Declaration of Conformity Certificate

We hereby declare that the distributed CE marked products, specified in the annexed product list, conform to the products(s) covered by the CE Marking of Conformity Certificate, reference number 2112558CE02, issued on October 26, 2011 and delivered by DEKRA Quality B.V., Arnhem, The Netherlands, Notified Body Identification Number 0344, in accordance with Annex IV of the "EC-Directive", the Council Directive 98/79/EC of 27th October 1998, concerning IVDD. In addition, we ensure and declare that the distributed CE marked products, as mentioned and falling within Annex IV, meet the provisions of the EC-Directive which apply to them.

This declaration is based on the application of the Quality System approved for the design, manufacture and final inspection of the products concerned, in accordance with Annex IV of the EC-Directive. The conformity of the full quality assurance systems set out in Annex IV, is described in the said CE Marking of Conformity Certificate, issued and delivered by DEKRA Quality B.V.

This declaration is supported by the Quality System certification based on the harmonized standards CAN/CSA ISO 13485: 2003, Quality System Certificate issued on February 4, 2011 and delivered by DEKRA Quality B.V.

This Declaration of Conformity Revision October 26, 2011 covers , Simplexa™ CMV (MOL2200) and Simplexa™ CMV Quantitation Standards (MOL2210) as specified in the product list belonging to this declaration, and is valid for all products concerned bearing the CE marking and manufactured at the following site(s): Focus Diagnostics, Inc. of 11331 Valley View Street, Cypress, California, 90630 U.S.A..

We hereby appoint mdi Europa GmbH, Langenhagener Str. 71, 30855 Langenhagen- Hannover, Germany to act as European Authorised Representative as explicitly defined in Article 1, § 2(g) of Directive 98/79/EC.

Manufacturer Represented by: _____

John Hurrell
Vice President and General Manager,
Focus Diagnostics, Inc.

Date signed: 11/2/2011

mdi Europa use only!

Signed this day 2 of November 2011

mdi Europa GmbH
Represented by:
Werner Sander - President

mdi Europa GmbH
Langenhagener Str. 71 · 30855 Langenhagen
Phone +49-511. 39 08 95 30
Fax +49-511. 39 08 95 39

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THE MEDICAL DEVICE SERVICE-MANAGEMENT

FOCUS Diagnostics

Declaration of Conformity Certificate
Revision October 26, 2011

EDMA Code	EDMA Description	Focus Description (Catalog No.)
15.04.02.40	CMV – NA Reagents	Simplexa™ CMV (MOL2200) Simplexa™ CMV Primer Mix (MOL2201) Simplexa™ Master Mix (MOL2000) Simplexa™ Extraction & Amplification Control (MOL9001) Simplexa™ CMV Low Positive Control (MOL2202) Simplexa™ CMV High Positive Control (MOL2203) Simplexa™ CMV Quantitation Standards (MOL2210) Simplexa™ CMV Quantitation Standard 1 (MOL2211) Simplexa™ CMV Quantitation Standard 2 (MOL2212) Simplexa™ CMV Quantitation Standard 3 (MOL2213) Simplexa™ CMV Quantitation Standard 4 (MOL2214) Simplexa™ CMV Quantitation Standard 5 (MOL2215)

2 of November 2011

mdi Europa GmbH
Langenhagener Str. 71 · 30855 Langenhagen
Phone +49-511. 39 08 95 30
Fax +49-511. 39 08 95 39

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THE MEDICAL DEVICE SERVICE-MANAGEMENT