Declaration of Conformity

RAPIDPoint® 500 SYSTEMS

SIEMENS Healthineers

LEGAL MANUFACTURER	Siemens Healthcare Diagnostics, Inc. 511 Benedict Avenue Tarrytown, NY 10591 USA
PLACE OF MANUFACTURE	Siemens Healthcare Diagnostics, Manufacturing Ltd. Northern Road, Chilton Industrial Estate Sudbury, Suffolk CO10 2XQ, UK
EU AUTHORIZED REPRESENTATIVE	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland
PRODUCT	***RAPIDPoint® 500 Systems (Instruments & Consumables)***
PRODUCT LIST	See Attachment I
CLASSIFICATION	Self-Declaration
CONFORMITY ASSESSMENT ROUTE	Annex III Applied
DOC CONTROL NO. / IDENTIFIER	63-04-02
REV	20.0

STANDARDS APPLIED

EN ISO 14971:2012	Application of Risk Management to Medical Devices
ISO 13485:2016	Medical Devices – Quality Management System Requirements - Requirements for Regulatory Purposes
EN ISO 13485:2016	Medical Device – Quality Management System Requirements – Requirement for Regulatory Purposes
EN ISO 17511:2003	In Vitro Diagonostic Medical Devcies – Measurement of Qualities of Biological samples – Metrological Traceabiliaty of Values assigned to Calibrators and Control Materials
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: 2012	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*

Digitally signed by Pripa Natalia
Date: 2021.02.17 18:34:38 EET
Reason: MoldSign Signature
Location: Moldova

SOCIETATE CU RASPUNDERE LIMITATA S.R.L. MEDECOSISTEM IDNO 1015602000245 REPUBLICA MOLDOVA

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STANDARDS APPLIED (cont.)

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*
EN 13612:2002	Performance evaluation of in vitro diagnostics medical devices
IEC 62366:2008	Medical Devices – Application of usability engineering to Medical Devices
IEC 61010-1:2001	Safety requirements for electrical equipment for measurement, control, and laboratory use. *Part 1: General requirements.*
EN IEC 62304:2006	Medical Device Software – Software life-cycle processes
EN 61010-1:2001	Safety Requirements for electrical equipment for measurement, control and laboratory use. *Part 1 General requirements*
IEC/EN 61010- 2 - 081:2001 (1st Edition), amendment 1-2003	Safety requirements for electrical equipment for measurement control and laboratory use
IEC/EN 61010- 2 - 101:2002	Safety requirements for electrical equipment for measurement control and laboratory use.
EN 61010- 2 – 081/A1:2003	Safety requirements for electrical equipment for measurement, control and laboratory use - *PART 2-081: Particular requirements for automatic and semi-automatic analytical equipment for analysis and other purposes*
EN 61010- 2 - 101:2002	Safety requirements for electrical equipment for measurement, control and laboratory use
UL 61010-1:2008	Safety requirements for electrical equipment for measurement, control and laboratory use - *PART 1: General Requirements*
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*

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STANDARDS APPLIED (cont.)

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 60825-1:2007	Safety of laser products - *Part 1: Equipment classification and requirements*
21 CFR 1040.10	Performance Standards for Light-Emitting Products – Laser Products
21 CFR 1040.11	Performance Standards for Light-Emitting Products – Specific purpose laser products
EN 60601-1-2:2007	Medical electrical equipment - *Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests*
IEC 60601-1-2 Ed. 2.1	Medical electrical equipment - *Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests*
EN 50581:2012	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances
EN 61326-1:2013 / IEC 61326-1:2012	Electrical equipment for measurement, control and laboratory use - EMC requirements - *Part 1: General requirements*
EN 61326-2-6:2013 / IEC 61326-2-6:2012	Electrical equipment for measurement, control and laboratory use - EMC requirements - *Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment*
EN 61000-3-2:2014/IEC 61000-3-2:2014	Electromagnetic compatibility (EMC) - *Part 3-2: Limits - Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)*
EN 61000-3-3:2013 / IEC 61000-3-3:2013	Electromagnetic compatibility (EMC) - *Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤ 16 A per phase and not subject to conditional connection*

