Obelis GROUP

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CERTIFICATE OF
IVDR NOTIFICATION

Reference No.: RDP 0281-2024 **Date:** 12/06/2024

Order No.: EU DL 0675-2023

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: RBC BIOSCIENCE CORP. **Address:** 15F., No. 15,
Qiaohe Rd., Zhonghe Dist.,
New Taipei City, 235029,
Taiwan.

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 13/05/2024

CLASS OF IVD DEVICE(S): Please See Annex A - List of Devices (1 Page, 1 Device)

As of the 14/05/2024, 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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Obelis s.a. - O.E.A.R.C.
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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.

*This certificate will become void automatically upon termination of the EAR agreement or removal of the products from EAR Mandate

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Annex A - List of Devices

Regulation (EU) 2017/746 on in vitro diagnostic medical devices

						Nomenclature				
#	Catalogue reference number	Commercial Name	Short description and intended use	Device already on the EU market? (y/n)	Legacy Device (y/n)	EMDN code	GMDN code	GIVD Code	BASIC UDI - DI	Risk class & Classification Rule
1	MRM-01 MRM-03	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.	N	N	W0105900101	52521	n/a	471989067M0000A9	A,5(a)

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Date: 12/06/2024

Stamp: