



Date: August 5<sup>th</sup>, 2025

**LETTER OF EXPLANATION**

To: Ministry of Health and To whom it may concern

Dear Sir/Madam,

We, **Nova Biomedical Corporation**, located at **200 Prospect Street, Waltham, MA 02454, USA**, are the legal owner of the medical devices listed in the **Certificate to Foreign Government (CFG) No.: 9959-6-2024-1**.

We confirm that all calibrators, controls and sensors listed under the aforementioned CFG are exclusively intended to be used with the Prime Plus Blood Gas Analyzer (*Stat Profile Prime Plus Analyzer*).

We also confirm that the **Stat Profile Prime Plus Analyzer** is a **point-of-care** (POC) blood analyzer. This is clearly stated in the official product Instructions for Use (IFU) issued by the owner, which states that the device is intended for use by healthcare professionals in clinical laboratory settings and for **point-of-care** usage.

Intended Use of Stat Profile Prime Plus Analyzer in Instructions for Use (IFU) (Page 14/152):

*“The Stat Profile Prime Plus Analyzer System is indicated for use by healthcare professionals in clinical laboratory settings and for **point-of-care** usage for quantitative determination of pH, Partial Pressure of Carbon Dioxide (pCO<sub>2</sub>), Partial Pressure of Oxygen (pO<sub>2</sub>), Hematocrit, Sodium, Potassium, Chloride, Ionized Calcium, Ionized Magnesium, Glucose, Lactate, Creatinine, Blood Urea Nitrogen, Oxygen Saturation, Total Hemoglobin, Oxyhemoglobin, Carboxyhemoglobin, Methemoglobin, and Deoxyhemoglobin in heparinized arterial and venous whole blood.*

*It is also indicated for use by healthcare professionals in clinical laboratory settings and for point-of-care usage for quantitative determination of pH, Partial Pressure of Carbon Dioxide (pCO<sub>2</sub>), Partial Pressure of Oxygen (pO<sub>2</sub>), Hematocrit, Sodium, Potassium, Chloride, Ionized Calcium, Ionized Magnesium, Glucose, and Lactate in heparinized capillary whole blood.”*

We hereby confirm that all the above statements are true and accurate, and we are willing to bear any legal responsibilities for any problems arising therefrom.

Representative of the product owner and manufacturer

**Nova Biomedical Corporation**

Signed:

Full Name: Bobby Zinck

Position: Director, Regulatory Affairs

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