



RBCBioscience

EU Declaration of Conformity

Manufacturer:

RBC Bioscience Corporation

Address:

15F., No.15, Qiaohe Rd., Zhonghe Dist.,

New Taipei City 235029, Taiwan

SRN (Single Registration Number):

TW-MF-000026757

Authorized Representative name and address (if applicable):

Obelis s.a.

Bd. Général Wahis 53

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Authorized Representative SRN:

BE-AR-000000106

We, RBC Bioscience Corp. hereby declare under our sole responsibility that the devices listed in the attached Annex complies with the provisions of the REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices and REGULATION (EU) 2023/1542 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 12 July 2023 concerning batteries and waste batteries.

This Declaration is applicable to the devices listed in the Annex to the Declaration of Conformity. Risk class and classification rules according to Annex VIII of REGULATION (EU) 2017/746 and other relevant data, e.g., intended purpose, catalogue number are provided in the Annex to the Declaration of Conformity.

The following conformity assessment procedure has been performed according to IVDR Art 48(10). Manufacturers of class A devices, other than devices for performance study, shall declare the conformity of their products by issuing the EU declaration of conformity referred to in Article 17, after drawing up the technical documentation set out in Annexes II and III and the following CE certificates. Our current Quality Management System (QMS) is formatted to international standards: ISO 13485:2016 have been issued by bsi MD 757696.

The following Common Specifications have been used and in relation to which conformity is declared:

- RoHS Directive 2011/65/CE + (EU) 2015/863
- EN 61010-1:2010+A1:2019
- EN 61326-1:2021; EN 61326-2-6:2025
- EN 61000-3-2:2018; EN 61000-3-3:2013+A1:2019+A2:2021;

Name: David Cho

Position: Managing Director

Place: New Taipei City, Taiwan (R.O.C.).

Date: March 20, 2026

Sincerely yours

RBC Bioscience Corp.

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David Cho



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Annex - List of Devices Covered by the Declaration of Conformity

#	Commercial name/ Trade name	Model/ Reorder/ Catalogue no.#	Description	Intended Purpose	Class	Classification rule applied	BASIC UDI - DI	GMDN/ EMDN code
1	MagCore® HF16 Automated Nucleic Acid Extractor	MCA1601	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)	471989067M0000A9	60736 W02050106
2	MagCore® Compact Automated Nucleic Acid Extractor	MCA0801	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)	471989067M0000A9	60736 W02050106
3	MagCore® Super Automated Nucleic Acid Extractor	MCA1602	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)	471989067M0000A9	60736 W02050106
4	MagCore® HF16 Plus Automated Nucleic Acid Extractor	MCA1603	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)	471989067M0000A9	60736 W02050106
5	MagCore® HF48 Automated Nucleic Acid Extractor	MCA4801	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)	471989067M0000A9	60736 W02050106

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6	MagCore® Plus II Automated Nucleic Acid Extractor	MCA1605	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)	471989067M0000A9	60736 W02050106
7	MagCore® EDA Automated Nucleic Acid Extractor	MDA4802	Automatic Nucleic Acid Purification Instrument and sample dispense	purification of nucleic acids from biological samples for in vitro diagnostic purposes by using MagCore reagent kit and sample dispense	A	5(b)	471989067M0000A9	60736 W02050106
8	MagCore® Genomic DNA Whole Blood Kit (Speedy installation) Cartridge code 101	MGB400-01/ MGB400-02	Nucleic Acid Purification reagent	extraction of genomic DNA from human whole blood sample	A	5(a)	471989067M0000A9	52521 W0105900101
9	MagCore® Genomic DNA Whole Blood Kit Cartridge code 102	MGB400-03/ MGB400-04	Nucleic Acid Purification reagent	extraction of genomic DNA from human whole blood sample	A	5(a)	471989067M0000A9	52521 W0105900101
10	MagCore® Genomic DNA Large Volume Whole Blood Kit Cartridge Code 104	MGB1200	Nucleic Acid Purification reagent	extraction of genomic DNA from human whole blood sample	A	5(a)	471989067M0000A9	52521 W0105900101

