y

**Obelis s.a.**

**Date: 18/03/2026**

**Stamp**

## Obelis s.a. - O.E.A.R.C.

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### History log

Version number	Version Date	Order Form number	Reference Number	Action
V1	21/06/2022	EU DF 0272-2022	FRA 0630-2022	First issuance
V2	04/06/2024	EU DL 0675-2023	RDP 0280-2024	Device #34 added
V3	18/03/2026	EU AL 0044-2026	RDP 0151-2026	Devices from #35 to #40 added and EUDAMED devices Verification