SIEMENS

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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 2120 (Attachment 1)
PRODUCT CATEGORY:	in vitro diagnostic instrument
CLASSIFICATION:	Self Declaration
CONFORMITY ASSESSMENT ROUTE:	Annex III applied
STANDARDS APPLIED:	• EN 591:2001 Instructions for use for in-vitro diagnostic instruments for professional use • EN 980:2008 Symbols for use in the labeling of medical devices • EN 1658:1997 Requirements for Marking IVD Instruments • EN 13612:2002/AC:2002 Performance evaluation of in-vitro diagnostic medical devices • EN ISO 14971:2007 Medical devices — Application of risk management to medical devices • EN 61010-1:2001 Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 1: General Requirements • EN 61010-2-081/ A1:2003 Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use, Part 2-081: Particular Requirements for Automatic and Semi-Automatic Laboratory Equipment for Analysis and Other Purposes • EN 61010-2-101:2002 Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use, Part 2-101: Particular Requirements for in Vitro Diagnostic (IVD) Medical Equipment • EN 61326-1:2006 Electrical Equipment for Measurement, Control, and Laboratory Use - EMC Requirements - Part 1: General Requirements, Equipment Class A, Group 1 • EN 61326-2-6:2006 Electrical Equipment for Measurement, Control, and Laboratory Use - EMC Requirements - Part 2-6: Particular Requirements - In Vitro Diagnostic (IVD) Medical Equipment • EN 60825-1:2007 Safety of Laser Products • EN ISO 13485:2003/AC:2007 Medical devices — Quality management systems — Requirements for regulatory purposes
DOCUMENT MANAGEMENT SYSTEM NO.	09-05-02
REV:	7.0

CE

2010/06/04

Diana M. Smith — Date
Director of Regulatory Affairs

Siemens Healthcare Diagnostics Inc.
Tarrytown, New York, USA

DMS No. 09-05-02, Rev. 7.0
DMR/REF(BAN) No. 067-1490-02, Rev. H / 09651754

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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.

Attachment 1			
SMN	**BAN**	**Product Code**	**Description**
10315413	01534112	067-A010-01	ADVIA 2120 W/Single Autosampler, W/ Auto Waste, English
10489086	06525243	067-A010-02	ADVIA 2120 W/Single Autosampler, W/ Auto Waste, French
10489087	09145603	067-A010-03	ADVIA 2120 W/ Single Autosampler, W/ Auto Waste, Italian
10489088	00826969	067-A010-04	ADVIA 2120 W/ Single Autosampler, W/ Auto Waste, German
10489089	03503389	067-A010-05	ADVIA 2120 W/ Single Autosampler, W/ Auto Waste, Spanish
10489090	04096922	067-A010-06	ADVIA 2120 W/ Single Autosampler, W/ Manual Waste, English
10489091	07207318	067-A010-07	ADVIA 2120 W/ Single Autosampler, W/ Manual Waste, French
10489092	04950583	067-A010-08	ADVIA 2120 W/ Single Autosampler, W/ Manual Waste, Italian
10489093	06948160	067-A010-09	ADVIA 2120 W/ Single Autosampler, W/ Manual Waste, German
10489094	09816826	067-A010-10	ADVIA 2120 W/ Single Autosampler, W/ Manual Waste, Spanish
N/A	04353380	067-A010-11	ADVIA 2120 w/o Autosampler, with Auto Waste, English
N/A	09736369	067-A010-12	ADVIA 2120 w/o Autosampler, with Auto Waste, French
N/A	09644103	067-A010-13	ADVIA 2120 w/o Autosampler, with Auto Waste, Italian
10478603	03340781	067-A010-14	ADVIA 2120 w/o Autosampler, with Auto Waste, German
10478604	01763464	067-A010-15	ADVIA 2120 w/o Autosampler, with Auto Waste, Spanish
10478605	00813069	067-A010-16	ADVIA 2120 w/o Autosampler, with Manual Waste, English
10478606	09644383	067-A010-17	ADVIA 2120 w/o Autosampler, with Manual Waste, French
10478607	09365891	067-A010-18	ADVIA 2120 w/o Autosampler, with Manual Waste, Italian
10478608	08226278	067-A010-19	ADVIA 2120 w/o Autosampler, with Manual Waste, German
10478609	02079095	067-A010-20	ADVIA 2120 w/o Autosampler, with Manual Waste, Spanish
10489095	02269684	067-A010-21	ADVIA 2120 W/ Single Autosampler, W/ Auto Waste, Japanese
10489096	08948109	067-A010-22	ADVIA 2120 W/ Single Autosampler, W/ Manual Waste, Japanese
10478610	09536254	067-A010-23	ADVIA 2120 with Autosampler, with Auto Waste, English
10478611	04935126	067-A010-24	ADVIA 2120 with Autosampler, with Auto Waste, French
10478612	09356922	067-A010-25	ADVIA 2120 with Autosampler, with Auto Waste, Italian
10478613	04300392	067-A010-26	ADVIA 2120 with Autosampler, with Auto Waste, German
10478614	06079162	067-A010-27	ADVIA 2120 with Autosampler, with Auto Waste, Spanish
10478615	05356901	067-A010-28	ADVIA 2120 with Autosampler, with Manual Waste, English
10478616	04038582	067-A010-29	ADVIA 2120 with Autosampler, with Manual Waste, French

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Attachment 1			
SMN	**BAN**	**Product Code**	**Description**
10478617	04830413	067-A010-30	ADVIA 2120 with Autosampler, with Manual Waste, Italian
10478618	01388957	067-A010-31	ADVIA 2120 with Autosampler, with Manual Waste, German
10478619	09058948	067-A010-32	ADVIA 2120 with Autosampler, with Manual Waste, Spanish
10478620	09825582	067-A010-33	ADVIA 2120 with Autosampler, with Auto Waste, Japanese
10478621	00462916	067-A010-34	ADVIA 2120 with Autosampler, with Manual Waste, Japanese
10316162	01935621	067-A011-01	ADVIA 2120 with SAA Autosampler
10313419	00426537	067-A011-02	ADVIA 2120 with DAA Autosampler
10315687	01671802	067-A012-01	ADVIA 2120 without Autosampler

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.

2010/06/04

Siemens Healthcare Diagnostics Inc.
Tarrytown, New York, USA

Diana M. Smith - **Date**
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