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

ATTACHMENT 1

SMN	REF/BAN	PRODUCT CODE	DESCRIPTION
10283221	06535606	10283221	RAPIDPoint®405 Measurement Cartridge BG-CO-OX 250 *Note: This product is also used with RAPIDPoint 400 and 405 Systems*
10283222	06535614	10283222	RAPIDPoint®405 Measurement Cartridge Full + CO-OX 250 *Note: This product is also used with RAPIDPoint 400 and 405 Systems*
10310310	01171974	118677	RAPIDPoint® 400/405/500 Wash/Waste Cartridge *Note: This product is also used with RAPIDPoint 400 and 405 Systems*
10310323	05293926	120241	AQC Cartridge Kit *Note: This product is also used with RAPIDLab 1200 and RAPIDPoint 400 and 405 Systems*
10310469	04913211	130522	RAPIDPoint® 405 Measurement Cartridge Full + CO-OX 750 *Note: This product is also used with RAPIDPoint 400 and 405 Systems*
10313971	00724090	130523	RAPIDPoint® 405 Measurement Cartridge Full + CO-OX 400 *Note: This product is also used with RAPIDPoint 400 and 405 Systems*
10323175	05768789	130520	RAPIDPoint®405 Measurement Cartridge BG-CO-OX 750 *Note: This product is also used with RAPIDPoint 400 and 405 Systems*
10327073	07846760	130521	RAPIDPoint®405 Measurement Cartridge BG-CO-OX 400 *Note: This product is also used with RAPIDPoint 400 and 405 Systems*
10329097	8930536	129672	RAPIDPoint® 400/405/500 Wash/Waste Cartridge
10341179	09734609	118678	RAPIDPoint® 400/405/500 Wash/Waste Cartridge
10491447	10491447	10491447	RAPIDPoint® 500 Measurement Cartridge
10491448	10491448	10491448	RAPIDPoint® 500 Measurement Cartridge
10491449	10491449	10491449	RAPIDPoint® 500 Measurement Cartridge
10492730	10492730	10492730	RP500 BLOOD GAS ANALYSER
10696855	10696855	10696855	RP500 SV BLOOD GAS ANALYSER
10696857	10696857	10696857	RP500 BLOOD GAS ANALYSER
10697306	10697306	10697306	RAPIDPoint® 500 System
11416751	11416751	11416751	RAPIDPoint® 500e Blood Gas System
11416752	11416752	11416752	RAPIDPoint® 500e Blood Gas System
11416754	11416754	11416754	RAPIDPoint® 500e Blood Gas System

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SMN	REF/BAN	PRODUCT CODE	DESCRIPTION
11416755	11416755	11416755	RAPIDPoint® 500e Blood Gas System
10697911	10697911	10697911	RP500 Software V2.0 Upgrade Kit
10844217	10844217	10844217	RP500 Software 2.1 Upgrade Kit
10844811	10844811	10844811	RAPIDPoint® 405/500 Measurement Cartridge
10844812	10844812	10844812	RAPIDPoint® 405/500 Measurement Cartridge
10844813	10844813	10844813	RAPIDPoint® 500 Measurement Cartridge
10845077	10845077	10845077	RAPIDPoint 500 Software Version 2.2A Upgrade Kit
10845078	10845078	10845078	RAPIDPoint 500 Software Version 2.2B (ROW) Upgrade Kit
10845079	10845079	10845079	RP500 Software V2.2B (US) Upgrade Kit
10845080	10845080	10845080	RAPIDPoint 500 Software Version 2.2C (ROW) Upgrade Kit
10845284	10845284	10845284	RP500 Software V2.2C (US) Upgrade Kit
11046609	11046609	11046609	RAPIDPoint 500 Software V2.2.1A Upgrade Kit
11046702	11046702	11046702	RAPIDPoint 500 Software V2.3A Upgrade Kit
11046704	11046704	11046704	RAPIDPoint 500 Software V2.3B Upgrade Kit
11046706	11046706	11046706	RAPIDPoint 500 Software V2.3C Upgrade Kit
11046708	11046708	11046708	RAPIDPoint 500 Software V2.3V Upgrade Kit
11046719	11046719	11046719	RAPIDPoint 500 Software V2.2.2A Upgrade Kit
11046720	11046720	11046720	RAPIDPoint 500 Software V2.2.2B Upgrade Kit
11046721	11046721	11046721	RAPIDPoint 500 Software V2.2.2C Upgrade Kit
11046722	11046722	11046722	RAPIDPoint 500 Software V2.2.2V Upgrade Kit
11046806	11046806	11046806	RAPIDPoint 500 Software V2.4A Upgrade Kit
11046807	11046807	11046807	RAPIDPoint 500 Software V2.4B Upgrade Kit
11046808	11046808	11046808	RAPIDPoint 500 Software V2.4V Upgrade Kit
11046813	11046813	11046813	RAPIDPoint 500 Software V2.4C Upgrade Kit
11317017	11317017	11317017	RP500 SW V. 2.3.1A Upgrade Kit
11317018	11317018	11317018	RP500 SW V. 2.3.1B Upgrade Kit
11317019	11317019	11317019	RP500 SW V. 2.3.1C Upgrade Kit
11317020	11317020	11317020	RP500 SW V. 2.3.1V Upgrade Kit
11317583	11317583	11317583	RP 500 SW V. 2.3.2A Upgrade Kit
11317584	11317584	11317584	RP 500 SW V. 2.3.2B Upgrade Kit
11317585	11317585	11317585	RP 500 SW V. 2.3.2V Upgrade Kit
11319006	11319006	11319006	RP 500 SW V. 3.0A USB Upgrade Kit
11319007	11319007	11319007	RP 500 SW V. 3.0B USB Upgrade Kit
11319038	11319038	11319038	RP500 SW V2.4.1A USB Upgrade Kit
11319039	11319039	11319039	RP500 SW V2.4.1B USB Upgrade Kit

END OF LIST

Lois Parillon
Regulatory Affairs Specialist

21-Aug-2019
DATE

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