DECLARATION OF CONFORMITY

RAPIDLab® 1200

SIEMENS Healthineers

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	**RAPIDLab® 1200 Instruments, Reagents, Sensors and Consumables**
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
ISO 13612:2002	Performance Evaluation of In Vitro Diagnostic Medical Devices
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 18113-2:2011	In Vitro Diagnostic Medical Devices – Information Supplied by the Manufacturer (Labeling) PART 2: In vitro diagnostic reagents for professional use
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

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STANDARDS APPLIED (continued)

EN IEC 63000:2018	Technical Documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances
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
IEC 62366:2008	Medical Devices – Application of Usability Engineering to Medical Devices
IEC 62304:2006	Medical Devices Software – Software Life-Cycle Processes
EN 13640:2002	Stability Testing of In Vitro Diagnostic Medical Devices
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
EN 61326-2-6:2006	Electrical Equipment for measurement, control, and laboratory use - EMC requirements - PART 2 - 6: Particular requirements - In vitro diagnostic (IVD) medical equipment
IEC / EN 61010-1:2001	Safety requirements for Electrical Equipment for measurement, control, and laboratory use – PART 1: General Requirements
IEC / EN 61010-2-101:2002	Safety requirements for Electrical Equipment for measurement, control, and laboratory use. Particular requirements for in vitro diagnostic (IVD) medical equipment
IEC / EN 61010-2-081:2002	Safety requirements for Electrical Equipment for measurement, control, and laboratory use. Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
UL 61010-1:2008	Electrical Equipment for measurement, control, and laboratory use; PART 1: General Requirement
CAN/CSA C22.2 No. 61010-1-2004	Safety requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - PART 1: General requirements

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STANDARDS APPLIED (continued)

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

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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* Medical Device(s). The Manufacturer retains all supporting documentation.

ATTACHMENT I

SMN	REF (BAN)	PRODUCT CODE	DESCRIPTION
10321840	05060298	05060298	RAPIDLab® 1240 Blood Gas Analyzer
10321844	05061537	05061537	RAPIDLab® 1245 Blood Gas Analyzer + CO-OX
10321846	05062460	05062460	RAPIDLab® 1260 Blood Gas Analyzer
10321852	05063769	05063769	RAPIDLab® 1265 Blood Gas Analyzer + CO-OX
10491395	10491395	10491395	RAPIDLab® 1265 Blood Gas Analyzer + CO-OX
11037663	11037663	11037663	RAPIDLab® Software Upgrade Kit V3.3
10286021	04794913	04794913	RAPIDLab® 1200 Bilirubin Upgrade Key
10321856	05065575	05065575	Electrode pO_2: 1200
10321857	05065729	05065729	Electrode pCO_2: 1200
10330133	09497305	476279	Chloride Sensor Electrode Fill Solution: Cl^-
10329947	09388182	478509	Reference Sensor Inner
10311081	02563698	478822	Reference Fill Solution
10315219	01428622	01428622	Calcium Sensor
10376880	10376880	10376880	Ready Sensor™ GOLD Chloride Sensor
10376879	10376879	10376879	Ready Sensor™ GOLD Potassium Sensor
10376878	10376878	10376878	Sodium (Na+) electrode IVD
10376882	10376882	10376882	RAPIDLab® 1200 Na+/K+/Ca++/CL- Electrode Fill
10376877	10376877	10376877	Ready Sensor™ GOLD pH Sensor
10376881	10376881	10376881	RAPIDLab® 1200 pH Electrode Fill
10324386	06449458	06449458	Reference Sensor
10324388	06451843	06451843	Reference Sensor Refill
10309775	08915030	105610	Deproteinizer Solution
10311078	02578644	478701	Electrode Conditioner
10319817	03913056	03913056	RAPIDLab® 1200 Systems Wash Cartridge
10319811	03909458	03909458	RAPIDLab® 1200 Systems Reagent Cartridge
10324165	06324604	06324604	RAPIDLab® 1200 Series CO-ox Sample Chamber
10324896	06641057	06641057	RAPIDLab® 1200 Waste Bottle Kit
10329817	09320618	673395000	Quick Disposable Ampule Adapter
10492695	10492695	10492695	Proficiency Survey Quick Adapter
10492250	10492250	10492250	Proficiency Survey Quick Adapter
10326588	07568094	07568094	Survey Material Aspiration Adapter
10309073	04142460	04142460	Luer Capillary (pack of 20)
10323407	05907827	106050	Luer Capillary (2)
10324909	06645648	06645648	RAPIDLab® 1200 Tubing Kit (CO OX)
10324903	06643971	06643971	Manifold 1245/1265 Spare
10323084	05719400	476273	Reference Sensor
10311030	05147202	476281	TB2 pH/Na+ Test/Blank Sensor
10311665	07939440	673702	TB3 K+/Ca++/Cl- Test/Blank Sensor
10327492	08053446	673396	Test/Blank Ref Sensor
10316620	02195443	02195443	TB1 pO2/pCO2 Test/Blank Sensor
10734331	10734331	10734331	RAPIDLab® 1200 SW V. 3.3.1 Upgrade Kit

END OF LIST

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Siemens Healthcare Diagnostics, Inc.

Jun Yan

*Electronically signed by: Jun Yan
Reason: I am the author of this document
Date: Dec 3, 2021 00:02 EST*

Jun Yan
Regulatory Affairs Specialist

12/2/2021
Date