SIEMENS

Declaration of Conformity

LEGAL MANUFACTURER:	**Siemens Healthcare Diagnostics Inc. 511 Benedict Avenue Tarrytown, New York 10591-5097 USA**
PLACE OF MANUFACTURE:	**Fisher Diagnostics, A division of Fisher Scientific Company LLC, A part of Thermo Fisher Scientific Inc., 8365 Valley Pike, Middletown, VA, 22645-0307, United States of America.**
EU AUTHORIZED REPRESENTATIVE	**Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland**
PRODUCT:	**Clinitek Atlas & Clinitek Novus (Calibrators and Rinse Additive)**
PRODUCT CATEGORY:	**See attachment 1**
CLASSIFICATION:	**Self Declaration**
CONFORMITY ASSESSMENT ROUTE:	**ANNEX III Applied**
STANDARDS APPLIED:	**EN ISO 14971:2012 – Medical Devices - Application of Risk Management to Medical Devices EN ISO 13485:2012; ISO 13485:2003 – Medical Devices-Quality Management Systems-Requirements for Regulatory Purposes EN 13612:2002 – Performance Evaluation of In Vitro Diagnostic Medical Devices EN 13640:2002 – Stability Testing of In Vitro Diagnostic Medical Devices EN 13641:2002 – Elimination or Reduction of Risk of Infection Related to In Vitro Diagnostic Reagents EN 980:2008 – Graphical symbols for use in the labeling of medical devices ISO 15223-1:2012 – Symbols to be Used with Medical Device Labels, Labeling, and Information to be Supplied – Part 1: General Requirements ISO 15223-2:2010 - Symbols to be Used with Medical Device Labels, Labeling, and Information to be Supplied – Part 2: Symbol Development, Selection, and Validation EN ISO 17511:2003 – In Vitro Diagnostic Medical Devices – Measurement of Quantities in Biological Samples – Metrological Traceability of Values Assigned to Calibrators and Control Materials**

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STANDARDS APPLIED:

EN ISO 18113-1:2011 – In Vitro Diagnostic Medical Devices – Information Supplied by the Manufacturer (Labelling) – Part 1: Terms, Definitions and General Requirements
EN ISO 18113-2:2011 - In Vitro Diagnostic Medical Devices – Information Supplied by the Manufacturer (Labelling) – Part 2: In Vitro Diagnostics Reagents for Professional Use
EN ISO 18113-3:2011 – In Vitro Diagnostic Medical Devices – Information Supplied by the Manufacturer (Labelling) – Part 3: In Vitro Diagnostic Instruments for Professional Use
IEC 61010-1:2001 (Second Edition) - Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements
IEC 61010-2-081:2001 (First Edition) – 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
IEC 61010-2-101:2002 (Second Edition) – Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
IEC 60825-1:1993 (First Edition) with Amendment No. 1 (1997) and Amendment No. 1 (2001) - Safety of laser products - Part 1: Equipment classification, requirements and user's guide (depends on whether the laser or diode is Class 1 or higher)
EN 61326-1:2006 - Electrical equipment for measurement, control and laboratory use – EMC requirements Part 1: General requirements - IEC 61326-1:2005;:1997
EN 61000-3-2: 2006 - Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current greater than or equal to 16 A per phase) - IEC 61000-3-2:2005
EN 61000-3-3:1995 - Electromagnetic Compatibility (EMC) - Part 3: Limits - Section 3: Limitation of Voltage Changes, Voltage Fluctuations and Flicker in Public Low-Voltage Supply Systems, for Equipment with Rated Current Less Than or Equal to 16 A per Phase and Not Subject to conditional connection
EN IEC 62304:2006 – Medical Device Software – Software Lifecycle Processes

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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	REF (BAN)	Product Code	Description
10311106	02413084	5006	Calibrator 4
10311123	07261789	5018 A	Calibration Kit
10311113	05791764	5007 A	Rinse Additive
10697753	10697753	10697753	Clinitek Novus Calibrator Kit
10697754	10697754	10697754	Clinitek Novus Rinse Additive
End of List			

Novesteras Jim

Digitally signed by Novesteras Jim
DN: serialNumber=Z003W8MR, givenName=Jim, sn=Novesteras, o=Siemens, cn=Novesteras Jim
Date: 2019.03.04 21:01:05 -05'00'

Jim Novesteras
Regulatory Affairs Associate

DATE

Siemens Healthcare Diagnostics Inc.
Norwood, Massachusetts, USA