DECLARATION OF CONFORMITY

CLINITEK Status+ Analyzer

SIEMENS Healthineers

EU DECLARATION OF CONFORMITY

LEGAL MANUFACTURER	SIEMENS Healthcare Diagnostics Inc. 511 Benedict Avenue Tarrytown, New York 10591 USA
PLACE OF MANUFACTURER	SIEMENS Healthcare Diagnostics Manufacturing Ltd. Northern Road, Chilton Industrial Estate Sudbury, Suffolk CO10 2XQ U.K.
EU AUTHORIZED REPRESENTATIVE	SIEMENS Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin IRELAND
PRODUCT	**CLINITEK Status+ Analyzer**
PRODUCT CATEGORY	See **TABLE I**
CLASSIFICATION	Self-Declaration
CONFORMITY ASSESSMENT ROUTE	Annex III Applied

STANDARDS APPLIED

ISO 13485:2016	MEDICAL DEVICES - Quality Management System Requirements - Requirements for Regulatory Purposes
EN ISO 14971:2019	MEDICAL DEVICES - Application of Risk Management to Medical Devices
UL 61010-1:2008	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
EN 61010-1:2010	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 BS EN 591:2001Instructions for Use for in Vitro Diagnostic Instruments for Professional Use
EN 61010-2-081:2003	Safety requirements for electrical equipment for measurement, control, and laboratory use. Part 2-081: Particular requirements for automatic and semi-automatic

EU DECLARATION OF CONFORMITY

	laboratory equipment for analysis and other purposes; Amendment A1
STANDARDS APPLIED (CONT.)	
EN 61010-2-101:2002	Safety requirements for electrical equipment for measurement, control, and laboratory use. Particular
CAN/CSA C22.2 No. 61010-1-2004	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements
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
EN 61326-1:2006	Electrical Equipment for Measurement, Control, and Laboratory Use-EMC Requirements
EN 61326-2-6:2006	Electrical equipment for measurement, control, and laboratory use. EMC requirements. Particular requirements. In vitro diagnostic (IVD) medical equipment
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
ISO 15223–1:2012	Symbols to be used with medical device labels, labeling, and information to be supplied—Part 1: General requirements
EN 62366-2008	Medical Devices – Application of Usability Engineering to Medical Devices
EN 62304:2006	Medical Device Software – Software Life – Cycle Processes

EU DECLARATION OF CONFORMITY

STANDARDS APPLIED (CONT.)

EN 13612:2002	Performance evaluation of in vitro diagnostics medical devices; First amendment to EN 13612:2002/AC:2002
EN 60601-1-2:2007	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 IEC 63000:2018	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

DECLARATION OF CONFORMITY

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EU DECLARATION OF CONFORMITY

We herewith declare that the below-mentioned product(s) meet the provisions of the Council Directive 98/79/EC and elements specified in the RoHS Directive 2011/65/EU as amended by Amendment 2015/863/EU for in vitro diagnostic medical devices therefore have fulfilled all requirements for applying the CE mark to the In Vitro Diagnostics Medical Device(s).
The Manufacturer retains all supporting documentation.

ATTACHMENT I

SMN	DESCRIPTION
10376322	CLINITEK Status® Connector
10376323	CLINITEK Status® Connector
11537761	CLINITEK Status® Connector (Non-Wifi)
11537759	CLINITEK Status® Connector (Wifi)
10379675	CLINITEK Status®+ Analyzer
10379676	CLINITEK Status®+ Analyzer
10379677	CLINITEK Status®+ Analyzer
10379678	CLINITEK Status®+ Analyzer
10379679	CLINITEK Status®+ Analyzer
10379680	CLINITEK Status®+ Analyzer
10379681	CLINITEK Status®+ Analyzer
10376324	CLINITEK Status®+ Analyzer
10379680	CLINITEK Status®+ Analyzer
10719594	CLINITEK Status+ / Connector 2.6/2.4.0.0 Software Upgrade Kit
10844416	Clinitek Status+ 2.5/2.3 Software Upgrade Kit
10844420	CLINITEK Status+ / Connector 2.6/2.4.0.0 Software Upgrade Kit
10844875	CLINITEK Status+ 2.6 Software Upgrade Kit MMC
10845305	CLINITEK Status+ 2.6 Software Upgrade Kit MMC
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

Siemens Healthcare Diagnostics, Inc.

Electronically signed by: Robert Zinck
Reason: I am approving this document
Date: Jul 19, 2021 19:38 EDT

Bobby Zinck
Manager, Regulatory Affairs

Jul 19, 2021
Date