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 Centaur XP (attachment 1)
PRODUCT CATEGORY:	in vitro diagnostic analyzer
CLASSIFICATION:	Self Declaration
CONFORMITY ASSESSMENT ROUTE:	Annex III applied
STANDARDS APPLIED:	• UL 61010-1(2nd Edition) Safety Requirements for Electrical Equipment for Laboratory Use • CAN/CSA 61010-1(2nd Edition) Canadian Safety Requirements for Electrical Equipment for Laboratory Use • EN 61326-1:2002 EMC Requirements for Laboratory Equipment • 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 60447:2004-03-04 Man-machine Interface; Actuating Principles • IEC 60073:2002-06 Basic and Safety Principles for Man-machine Interface • EN 61010-1:2001(2nd Edition) Safety Requirements for Laboratory Equipment • EN 61010-2-101:2002(2nd Edition) Safety of Laboratory Equipment; Particular Requirements for IVD Medical Equipment • ISO 14971:2007 Application of Risk Management to Medical Devices • EN 13612:2002 Performance Evaluation of in vitro Diagnostic Medical Devices • IEC 60825-1:2007 Safety of Laser Products
DOCUMENT MANAGEMENT SYSTEM NO:	17-05-02
REV:	6.0

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.

Siemens Healthcare Diagnostics Inc.
Tarrytown, New York, USA

Mary Lou Mattes-Pound 6 Oct. 2009

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

DMS No. 17-05-02, Rev. 6.0
DMR/REF(BAN) No. 078-0460-01, Rev. H / 06413348

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Declaration of Conformity

Attachment 1			
SMN	**BAN**	**Product Code**	**Description**
10338631	07316753	078-A010-01	ADVIA Centaur XP System English-US
10320757	04447415	078-A010-02	ADVIA Centaur XP System French
10327836	08220547	078-A010-03	ADVIA Centaur XP System German
10323213	05794402	078-A010-04	ADVIA Centaur XP System Italian
10336292	05360445	078-A010-05	ADVIA Centaur XP System Japanese
10319668	03829675	078-A010-06	ADVIA Centaur XP System Spanish
10329339	09066916	078-A010-07	ADVIA Centaur XP System English Ex-US
10317207	02520174	078-A010-08	ADVIA Centaur XP System Swedish
10324519	06516112	078-A010-09	ADVIA Centaur XP System Finnish
10327135	07878697	078-A010-10	ADVIA Centaur XP System Danish
10316507	02133464	078-A010-11	ADVIA Centaur XP System Portuguese
10328940	08841789	078-A010-12	ADVIA Centaur XP System Greek
10388696	06454177	078-A010-13	ADVIA Centaur XP System Norwegian
10364455	N/A	078-A011-03	ADVIA Centaur XP 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. 17-05-02, Rev. 6.0
DMR/REF(BAN) No. 078-0460-01, Rev. H / 06413348

EC Declaration of Conformity
according to directive 98/79/EC

We,

Siemens Healthcare Diagnostics Inc.
62 Flanders-Bartley Road
Flanders, NJ 07836
5210 Pacific Concourse Drive
Los Angeles, CA 90045

declare under sole responsibility that the following equipment to which this declaration relates, meets the essential health and safety requirements and is in conformity with the relevant sections of applicable EC standards and other normative documents. If changes are made to the product which is covered by this declaration of conformity, the declaration of conformity is no longer valid.

Equipment Type:	**In Vitro Diagnostic Medical Device**
Model:	**IMMULITE® 2000 Xpi**
Catalog Number:	**030002-33**
Serial Number:	**ALL**
Harmonized Standards Used:	**EN 61326-1:2002, EN 61326-2-6:2006, EN 61010-1:2001, EN 61010-2-081:2002, EN 61010-2-101:2002**
National and other standards and technical specifications:	**21CFR, Part 820 FDA cGMP, ISO 13485: 2003, UL61010-1 2nd Ed., CAN/CSA-C22.2 No. 61010-1 2nd Ed.**
Conformity Assessment	**Annex III**
EU Representative:	**Siemens Healthcare Diagnostics Limited** **Faraday House** **Sir William Siemens Square, Frimley** **Camberley, GU16 8QD** **United Kingdom**

Signature/Date of Manufacturer or Responsible Party: _____ (Signature) 05/27/09 (Date)

Name/Title of Signatory: Kambiz Drake (Print Name) Dir of QA (Title)

SIEMENS

EC Declaration of Conformity

CE

We hereby declare that the products described below conform to all applicable requirements of Council Directive 98/79/EC for in vitro diagnostic medical devices.

Legal Manufacturer:	Siemens Healthcare Diagnostics Inc. 62 Flanders-Bartley Road Flanders, NJ, 07836, USA
Place of Manufacture:	Siemens Healthcare Diagnostics Inc. 101 Silvermine Road Brookfield, CT, 06804, USA
EC Authorized Representative:	Siemens Healthcare Diagnostics Ltd. Sir William Siemens Square Frimley, Camberley, GU16 8QD, UK
Product Type:	
Product Names:	See *List of Products*
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Control Number:	DOC_VersaCell X3_VersaCell Expansion Pack
Version:	01

This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Inc.
This declaration supersedes any declaration issued previously for the same product.

Signature:

Lesley Traver
V.P. Quality Management, CAI
Siemens Healthcare Diagnostics Inc.
Flanders, New Jersey USA

11/13/2013
Date
[YYYY-MM-DD]

EC DECLARATION OF CONFORMITY

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EC Declaration of Conformity

List of Products

Product Name	Catalogue Number (REF)	Siemens Material Number (SMN)
VersaCell X3	10793839	10793839
VersaCell Expansion Pack	10913528	10913528

EC DECLARATION OF CONFORMITY

EC Declaration of Conformity
according to directive 98/79/EC

We,

Siemens Healthcare Diagnostics Inc.
62 Flanders-Bartley Road
Flanders, NJ 07836
5210 Pacific Concourse Drive
Los Angeles, CA 90045

declare under sole responsibility that the following equipment to which this declaration relates, meets the essential health and safety requirements and is in conformity with the relevant sections of applicable EC standards and other normative documents. If changes are made to the product which is covered by this declaration of conformity, the declaration of conformity is no longer valid.

Equipment Type:	**In Vitro Diagnostic Medical Device**
Model:	**VersaCell**
Catalog Number:	**030102**
Serial Number:	**ALL**
Harmonized Standards Used:	**EN 61326-1:2002, EN 61326-2-6:2006, EN 61010-1:2001, EN 61010-2-081:2002, EN 61010-2-101:2002**
National and other standards and technical specifications:	**21CFR, Part 820 FDA cGMP, ISO 13485: 2003, UL61010-1 2nd Ed., CAN/CSA-C22.2 No. 61010-1 2nd Ed.**
Conformity Assessment	**Annex III**
EU Representative:	**Siemens Healthcare Diagnostics Limited** **Faraday House** **Sir William Siemens Square, Frimley** **Camberley, GU16 8QD** **United Kingdom**
Signature/Date of Manufacturer or Responsible Party:	Robert Eusebio (Signature) — 03-09-2009 (Date)
Name/Title of Signatory:	Robert Eusebio (Print Name) — RA Director (Title)