Siemens Healthcare Diagnostics Products GmbH, Marburg, Germany

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Our reference 18-0059
Date June 11, 2018

To whom it may concern
For presentation in
the Republic of Moldova

MANUFACTURER'S AUTHORIZATION

SIEMENS HEALTHCARE DIAGNOSTICS PRODUCTS GMBH a company incorporated and existing under the laws of the Federal Republic of Germany, with offices located at Emil-von-Behring-Strasse 76, 35041 Marburg, Germany (the "Company"), hereby acknowledges that it has designated **ICS Diamedix Impex SRL,** a company incorporated in the Republic of Moldova under the fiscal code (IDNO) 1012600019967 ("Representative") as an AUTHORIZED REPRESENTATIVE for the Republic of Moldova. As such Representative is duly authorized to register and re-register the Siemens Healthineers in-vitro products (the "Products"). The manufacturing facilities of the Company and its affiliates are listed in Attachment A.

In accordance with an Authorized Representative Agreement dated November 23, 2015, Siemens will, among other things, provide to the Representative such product-related technical documentation relevant to market surveillance investigations being undertaken by the Medicines and Medical Devices Agency in the Territory as may reasonably be required. In connection with the requirements of Annex 3 to the Administrative Procedures for Registration of medical devices nr. A07PS-01Rg04-112 dated 03.07.2014, however, we point out that the following information relating to the Products, to the extent not disclosed in documentation accompanying the Products (such as Instructions for Use) concerns trade secrets and/or binding confidentiality obligations:

3. Information on design and manufacturing
4. General requirements on safety and performance
5. Risk-benefit analysis and risk management
6. Verification and validation of product.

This Manufacturer's **Authorization** does not confer any powers or authorizations beyond those contained herein. The present authorization should not be interpreted as an extension or renewal of any Authorized Representative Agreement or other contractual relationship. This letter of authorization shall remain valid until the process of registration ends or for **1 year** from the date of this letter, whichever comes later, unless revoked sooner by the Company.

On behalf of Siemens Healthcare Diagnostics Products GmbH

Name: Michael Heinold
Title: Managing Director

Name: Jörg Berner
Title: Managing Director

REPUBLICA MOLDOVA, mun. CHISINAU PENTRU FACTURI I.C.S. «DIAMEDIX IMPEX» S.R.L. IDNO 1012600019967 SOCIETATEA CU RASPUNDERE LIMITATA

Attachment A– List of Affiliates and Manufacturing Facilities:

Siemens Healthcare Diagnostics Inc. 511 Benedict Avenue Tarrytown, NY 10591-5097 USA	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin Ireland
Siemens Healthcare Diagnostics Manufacturing Ltd. Northern Road Chilton Industrial Estate Sudbury, Suffolk CO 10 2XQ United Kingdom	Siemens Healthcare Diagnostics Products Ltd. Glyn Rhonwy Llanberis, Gwynedd LL55 4EL United Kingdom
Siemens Healthcare Diagnostics Inc. 2 Edgewater Drive Norwood, MA 02062-4658 USA	Siemens Healthcare Diagnostics Inc. 3400 Middlebury Street Elkhart, IN 46516 USA
Siemens Healthcare Diagnostics Inc. 333 Coney Street East Walpole, MA 02032 USA	Siemens Healthcare Diagnostics Inc. 62 Flanders-Bartley Road Flanders, NJ 07836 USA
Siemens Healthcare Diagnostics Inc. 725 Potter Street Berkeley, CA 94710 USA	Siemens Healthcare Diagnostics Inc. 5210 Pacific Concourse Drive Los Angeles, CA 90045-6900 USA
Siemens Healthcare Diagnostics Inc. 115 Norwood Park South Norwood, MA 02062 USA	Siemens Healthcare Diagnostics Inc. 45764 Copco Avenue Gorman, California 93243 USA
Siemens Healthcare Diagnostics Inc. 500 GBC Dr., Mailstop 514 P.O. Box 6101 Newark, DE 19714 USA	Siemens Healthcare Diagnostics Products GmbH Emil-von-Behring-Strasse 76 35041 Marburg Germany
Siemens Healthcare Diagnostics Inc. 430 S. Beiger Street Mishawaka, Indiana 46544 USA	Siemens Healthcare Diagnostics Inc. 101 Silvermine Road Brookfield, CT 06804 USA

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SIEMENS

Declaration of Conformity

LEGAL MANUFACTURER:	Siemens Healthcare Diagnostics, Inc. 511 Benedict Avenue Tarrytown, New York 10591-5097 USA
PLACE OF MANUFACTURE:	Siemens Healthcare Diagnostics Manufacturing Limited Northern Road, Chilton Industrial Estate Sudbury, Suffolk CO10 2XQ UK
EU AUTHORIZED REPRESENTATIVE	Siemens Healthcare Diagnostics Ltd. Sir William Siemens SQ. Frimley, Camberley, UK GU16 8QD
PRODUCT:	RAPIDPoint 500 Instruments and Consumables
PRODUCT CATEGORY:	See Attachment 1
CLASSIFICATION:	Self-Declaration
CONFORMITY ASSESSMENT ROUTE:	ANNEX III Applied

STANDARDS APPLIED:

EN ISO 14971:2012 - Application of risk management to Medical Devices

ISO 13485:2003 – Quality System for 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

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

29 MAR 2017

Siemens Healthcare Diagnostics Inc.