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11	MagCore® Plasma DNA Extraction Kit Cartridge Code 105	MPD1200	Nucleic Acid Purification reagent	extraction of free circulating DNA from human plasma or serum	A	5(a)	471989067M0000A9	52521 W0105900101
12	MagCore® Genomic DNA Whole Blood Kit (For Genotyping) Cartridge Code 106	MGB400-07/MGB400-08	Nucleic Acid Purification reagent	extraction of Purify genomic DNA from human whole blood for genotyping	A	5(a)	471989067M0000A9	52521 W0105900101
13	MagCore® Cultured Cells DNA Kit Cartridge Code 110	MCC-01/MCC-02	Nucleic Acid Purification reagent	extraction of genomic DNA from cultured cells and amniotic fluid	A	5(a)	471989067M0000A9	52521 W0105900101
14	MagCore® Genomic DNA large volume whole blood kit (3ml) Cartridge Code: 114	MGB3000	Nucleic Acid Purification reagent	extraction of genomic DNA from human whole blood sample	A	5(a)	471989067M0000A9	52521 W0105900101
15	MagCore® Circulating DNA large volume kit (3-4 ml) Cartridge Code: 115	MPD4000-01/MPD4000-03	Nucleic Acid Purification reagent	extraction of free circulating DNA from human plasma or serum	A	5(a)	471989067M0000A9	52521 W0105900101
16	MagCore® Viral Nucleic Acid Extraction Kit Cartridge Code 201	MVN400-01/MVN400-02	Nucleic Acid Purification reagent	extraction of viral DNA/RNA from serum, plasma and cell-free body fluids	A	5(a)	471989067M0000A9	52521 W0105900101

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17	MagCore® Viral Nucleic Acid Extraction Kit (Low PCR Inhibition) Cartridge Code 202	MVN400-03/MVN400-04	Nucleic Acid Purification reagent	extraction of viral DNA/RNA from serum, plasma and cell-free body fluids	A	5(a)	471989067M0000A9	52521 W0105900101
18	MagCore® Viral nucleic acid extraction kit (high sensitivity) Cartridge Code: 203	MVN400-05/MVN400-06	Nucleic Acid Purification reagent	extraction of viral DNA/RNA from serum, plasma and cell-free body fluids	A	5(a)	471989067M0000A9	52521 W0105900101
19	MagCore® Viral Nucleic Acid Large Volume Extraction Kit (2.4 mL) Cartridge Code 210	MVN2400	Nucleic Acid Purification reagent	extraction of viral DNA/RNA from serum, plasma and cell-free body fluids	A	5(a)	471989067M0000A9	52521 W0105900101
20	MagCore® Viral Nucleic Acid Large Volume Extraction Kit (1.2 mL) Cartridge Code 211	MVN1200	Nucleic Acid Purification reagent	extraction of viral DNA/RNA from serum, plasma and cell-free body fluids	A	5(a)	471989067M0000A9	52521 W0105900101
21	MagCore® Viral Nucleic Acid Large Volume Extraction Kit (2.4 mL) High Sensitivity Cartridge Code 220	MVN2401	Nucleic Acid Purification reagent	extraction of viral DNA/RNA from serum, plasma and cell-free body fluids	A	5(a)	471989067M0000A9	52521 W0105900101
22	MagCore® Genomic DNA Plant Kit Cartridge Code 301	MGP-01/MGP-02	Nucleic Acid Purification reagent	extraction of plant DNA from plant tissues	A	5(a)	471989067M0000A9	52521 W0105900101

