SIEMENS

Declaration of Conformity

LEGAL MANUFACTURER:	**Siemens Healthcare Diagnostics Inc.** **511 Benedict Avenue** **Tarrytown, New York 10591-5097** **USA**
PLACE OF MANUFACTURE:	**Universal Biosensor Pty Ltd.** **1 Corporate Avenue** **Rowville** **Victoria, 3178** **Australia**
EU AUTHORIZED REPRESENTATIVE	**Siemens Healthcare Diagnostics Manufacturing Ltd.** **Chapel Lane** **Swords, Co. Dublin, Ireland**
PRODUCT:	**Xprecia Systems™ PT/INR Test Strips**
PRODUCT CATEGORY:	**See Attachment 1**
CLASSIFICATION:	**Self-Declaration**
CONFORMITY ASSESSMENT ROUTE:	**Annex III Applied**

EN ISO 13485:2016 – Medical devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2012 – Medical devices – Application of risk management to medical devices
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 diagnostic 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
BS EN 980:2008 – Symbols for use in the labelling of medical devices
EN 13612:2002 – Performance evaluation of in vitro diagnostic medical devices
EN 13640:2002 – Stability testing of in vitro diagnostic reagents
ISO 15198:2004 – Clinical laboratory medicine — In vitro diagnostic medical devices — Validation of user quality control procedures by the manufacturer

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ISO 17511:2003 – In Vitro Diagnostic Medical Devices-Measurement of Quantities in Biological Samples-Metrological Traceability of Values assigned to Calibrators and Control Materials.
ISO 17593:2007 – Clinical laboratory testing and in vitro medical devices – Requirements for in vitro monitoring systems for self-testing of oral anticoagulant therapy (Chapter 6 to be used for verification testing)
WHO Technical Report Series 889 - Annex 3 – Guidelines for Thromboplastins and Plasmas used to control Oral anticoagulant therapy
ISO 5725-2:1994 – Accuracy (trueness and precision) of measurement methods and results -- Part 2: Basic method for the determination of repeatability and reproducibility of a standard measurement method
Reach Article 33 & 67 – The system shall not contain Substances of Very High Concern (SVHC) in excess of limits set by Reach Articles 33 & 67
IEC 62321, Ed.1:2008 – Procedures for the determination of levels of six regulated substances (Lead, Mercury, Cadmium, Hexavalent Chromium, Polybrominated Biphenyls, Polybrominated Diphenyl Ethers) in electrotechnical products
(EC) 1907/2006 – Regulation (EC) 1907/2006 of the European Parliament and the Council concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)
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
CAN/CSA C22.2 No. 61010-1:2009 – Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use – Part 1: General Requirements.
CAN/CSA C22.2 No. 61010-2-101:2009 – Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
UL 61010-1-2008 – Safety Requirements for Electrical Equipment for Measurement,

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Control, and Laboratory Use – Part 1: General Requirements.
EN 61326-2-6:2006 – Electrical equipment for measurement, control and laboratory use. EMC requirements. Particular requirements. In vitro diagnostic (IVD) medical equipment
IEC/EN 61010-1:2001 – 2nd Edition - Safety requirements for electrical equipment for measurement, control, and laboratory use. General requirements
IEC/EN 61010-1:2010 – 3rd Edition - Safety requirements for electrical equipment for measurement, control, and laboratory use. General requirements
IEC 61010-2-101 Ed. 1 – Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
EN 62304:2006 – Medical device software – Software life-cycle processes
EN 62366:2008 – Medical devices – Application of usability engineering to medical devices
ISTA Procedure 3A - Packaged-Products for Parcel Delivery System Shipments 70kg (150 lb) or Less (standard, small, flat or elongated)
2002/96/EC – Council Directive relating to the waste of electrical and electronic equipment (WEEE)
AS 60417.1:2004 – Graphical symbols for use on equipment
ASTM D3363-05 – Standard Test Method for Film Hardness by Pencil Test
IEC 60068-2-64:1993 – Environmental testing – Part 2: Test methods – Test Fh: Vibration, broadband random (digital control) and guidance
IEC 60529:2001 – Degrees of protection by enclosures (IP code)

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.

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Attachment 1		
REF (BAN)/SMN	**Product Code**	**Description**
10714623	10714623	Xprecia Systems™ PT/INR Test Strips
11064957	11064957	Xprecia Systems™ PT/INR Test Strips
11064958	11064958	Xprecia Systems™ PT/INR Test Strips

End of list

Novesteras Jim

Digitally signed by Novesteras Jim
DN: serialNumber=Z003W8MR, givenName=Jim, sn=Novesteras, o=Siemens, cn=Novesteras Jim
Date: 2019.03.10 07:02:24 -04'00'

Jim Novesteras
Regulatory Affairs Associate

Date

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Norwood, Massachusetts, USA