अखिल भारतीय आयुर्विज्ञान संस्थान, नागपुर
ALL INDIA INSTITUTE OF MEDICAL SCIENCES, NAGPUR
Address: Plot No. 2, Sector-20, MIHAN, Nagpur – 441124
Email: - hospitalstore@aiimsnagpur.edu.in

No. ADMIN-18.0/163/2026-AO(ADMIN)-AIIMS-NAGPUR /4209/Comt &Obj./ 16 **Date:13./08./2026**

Invitations for Comments / Objections

Subject: **Rate Contract for "Measurement Cartridge and Wash Cartridge for ABG Analyzer Make/ Model: Siemens Rapid Point 500e" for Trauma & Emergency Department and MICU** on Proprietary basis at AIIMS Nagpur – Inviting comments/Objection thereon.

The Institute is in the process of Rate Contract for "Measurement Cartridge and Wash Cartridge for ABG Analyzer Make/ Model: Siemens Rapid Point 500e" for Trauma & Emergency Department and MICU at AIIMS Nagpur on proprietary basis from **M/s Medico Distributors, Mumbai** who is authorized distributor of **M/s Siemens Healthcare Pvt. Ltd., Mumbai (Authorized Indian representative of M/s Siemens Healthcare Diagnostics Inc., USA -OEM)**. PAC certificate of OEM along with authorization letter attached.

The above documents are being uploaded for open information to submit objection / comments, if any from any manufacturer regarding proprietary nature of the above said items **within 14 days from the date of issue of the notification.** The comments should be sent to **Central Medical Store, 1st Floor, IPD Building, AIIMS Nagpur** by post or through e-mail on given email id within working hour of Institute. If last date is Sunday or holiday, next working day will be considered last date of submission. Failing which, it will be presumed that any other vendor is having no comment to offer and case will be decided on merits.

18.08.2026

(Vipin Kumar)
Administrative officer (P & MM)
AIIMS, Nagpur

विपिन कुमार/Vipin Kumar
प्रशासनिक अधिकारी (पी अॅन्ड एमएम)/Administrative Officer (P & MM)
अ.भा.आ.स. नागपुर/AIIMS, Nagpur

Enclosure:
i) Proprietary Article Certificate from OEM
ii) Authorization certificate from OEM

07-April-2026

Proprietary Certificate

To Whom It May Concern

We, Michelle Oliver, Vice President Legal & Assistant Secretary, and Andrea Frisch, Controller and Head of Business Performance Controlling, authorized to sign this Power of Attorney, on behalf of Siemens Healthcare Diagnostics Inc. (the "Company"), with office located at 511 Benedict Avenue, Tarrytown, NY, 10591, USA, hereby certify that the products listed below are proprietary products of the Company and Siemens Healthcare Pvt Ltd., GF, Building 10 A, DLF Cyber city Phase II, Gurgaon-122002, India having registered address at Unit No. 9A, 9th Floor, North Tower, Godrej One, Pirojshanagar, Eastern Express Highway, Vikhroli East, Mumbai – 400 079, India is the sole authorized representative for the sales & distribution of this product in India directly or through its authorized distributor.

SMN	Product Description
11416755	RAPIDPoint 500e Blood Gas Analyzer ROW
10844813	RAPIDPoint 500 Measurement Cartridge LAC 100 Test
10491447	RAPIDPoint 500 Measurement Cartridge LAC 250 Test
10491448	RAPIDPoint 500 Measurement Cartridge LAC 400 Test
10491449	RAPIDPoint 500 Measurement Cartridge LAC 750 Test
10329097	Wash/Waste Cartridge (4)
10310323	Automatic QC Cartridge Kit

This 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 Distribution Agreement or other contractual relationship. This letter shall be valid for one (1) year from the date of signature unless revoked sooner by the Company in writing.

