SIEMENS

Declaration of Conformity

LEGAL MANUFACTURER:	Siemens Healthcare Diagnostics Inc. Tarrytown, New York 10591-5097 USA
PLACE OF MANUFACTURE:	Siemens Healthcare Diagnostics Manufacturing Limited Chapel Lane, Swords County Dublin, Ireland
PRODUCT:	ADVIA 120 (Attachment 1)
PRODUCT CATEGORY:	in vitro diagnostic instrument
CLASSIFICATION:	Self Declaration
CONFORMITY ASSESSMENT ROUTE:	Annex III applied
STANDARDS APPLIED:	• UL61010 A-1, 1st ed. Electrical Equipment for Laboratory use • CAN/CSA-C22.2 No. 61010-1, 2nd ed. Canadian Standard for Safety of Electrical Equipment • EN 61326-1:1997 + A1:1998 + A2:2001 EMC Requirements for Laboratory Equipment including Japan PAL Requirements • IEC 61326-2-6:2005 Particular Requirements for In Vitro Diagnostic(IVD) Medical Equipment • CISPR 11:2003 Class A, Group 1 • EN 1658:1996 Requirements for Marking IVD Instruments • EN 980:2003 Graphical Symbols for Use in the Labeling of Medical Devices • EN 591:2001 Instructions for Use for in vitro Diagnostic Instruments for Professional Use • IEC 60447:2004-01 Man-machine Interface; Actuating Principles • IEC 60073:2002-05 Basic and Safety Principles for Man-machine Interface • IEC 61010-(2001) 2nd Ed. Safety requirements for electrical equipment for measurement, control, and laboratory use • IEC 61010-2-101 (2002) 1st Ed. In vitro Diagnostic (IVD) equipment • IEC 60825-1:2007 Safety of Laser Products
DOCUMENT MANAGEMENT SYSTEM NO.	05-05-02
REV:	5.0

CE

We herewith declare that the above-mentioned product(s) meet the provisions of the Council Directive 98/79/EC for in vitro diagnostic medical devices. The Manufacturer retains all supporting documentation.

Mary Lou Mattes-Pound 6 Oct. 2009

Siemens Healthcare Diagnostics Inc.
Tarrytown, New York, USA

Mary Lou Mattes-Pound **Date**
Director of Quality Systems and Compliance

DMS No. 05-05-02, Rev. 5.0
DMR/REF(BAN) No. 067-1443-01, Rev. H / 05407646

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Attachment 1			
SMN	**BAN**	**Product Code**	**Description**
10310973	07710087	453-0024-14	ADVIA 120 with autosampler
10317457	02648340	453-0024-15	ADVIA 120 without autosampler
10489514	01264387	453-0024-16	ADVIA 120 with autosampler for Japan
10310974	05779705	453-0024R14	ADVIA 120 Refurbished with autosampler
10315737	01697267	453-0024R15	ADVIA 120 Refurbished without autosampler
10284981	06040878	453-0024R16	ADVIA 120 Refurbished with autosampler for Japan
10360958	N/A	067-A004-13	ADVIA 120 with autosampler Instrument
10360959	N/A	067-A004-14	ADVIA 120 without autosampler Instrument
10360970	N/A	067-A004R13	ADVIA 120 Refurbished with autosampler Instrument
10360971	N/A	067-A004R14	ADVIA 120 Refurbished without autosampler Instrument

Siemens Healthcare Diagnostics Inc. is the current legal manufacturer of all diagnostics products previously manufactured by Siemens Medical Solutions Diagnostics. During a transition period to update product labeling and customer documentation to indicate Siemens Healthcare Diagnostics Inc. as the legal manufacturer, products may be identified and labeled as either Siemens Healthcare Diagnostics Inc. or Siemens Medical Solutions Diagnostics.

This Declaration of Conformity is applicable for either Siemens Healthcare Diagnostics Inc., or Siemens Medical Solutions Diagnostics labeled product.

Siemens Healthcare Diagnostics Inc.
Tarrytown, New York, USA

M L Mattes-Pound 6 Oct. 2009

Mary Lou Mattes-Pound **Date**
Director of Quality Systems and Compliance

DMS No. 05-05-02, Rev. 5.0
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