Name: Priyank Patel, Date
Regulatory Technical Specialist

Norwood, Massachusetts 02062 USA

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Declaration of Conformity

STANDARDS APPLIED:

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

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.

P. B. Patel 29 MAY 2014

Name: Priyank Patel Date:

Regulatory Technical Specialist

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Siemens Healthcare Diagnostics Inc.

Norwood, Massachusetts 02062 USA

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Declaration of Conformity

STANDARDS APPLIED:

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

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 - 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.

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

P.B. Patel 29 MAR 2017

Siemens Healthcare Diagnostics Inc.

Norwood, Massachusetts 02062 USA

Name: Priyank Patel
Regulatory Technical Specialist

Date:

SIEMENS

Declaration of Conformity

We herewith declare that the below-mentioned product(s) meet the provisions of the Council Directive 98/79/EC for in vitro diagnostic medical devices 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 device(s). The Manufacturer retains all supporting documentation.

Attachment 1

SMN	REF (BAN)	Product Code	Description
10492730	10492730	10492730	RP500 BLOOD GAS ANALYSER USA
10696855	10696855	10696855	RP500 SV BLOOD GAS ANALYSER (CHINA)
10696857	10696857	10696857	RP500 BLOOD GAS ANALYSER JAPAN
10697306	10697306	10697306	RP500 BLOOD GAS ANALYSER ROW
10329097	8930536	129672	Wash Waste Cartridge Package (4)
10310310	01171974	118677	Wash Waste Cartridge Package (3)
10341179	09734609	118678	Wash Waste Cartridge Package
10310323	05293926	120241	AQC Cartridge Kit
10844811	10844811	10844811	RAPIDPoint 405 Measurement Cartridge BG + CO-OX 100
10283221	06535606	10283221	RAPIDPoint 405 Measurement Cartridge BG + CO-OX 250
10327073	07846760	130521	RAPIDPoint 405 Measurement Cartridge BG + CO-OX 400
10323175	05768789	130520	RAPIDPoint 405 Measurement Cartridge BG + CO-OX 750
10844812	10844812	10844812	RAPIDPoint 405 Measurement Cartridge Full + CO-OX 100
10283222	06535614	10283222	RAPIDPoint 405 Measurement Cartridge Full + CO-OX 250
10313971	00724090	130523	RAPIDPoint 405 Measurement Cartridge Full + CO-OX 400
10310469	04913211	130522	RAPIDPoint 405 Measurement Cartridge Full + CO-OX 750
10844813	10844813	10844813	Measurement Cartridge, RAPIDPoint 500 100 (MCART LAC)
10491447	10491447	10491447	Measurement Cartridge, RAPIDPoint 500 250 (MCART LAC)
10491448	10491448	10491448	Measurement Cartridge, RAPIDPoint 500 400 (MCART LAC)
10491449	10491449	10491449	Measurement Cartridge, RAPIDPoint 500 750 (MCART LAC)
10697911	10697911	10697911	RP500 Software V2.0 Upgrade Kit
10844217	10844217	10844217	RP500 Software V2.1 Upgrade Kit
10845077	10845077	10845077	RP500 Software V2.2A Upgrade Kit
10845078	10845078	10845078	RP500 Software V2.2B (ROW) Upgrade Kit
10845079	10845079	10845079	RP500 Software V2.2B (US) Upgrade Kit
10845080	10845080	10845080	RP500 Software V2.2C (ROW) Upgrade Kit

P. B. Patel 29 MAR 2017

Siemens Healthcare Diagnostics Inc.

Norwood, Massachusetts 02062 USA

Name: Priyank Patel
Regulatory Technical Specialist

Date

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SMN	REF (BAN)	Product Code	Description
10845284	10845284	10845284	RP500 Software V2.2C (US) Upgrade Kit
11046609	11046609	11046609	RAPIDPoint 500 Software V2.2.1A 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
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
11046806	11046806	11046806	RAPIDPoint 500 Software V2.4A Upgrade Kit
11046807	11046807	11046807	RAPIDPoint 500 Software V2.4B Upgrade Kit
11046813	11046813	11046813	RAPIDPoint 500 Software V2.4C Upgrade Kit
11046808	11046808	11046808	RAPIDPoint 500 Software V2.4V 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
End of List			

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29 MAR 2017

Siemens Healthcare Diagnostics Inc.

Norwood, Massachusetts 02062 USA

Name: Priyank Patel Date:
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