

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: HF16 plus
Device Classification: Device other than those covered by Annex II, Article 9,
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

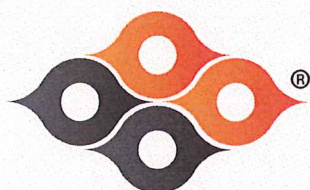
To which this declaration relates, we hereby declare that the above-mentioned device is in conformity with the essential requirements of the following Directive and Standards:

- *In vitro* Diagnostic Medical Devices Directive 98/79/EC
- EN60601-1:2007
- EN61326-1:2013

Name: David Cho
Position: Managing Director
Place: New Taipei City, Taiwan (R.O.C.).
Date: September 18, 2018

Signature: David Cho

RBC Bioscience Corp.
TEL: +886-2-8912-1200 FAX: +886-2-8912-1300
3F, No.132, Lane 235, Baoqiao Rd, Xindian Dist, New Taipei City 23145, Taiwan



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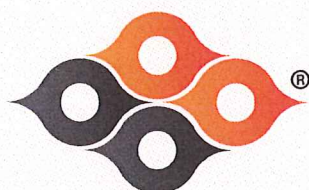
Product List:

Instrument Name	Types/Models	EC Directive	Classification
MagCore® Automated Nucleic Acid Extractor	HF16 plus	IVDD	Others / General

Reagent Name	Catalog Number	EC Directive	GMDN Classification
MagCore® Genomic DNA Whole Blood Kit (Speedy installation)	MGB400-01 MGB400-01SP MGB400-02 MGB400-02SP	IVDD	52521
MagCore® Genomic DNA Whole Blood Kit	MGB400-03 MGB400-03SP MGB400-04 MGB400-04SP	IVDD	52521
MagCore® Genomic DNA Large Volume Whole Blood Kit (1.2 ml)	MGB1200 MGB1200SP	IVDD	52521
MagCore® Plasma DNA Extraction Kit (1.2 ml)	MPD1200 MPD1200SP	IVDD	52521
MagCore® Genomic DNA Whole Blood Kit (For Genotyping)	MGB400-07 MGB400-07SP MGB400-08 MGB400-08SP	IVDD	52521
MagCore® Cultured Cells DNA Kit	MCC-01 MCC-01SP MCC-02 MCC-02SP	IVDD	52521
MagCore® Viral Nucleic Acid Extraction Kit	MVN400-01 MVN400-01SP MVN400-02 MVN400-02SP	IVDD	52521
MagCore® Viral Nucleic Acid Extraction Kit (Low PCR Inhibition)	MVN400-03 MVN400-03SP MVN400-04 MVN400-04SP	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 MVN1200SP	IVDD	52521
MagCore® Genomic DNA Plant Kit	MGP-01 MGP-01SP MGP-02 MGP-02SP	IVDD	52521
MagCore® Genomic DNA Tissue Kit	MGT-01 MGT-01SP MGT-02 MGT-02SP	IVDD	52521
MagCore® Genomic DNA FFPE One-Step Kit	MGF-01 MGF-01SP MGF-03 MGF-03SP	IVDD	52521
MagCore® Forensic DNA Direct Kit	MFC-03 MFC-03SP	IVDD	52521
MagCore® Genomic DNA Bacterial Kit	MBB-01 MBB-01SP MBB-02 MBB-02SP	IVDD	52521
MagCore® Total RNA Whole Blood Kit	MRN-01 MRN-01SP MRN-02 MRN-02SP	IVDD	52521
MagCore® Total RNA Cultured Cells Kit	MRC-01 MRC-01SP MRC-02 MRC-02SP	IVDD	52521
MagCore® triXact RNA Kit	MRX-01 MRX-01SP MRX-03 MRX-03SP	IVDD	52521

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Product List:

Reagent Name	Catalog Number	EC Directive	GMDN Classification
MagCore® Total RNA FFPE one-step kit	MRF-01 MRF-01SP MRF-03 MRF-03SP	IVDD	52521
MagCore® Genomic DNA large volume whole blood kit (3ml)	MGB3000 MGB3000SP	IVDD	52521
MagCore® Circulating DNA large volume kit (3-4 ml)	MPD4000-01 MPD4000-01SP MPD4000-02 MPD4000-02SP	IVDD	52521
MagCore® Viral nucleic acid extraction kit (high sensitivity)	MVN400-05 MVN400-05SP MVN400-06 MVN400-06SP	IVDD	52521
MagCore® NGS Clean-up kit	MNC-01 MNC-01SP MNC-02 MNC-02SP	IVDD	52521

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