



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.
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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 .
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.

Name: David Cho
Position: Managing Director
Place: New Taipei City, Taiwan (R.O.C.).
Date: June 13, 2025

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® 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
2	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
3	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
4	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
5	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

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#	Commercial name/ Trade name	Model/ Reorder/ Catalogue no.#	Description	Intended Purpose	Class	Classification rule applied	BASIC UDI - DI	GMDN/EMDN code
6	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
7	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
8	MagCore® Circulating DNA large volume kit (3-4 ml) Cartridge Code: 115	MPD4000-01/ MPD4000-02	Nucleic Acid Purification reagent	extraction of free circulating DNA from human plasma or serum	A	5(a)	471989067M0000A9	52521 W0105900101
9	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
10	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

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11	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
12	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
13	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
14	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
15	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
16	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

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17	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
18	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
19	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
20	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
21	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
22	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

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23	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
24	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
25	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
26	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
27	MagCore® mRNA One-Step Kit Code: 639	MRM-01/MRM-03	Nucleic Acid Purification reagent	For extraction of poly(A)-mRNA from human whole blood, culture animal cell, total RNA	A	5(a)	471989067M0000A9	52521 W0105900101

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