



**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:** HF48  
**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:**

<b>EC</b>	<b>REP</b>
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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:** February 26, 2018

**Signature:** David Cho.

**RBC Bioscience Corp.**  
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## Product List:

Instrument Name	Types/Models	EC Directive	Classification
<b>MagCore® Automated Nucleic Acid Extractor</b>	<b>HF48</b>	<b>IVDD</b>	<b>Others / General</b>

Reagent Name	Catalog Number	EC Directive	GMDN Classification
<b>MagCore® Genomic DNA Whole Blood Kit (Speedy installation)</b>	<b>MGB400-01 MGB400-02</b>	<b>IVDD</b>	<b>52521</b>
<b>MagCore® Genomic DNA Whole Blood Kit</b>	<b>MGB400-03 MGB400-04</b>	<b>IVDD</b>	<b>52521</b>
<b>MagCore® Genomic DNA Large Volume Whole Blood Kit (1.2 ml)</b>	<b>MGB1200</b>	<b>IVDD</b>	<b>52521</b>
<b>MagCore® Plasma DNA Extraction Kit (1.2 ml)</b>	<b>MPD1200</b>	<b>IVDD</b>	<b>52521</b>
<b>MagCore® Genomic DNA Whole Blood Kit (For Genotyping)</b>	<b>MGB400-07 MGB400-08</b>	<b>IVDD</b>	<b>52521</b>
<b>MagCore® Viral Nucleic Acid Extraction Kit</b>	<b>MVN400-01 MVN400-02</b>	<b>IVDD</b>	<b>52521</b>
<b>MagCore® Viral Nucleic Acid Extraction Kit (Low PCR Inhibition)</b>	<b>MVN400-03 MVN400-04</b>	<b>IVDD</b>	<b>52521</b>
<b>MagCore® Viral Nucleic Acid Extraction Large Volume Kit (1.2 mL)</b>	<b>MVN1200</b>	<b>IVDD</b>	<b>52521</b>
<b>MagCore® Genomic DNA Tissue Kit</b>	<b>MGT-01 MGT-02</b>	<b>IVDD</b>	<b>52521</b>
<b>MagCore® Genomic DNA Bacterial Kit</b>	<b>MBB-01 MBB-02</b>	<b>IVDD</b>	<b>52521</b>
<b>MagCore® Total RNA Whole Blood Kit</b>	<b>MRN-01 MRN-02</b>	<b>IVDD</b>	<b>52521</b>
<b>MagCore® Total RNA Cultured Cells Kit</b>	<b>MRC-01 MRC-02</b>	<b>IVDD</b>	<b>52521</b>

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