

Siemens Healthcare Diagnostics Products GmbH, Marburg, Germany

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 Our reference 21-0045  
 Date April 12, 2021

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 ("Territory"). As such Representative is duly authorized to register and re-register the products of the Siemens Healthineers in-vitro diagnostic portfolio (the "Products") listed in Attachment A within the Territory. The manufacturing facilities of the Company and its affiliates are listed in Attachment B.

In accordance with an Authorized Representative Agreement, Siemens Healthineers 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 ("Procedure Document"), 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 (numbering reflects that of the Procedure Document):

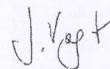
3. Information on design and manufacturing
4. General requirements on safety and performance
5. Risk-benefit analysis and risk management
6. Verification and validation of product.

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 **one year** from the date of this letter, whichever comes later, unless revoked sooner by the Company.

On behalf of Siemens Healthcare Diagnostics Products GmbH



Electronically signed by:  
 Alexander Socarras  
 Reason: I am approving this document  
 Date: Apr 12, 2021 13:44 GMT+1



Electronically signed by: Juergen Vogt  
 Reason: I have reviewed this document  
 Date: Apr 14, 2021 15:28 GMT+2

Name: A. Socarrás  
 Title: Executive Vice President Head of EMEA  
 – Laboratory Diagnostics

Name: Jürgen Vogt  
 Title: Authorized Representative

**Siemens Healthcare Diagnostics Products GmbH**  
 Management: Dr. Frank Vitzthum, Magali Gob, Tobias Thaens

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 35041 Marburg  
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Chairman of the Supervisory Board: Dr. Deepak Nath; Registered Office: Marburg an der Lahn; Commercial registry: Marburg an der Lahn HRB 2054

Letter dated April 12, 2021

REF: 21-0045

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**Attachment A– List of Products:**

Automation Lines (StreamLab®, Workcell and Labcell)	Blood Gas
Clinical Chemistry (ADVIA® only)	Dimension – Dimension EXL, RXL Max, XPand Plus
Hematology	Hemostasis
Immunology (CENTAUR® and IMMULITE® lines)	Molecular Biology
Plasma Protein	Point of Care (DCA and Urine not including STRATUS®)
Stratus CS Acute CARE	Urine
Viva line: V-Twin, Viva E, Viva jr (TDM and drugs)	Atellica Solution System and reagents and consumables



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## Attachment B– 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
Epocal Inc. (a Siemens Healthineers company) 2060 Walkley Road Ottawa K1G 3P5 Canada	Fast Track Diagnostics Luxemburg sarl (a Siemens Healthineers company) 29 rue Henri Koch Esch-sur-Alzette 4354 Luxembourg