DECLARATION OF CONFORMITY

CLINITEK Status®+ Analyzer (Self-Test)

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 (Self-Test)**
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

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	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 ISO 18113-5:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 5: In vitro diagnostic instruments for self-testing
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 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

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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

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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
11317309	CLINITEK Status® + Analyzer
11317310	CLINITEK Status® + Analyzer
11317311	CLINITEK Status® + Analyzer
11317312	CLINITEK Status® + Analyzer
11317313	CLINITEK Status® + Analyzer
11317314	CLINITEK Status® + Analyzer

END OF LIST

Siemens Healthcare Diagnostics, Inc.

Jun Yan

*Electronically signed by: Jun Yan
Reason: I am the author of this document
Date: Aug 2, 2021 20:17 EDT*

Jun Yan
Regulatory Affairs Specialist

Aug 2, 2021
Date