



## 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 2112558CE01, issued on January 25, 2011 and delivered by DEKRA CERTIFICATION 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 CERTIFICATION 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.

This Declaration of Conformity Revision August 26, 2011 covers Chlamydia MIF (IF1250) 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: \_\_\_\_\_

*August 26, 2011*

mdi Europa use only!

Signed this day *6<sup>th</sup>* of *September* 20*11*

**mdi Europa GmbH**  
**Represented by:**  
**Werner Sander - President**

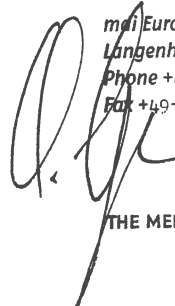
*W. Sander*  
mdi Europa GmbH  
Langenhagener Str. 71 · 30855 Langenhagen  
Phone +49-511. 39 08 95 30  
Fax +49-511. 39 08 95 39  
  
**mdiEuropa**  
THE MEDICAL DEVICE SERVICE-MANAGEMENT


## Declaration of Conformity Certificate

### Revision August 26, 2011

EDMA Code	EDMA Description	Focus Description (Catalog No.)
15.01.01.05.00	Infectious Immunology/ Bacteriology (Infect. Immunology)/ Chlamydia/ Chlamydia Antibody IgG	Chlamydia MIF IgG (IF1250G)
15.01.01.06.00	Infectious Immunology/ Bacteriology (Infect. Immunology)/ Chlamydia/ Chlamydia Antibody IgM	Chlamydia MIF IgM (IF1250M)
15.01.01.04.00	Infectious Immunology/ Bacteriology (Infect. Immunology)/ Chlamydia/ Chlamydia Antibody IgA	Chlamydia MIF IgA (IF1250A)
15.01.01.90.00	Infectious Immunology/ Bacteriology (Infect. Immunology)/ Chlamydia/ Other Chlamydia Reagents	Chlamydia Substrate Slides (IF1201) Chlamydia Non-Detectable Control (IF1213) Chlamydia Polyvalent Detectable Control (IF1214)

6<sup>th</sup> September 2011


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

  
**mdiEuropa**  
 THE MEDICAL DEVICE SERVICE-MANAGEMENT