

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

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


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

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

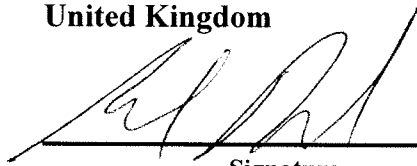
Harmonized Standards Used: EN 61326-1:2002, EN 61326-2-6:2006, EN 61010-1:2001, EN 61010-2-081:2002, EN 61010-2-101:2002

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

EC Declaration of Conformity



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]

SIEMENS

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
according to directive 98/79/EC**


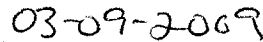
We,

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

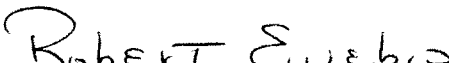

declare under sole responsibility that the following equipment to which this declaration relates, meets the essential health and safety requirements and is in conformity with the relevant sections of applicable EC standards and other normative documents. If changes are made to the product which is covered 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:**

	
Signature	Date

Name/Title of Signatory:

	
Print Name	Title