Declaration of Conformity

LEGAL MANUFACTURER:	Siemens Healthcare Diagnostics Inc. 511 Benedict Road Tarrytown, New York 10591-5097 UNITED STATES
PLACE OF MANUFACTURE:	Siemens Healthcare Diagnostics Manufacturing Ltd. Northern Road, Chilton Industrial Estate Sudbury, Suffolk CO10 2XQ UNITED KINGDOM
AUTHORIZED REPRESENTATIVE:	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland
PRODUCT:	CLINITEK Status+ Analyzer
PRODUCT LIST:	See Attachment 1
CLASSIFICATION:	Self-Declaration (not List A/List B Annex II)
CONFORMITY ASSESSMENT ROUTE:	Annex III Applied
STANDARDS APPLIED:	**EN ISO 14971:2012** - Medical devices - Application of risk management to medical devices **EN ISO 13485:2016** – Medical devices -- Quality Management Systems -- Requirements for Regulatory Purposes **EN ISO 18113-1:2011** - In vitro diagnostic medical devices - Information supplied by the manufacturer (labeling) - Part 1: Terms, definitions and general requirements **EN ISO 18113-3:2011** - In vitro diagnostic medical devices - Information supplied by the manufacturer (labeling) - Part 3: In vitro diagnostic instruments for professional use **EN 13612:2002** - Performance Evaluation of In Vitro Diagnostic 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 62366:2008** – Medical devices – Application of usability engineering to medical devices.

Siemens Healthcare Diagnostics Inc.
Norwood, Massachusetts, USA

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STANDARDS APPLIED CONT'D:

EN 62304:2006 - Medical device software - Software life-cycle processes

IEC/EN 61010-1:2001 (2nd Edition) - Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements

IEC/EN 61010-2-081:2002 (1st 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 purposes

IEC/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. 61010-1:2004 - Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 1: General Requirements. Certification Body must be accredited by the Standards Council of Canada.

CAN/CSA C22.2 No. 61010-2-081:2004 - 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

CAN/CSA C22.2 No. 61010-2-101:2004 - 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, Control, and Laboratory Use - Part 1: General Requirements. Certification Body must be a Nationally Recognized Testing Laboratory authorized by the Occupational Safety & Health Administration.

EN 60601-1-2:2007 - Electromagnetic emissions and immunity requirements for medical electrical equipment – Group 1 Equipment, Class B for non-life supporting equipment

IEC 60601-1-2 Ed. 2.1 - Electromagnetic emissions and immunity requirements for medical electrical equipment – Group 1 Equipment, Class B for non-life supporting equipment

2002/96/EC - Council Directive 2002/96/EC relating to the waste of electrical and electronic equipment (WEEE)

EN 50581:2012 – Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

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We herewith declare that the below-mention product(s) meet the provisions of the Council Directive 98/79/EC for In Vitro Diagnostic Medical Devices and the relevant elements specified in RoHS Directive 2011/65/EU, therefore has fulfilled all requirements for applying the CE mark to the Medical Devices(s). The Manufacturer retains all supporting documentation.

Attachment 1

SMN	Description
10376322	CLINITEK Status® Connector
10376323	CLINITEK Status® Connector
10379676	CLINITEK Status®+ Analyzer
10379677	CLINITEK Status®+ Analyzer
10379678	CLINITEK Status®+ Analyzer
10379679	CLINITEK Status®+ Analyzer
10379680	CLINITEK Status®+ Analyzer
10379681	CLINITEK Status®+ Analyzer
10379675	CLINITEK Status®+ Analyzer
10844416	Clinitek Status+ 2.5/2.3 Software Upgrade Kit
10844875	CLINITEK Status+ 2.6 Software Upgrade Kit MMC (OUS)
10845305	CLINITEK Status+ 2.6 Software Upgrade Kit MMC (US)
10844420	CLINITEK Status+ / Connector 2.6/2.4.0.0 Software Upgrade Kit (OUS)
10719594	CLINITEK Status+ / Connector 2.6/2.4.0.0 Software Upgrade Kit (US)
11046799	Status SW Upgrade Kit MMC 2.62
11046800	Status SW Upgrade Kit MMC 2.62
11046801	Status SW Upgrade Kit MMC 2.62
11046802	Status SW Upgrade Kit MMC 2.62

End of list

Novesteras Jim

Digitally signed by Novesteras Jim
DN: serialNumber=Z003W8MR, givenName=Jim, sn=Novesteras, o=Siemens, cn=Novesteras Jim
Date: 2019.03.07 15:58:39 -05'00'

Jim Novesteras
Regulatory Affairs Associate

Date

Siemens Healthcare Diagnostics Inc.
Norwood, Massachusetts, USA