



RBCBioscience

Declaration of Conformity

Manufacturer: RBC Bioscience Corporation
Address: 3F., 3F-1, 2, No.132, Lane 235, Baoqiao Rd.,
Xindian Dist., New Taipei City, 23145, Taiwan (R.O.C.).

Device Name: MagCore®
Device Model: Plus II

Device Classification: Device other than those covered by Annex A, Article 10.3,
Directive 98/79/EC.

Device Description: Automated Nucleic Acid purification System,
including instrument and reagents (See Product List).

European Authorized Representative:

EC	REP
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 Obelis s.a (obelis.net) Bd. Général
Wahis 53 1030 Brussels, BELGIUM

To which this declaration relates, we hereby declare that the above-mentioned device is in conformity with the essential requirements of the following Directive and Standards:

- *In vitro* Diagnostic Medical Devices Directive 98/79/EC
- EN 61010-1:2010
- EN 61326-1:2013
- EN 61326-2-6: 2013
- EN 61000-3-2: 2014
- EN 61000-3-3: 2013

Name: David Cho
Position: Managing Director
Place: New Taipei City, Taiwan (R.O.C.).
Date: November 18, 2019

Signature: David Cho.

RBC Bioscience Corp.

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3F, No.132, Lane 235, Baoqiao Rd, Xindian Dist, New Taipei City 23145, Taiwan



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Product List:

Instrument Name	Types/Models	EC Directive	Classification
"MagCore® Plus II Automated Nucleic Acid Extractor"	Plus II	IVDD	All Others

Reagent Name	Catalog Number	EC Directive	GMDN Classification
MagCore® Genomic DNA Whole Blood Kit (Speedy installation)	MGB400-01 MGB400-02	IVDD	52521
MagCore® Genomic DNA Whole Blood Kit	MGB400-03 MGB400-04	IVDD	52521
MagCore® Genomic DNA Large Volume Whole Blood Kit (1.2 ml)	MGB1200	IVDD	52521
MagCore® Plasma DNA Extraction Kit (1.2 ml)	MPD1200	IVDD	52521
MagCore® Genomic DNA Whole Blood Kit (For Genotyping)	MGB400-07 MGB400-08	IVDD	52521
MagCore® Cultured Cells DNA Kit	MCC-01 MCC-02	IVDD	52521
MagCore® Viral Nucleic Acid Extraction Kit	MVN400-01 MVN400-02	IVDD	52521
MagCore® Viral Nucleic Acid Extraction Kit (Low PCR Inhibition)	MVN400-03 MVN400-04	IVDD	52521

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Product List:

Reagent Name	Catalog Number	EC Directive	GMDN Classification
MagCore® Viral Nucleic Acid Extraction Large Volume Kit (1.2 mL)	MVN1200	IVDD	52521
MagCore® Genomic DNA Plant Kit	MGP-01 MGP-02	IVDD	52521
MagCore® Genomic DNA Tissue Kit	MGT-01 MGT-02	IVDD	52521
MagCore® Genomic DNA FFPE One-Step Kit	MGF-01 MGF-03	IVDD	52521
MagCore® Forensic DNA Direct Kit	MFC-03	IVDD	52521
MagCore® Genomic DNA Bacterial Kit	MBB-01 MBB-02	IVDD	52521
MagCore® Total RNA Whole Blood Kit	MRN-01 MRN-02	IVDD	52521
MagCore® Total RNA Cultured Cells Kit	MRC-01 MRC-02	IVDD	52521
MagCore® triXact RNA Kit	MRX-01 MRX-03	IVDD	52521
MagCore® Total RNA FFPE one-step kit	MRF-01 MRF-03	IVDD	52521
MagCore® Circulating DNA large volume kit (4 ml)	MPD4000-01 MPD4000-03	IVDD	52521
MagCore® Viral nucleic acid extraction kit (high sensitivity)	MVN400-05 MVN400-06	IVDD	52521

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