EU DECLARATION OF CONFORMITY

Manufacturer	
Name:	*Siemens Healthcare Diagnostics Inc.*
Address:	*511 Benedict Avenue,* *Tarrytown, NY 10591 USA*
Single Registration Number (SRN):	*US-MF-000016560*
Authorized Representative	
Name:	*Siemens Healthcare Diagnostics Manufacturing Ltd.*
Address:	*Chapel Lane,* *Swords, Co. Dublin, Ireland*
SRN Authorized Representative:	*IE-AR-000006763*
Manufacturing Facility	
Name:	*Siemens Healthcare Diagnostics Manufacturing Ltd.*
Address:	*Northern Road, Chilton Industrial Estate,* *Sudbury, Suffolk CO10 6DX, UK*
Product Identification	See Product Identification table

We declare that the in vitro diagnostic medical device(s) listed in the Product Identification table is/are in conformity with the following legislation(s):

Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices

The conformity of the quality management system is declared according to Article 48.

Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment and Directive 2015/863/EU of 31 March 2015.

This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Inc.
This declaration supersedes any declaration issued previously for the same products.

On Behalf of Siemens Healthcare Diagnostics Inc.:

Place and date *Norwood, 23 May 2022*

Signature:

Electronically signed by:
Darius Daruwala
Reason: I am approving this document
Date: May 23, 2022 16:56 EDT

Email: darius.daruwala@siemens-healthineers.com

Darius Daruwala
Manager, Regulatory Affairs

Product Identification Table

Product/ Trade Name	Model	Basic UDI-DI	Risk Class	Intended Purpose
RAPIDPoint® 500 Blood Gas Analyzer	10697306	0405686901944WB	**Class A** (According to rule 5 Annex VIII In-Vitro Diagnostic Medical Devices Regulation (EU) 2017/746)	The RAPIDPoint® 500 and RAPIDPoint® 500e Blood Gas Systems are intended for in vitro diagnostic use and are designed to provide the determination in whole blood for the following parameters: • Partial pressure of carbon dioxide • Partial pressure of oxygen • pH • Sodium • Potassium • Ionized calcium • Chloride • Glucose • Lactate • Total hemoglobin and fractions: FO2Hb, FCOHb, FMetHb, FHHb • Neonatal bilirubin The RAPIDPoint® 500 and RAPIDPoint® 500e Blood Gas Systems are also intended for in vitro testing of pleural fluid samples for the pH parameter. The pH measurement of pleural fluid can be a clinically useful tool in the management of patients with parapneumonic effusions. The following critical value applies to pleural fluid pH: pH > 7.3 is measured in uncomplicated parapneumonic effusions. All pleural fluids with a pH measurement < 7.3 are referred to as complicated parapneumonic effusions and are exudative in nature. These test systems are intended for professional use in point-of-care or laboratory settings.
RAPIDPoint® 500 Blood Gas Analyzer	10492730			
RAPIDPoint® 500 Blood Gas Analyzer	10696855			
RAPIDPoint® 500 Blood Gas Analyzer (Japan)	10696857			
RAPIDPoint® 500e Blood Gas Analyzer	11416755			
RAPIDPoint® 500e Blood Gas Analyzer	11416752			
RAPIDPoint® 500e Blood Gas Analyzer (Japan)	11416754			