On behalf of Siemens Healthcare Diagnostics Inc.,

Oliver Michelle
Digitally signed by Oliver Michelle
DN: cn=Oliver Michelle, c=DE, o=Siemens, email=michelle.oliver@siemens-healthineers.com
Date: 2026.04.07 12:20:46 -04'00'

Michelle Oliver
Vice President, Legal & Assistant Secretary

Date:

Frisch Andrea
Digitally signed by Frisch Andrea
DN: cn=Frisch Andrea, c=DE, o=Siemens, email=andrea.frisch@siemens-healthineers.com
Date: 2026.04.07 12:32:49 -04'00'

Andrea Frisch
Vice President &
Head of Business Performance Controlling
Date:

Siemens Healthcare Private Limited
Atrium Place, Tower 2, 9th Floor,
Udyog Vihar, Phase V, Sector 19,
Gurugram-122016 (Haryana)

SIEMENS Healthineers

Name Rakesh Kumar Pattnaik & Amit Kumar
Department HC DX
Healthcare Diagnostics
Telephone +91 0124-4089551
Mobile +91 97482 99552
E-mail rakeshkumar.pattnaik@siemens-healthineers.com

Our reference SHPL/Hi-Boat- 01440/24062026
Date 24.06.2026

To,
The Director,
All India Institute of Medical Sciences
Nagpur, Maharashtra

Subject: Authorization for supply of Blood Gas Analyzer Consumables (RP 500).
Ref: HITES/PCD/PMSSY-IV/AIIMS/NAGPUR/19-20/3137 (Dept of Pediatrics)

Dear Sir/Madam

We, Siemens Healthcare Private Limited having registered office at Unit No. 9A, 9th Floor, North Wing, Godrej One, Pirojshanagar, Vikhroli (East), Mumbai-400079 (India) who are principal suppliers of Instrument, reagents and consumables of which Siemens Healthcare Diagnostics Inc, 511, Benedict avenue, Tarrytown, NY, 10591-5097, USA is a legal manufacturer.

We hereby confirm that **Medico Distributors having its registered address at D11/11A, Ghatkopar Industrial Estate, LBS Marg, Behind R City Mall Ghatkopar West, Mumbai - 400086. INDIA Mobile No.+91 9820457999, email - janit.parekh@medicodistributors.in** is our authorized distributor for POC Business (Instruments, Reagents/Consumables, Service and Spares).

We hereby authorize **MEDICO DISTRIBUTORS** to supply the Consumables of ABG analyzer, raise invoices and collect payments in its own name and account.

This authorization will be valid till the completion of contractual obligations unless it is terminated.

for Siemens Healthcare Pvt. Ltd.
Pattnaik Rakesh Kumar
Digitally signed by Pattnaik Rakesh Kumar
DN: cn=Pattnaik Rakesh Kumar, c=DE, o=Siemens, email=rakeshkumar.pattnaik@siemens-healthineers.com
Date: 2026.06.25 09:59:10 +05'30'
Rakesh Kumar Pattnaik
National Sales Manager

for Siemens Healthcare Pvt. Ltd.
Kumar Amit
Digitally signed by Kumar Amit
Date: 2026.06.25 10:25:25 +05'30'
Amit Kumar
General Manager-Finance

Duly authorized to sign the Authorization for and on behalf of:
Siemens Healthcare Private Limited

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 2XQ, 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, Oct 18, 2022*

Electronically signed by: Darius Daruwala
Reason: I am approving this document
Date: Nov 15, 2022 11:13 EST

Darius Daruwala
Manager, Regulatory Affairs

Product Identification Table

Product/ Trade Name	Proprietary Name	Model	Basic UDI-DI	Risk Class	Intended Purpose
RAPIDPoint® 500 Blood Gas Analyzer	RAPIDPoint® 500 Blood Gas System	10697306	040568690194 4WB	**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	RAPIDPoint® 500 Blood Gas System	10492730			
RAPIDPoint® 500 Blood Gas Analyzer	RAPIDPoint® 500 Blood Gas System	10696855			
RAPIDPoint® 500 Blood Gas Analyzer	RAPIDPoint® 500 Blood Gas System	10696857			
RAPIDPoint® 500e Blood Gas Analyzer	RAPIDPoint® 500e Blood Gas System	11416755			
RAPIDPoint® 500e Blood Gas Analyzer	RAPIDPoint® 500e Blood Gas System	11416752			
RAPIDPoint® 500e Blood Gas Analyzer	RAPIDPoint® 500e Blood Gas System	11416754			

U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 6425-3-2025-1

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries , the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)	**Name of Manufacturer/Distributor, Address**
See Attached List	See Attached List
(Six Pages)	(One Page)

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections.The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

Sincerely,

CDR Cesar A. Perez, PhD, Director
DRP2: Division of Establishment Support
Office of Regulatory Programs
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from March 25, 2025 to March 24, 2027.

To verify the authenticity of the information on this certificate, you may scan the QR code or visit www.access.fda.gov/fecv/CDRH.