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23	MagCore® Genomic DNA Tissue Kit Cartridge Code 401	MGT-01/MGT-02	Nucleic Acid Purification reagent	extraction of genomic DNA from a variety to animal tissues, paraffin-embedded tissue, swab, blood stain, forensic specimens and cultured yeast.	A	5(a)	471989067M0000A9	52521 W0105900101
24	MagCore® Genomic DNA FFPE One-Step Kit Cartridge Code 405	MGF-01/MGF-03	Nucleic Acid Purification reagent	extraction of total DNA from formalin-fixed paraffin-embedded (FFPE), tissue and forensic samples	A	5(a)	471989067M0000A9	52521 W0105900101
25	MagCore® Forensic DNA Direct Kit Cartridge Code 406	MFC-03	Nucleic Acid Purification reagent	extracting genomic DNA from forensic samples	A	5(a)	471989067M0000A9	52521 W0105900101
26	MagCore® Genomic DNA Bacterial Kit Cartridge Code 502	MBB-01/MBB-02	Nucleic Acid Purification reagent	extraction of genomic DNA from bacteria	A	5(a)	471989067M0000A9	52521 W0105900101
27	MagCore® Gut Microbiome DNA kit Cartridge Code: 504	MGM-01/MGM-02	Nucleic Acid Purification reagent	the purification of Microbial genomic DNA from fecal samples.	A	5(a)	471989067M0000A9	52521 W0105900101
28	MagCore® Total RNA Whole Blood Kit Cartridge Code 601	MRN-01/MRN-02	Nucleic Acid Purification reagent	total RNA extraction from human whole blood	A	5(a)	471989067M0000A9	52521 W0105900101

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29	MagCore® Total RNA FFPE one-step kit Cartridge Code: 605	MRF-01/MRF-03	Nucleic Acid Purification reagent	extraction of Total RNA from formalin-fixed paraffin-embedded (FFPE) tissue.	A	5(a)	471989067M0000A9	52521 W0105900101
30	MagCore® Total RNA Cultured Cells Kit Cartridge Code 610	MRC-01/MRC-02	Nucleic Acid Purification reagent	total RNA extraction from cultured cells	A	5(a)	471989067M0000A9	52521 W0105900101
31	Magcore Plasma microRNA Extraction Kit Cartridge Code 620	MMR-01/MMR-03	Nucleic Acid Purification reagent	extraction of free circulating miRNA from human plasma or serum	A	5(a)	471989067M0000A9	52521 W0105900101
32	MagCore® triXact RNA Kit Cartridge Code: 631	MRX-01/MRX-03	Nucleic Acid Purification reagent	extraction of total RNA from cultured cells, human whole blood and animal tissues.	A	5(a)	471989067M0000A9	52521 W0105900101
33	MagCore® mRNA One-Step Kit Code: 639	MRM-01/MRM-03	Nucleic Acid Purification reagent	extraction of total RNA from cultured cells, human whole blood and animal tissues.	A	5(a)	471989067M0000A9	52521 W0105900101
34	MagCore® NGS Auto Size-Select purification kit Cartridge Code: 701	MNC-01/MNC-02	Nucleic Acid Purification reagent	purification of PCR products for downstream NGS application.	A	5(a)	471989067M0000A9	52521 W0105900101

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35	MagCore® Giga Automated Nucleic Acid Extractor	MCA0802	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)	471989067M0000A9	60736 W02050106
36	MagCore® Genomic DNA Microbial Library-Ready Kit Cartridge Code: 506	MGL-01/ MGL-02	Nucleic Acid Purification reagent	purification of PCR products for downstream NGS application.	A	5(a)	471989067M0000A9	52521 W0105900101
37	MagCore® Giga Genomic DNA Kit Cartridge Code: 812	GGD-01/ GGD-02	Nucleic Acid Purification reagent	purification of PCR products for downstream NGS application.	A	5(a)	471989067M0000A9	52521 W0105900101
38	MagCore® Giga Cell Free DNA Kit Cartridge Code: 815	GPD-01/ GPD-02	Nucleic Acid Purification reagent	purification of PCR products for downstream NGS application.	A	5(a)	471989067M0000A9	52521 W0105900101
39	MagCore® Giga Total RNA Kit Cartridge Code: 861	GRN-01/ GRN-02	Nucleic Acid Purification reagent	purification of PCR products for downstream NGS application.	A	5(a)	471989067M0000A9	52521 W0105900101
40	MagCore® Giga Viral Nucleic Acid Kit Cartridge Code: 821	GVN-01/GVN-02	Nucleic Acid Purification reagent	purification of PCR products for downstream NGS application.	A	5(a)	471989067M0000A9	52521 W0105900101

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