



Date: May 27<sup>th</sup>, 2025

**LETTER OF EXPLANATION**

To: Ministry of Health and To whom it may concern

We, **Nova Biomedical Corporation**, located at **200 Prospect Street, Waltham MA 02454, USA** as the owner of the medical devices listed on Certificate To Foreign Government (CFG) with Certificate No.: **9959-6-2024-1; 3948-1-2024-1; 4365-1-2024-1**.

❖ We hereby confirm that the company name and address as stated in all accompanying documents and certificates are accurate and correspond to our company’s registered information. Specifically as shown in the table below:

	<b>Certificate To Foreign Government (CFG)</b> (No.: 3948-1-2024-1)	<b>Certificate To Foreign Government (CFG)</b> (No.: 9959-6-2024-1)	<b>Certificate To Foreign Government (CFG)</b> (No.: 4365-1-2024-1)	<b>ISO 13485</b>	<b>LOA (Letter Of Authorization) and Certificate Of Eligibility To Provide Warranty</b>	<b>Label</b>
<b>Product owner</b>	NOVA BIOMEDICAL CORP.	NOVA BIOMEDICAL CORPORATION		Nova Biomedical Corporation	Nova Biomedical Corporation	Nova Biomedical
<b>Manufacturer</b>	Nova Biomedical Corporation					
<b>Owner’s Address</b>	200 PROSPECT ST. Waltham, MA USA 02454	200 Prospect St WALTHAM, MA USA 02454		200 Prospect Street Waltham MA 02454 USA	200 Prospect Street, Waltham MA 02454, USA	200 Prospect Street, Waltham, MA 02454 USA
<b>Manufacturer’s Address</b>	200 Prospect St WALTHAM, MA USA 02454					

We confirm the use of the company name, owner’s address, and manufacturer’s address as specified in detail below:

Owner and manufacturer name: **Nova Biomedical Corporation**  
 Owner and manufacturer address: **200 Prospect Street, Waltham MA 02454, USA**

- ❖ We also hereby declare that: The product names on CFG have the following product codes, which are displayed on the product label:

<b>No</b>	<b>Product name on CFG (Model)</b>	<b>Product Code</b>
1	Prime Calibrator Cartridge CCS Comp 600 Sample	53470
2	Prime Calibrator Cartridge CCS Comp 500 Sample	53469
3	Prime Calibrator Cartridge CCS Comp 400 Sample	53105
4	Prime Calibrator Cartridge CCS Comp 300 Sample	52427
5	Prime Calibrator Cartridge CCS Comp 200 Sample	53365
6	Prime Calibrator Cartridge CCS Comp 100 Sample	52861
7	Prime Auto QC Cartridge CCS 300 Sample	52864
8	Prime Auto QC Cartridge CCS 200 Sample	45150
9	Prime Auto QC Cartridge CCS 100 Sample	53455
10	Prime Ampuled Control ABG/CCS	52714
11	Nova Linearity Level 1,2,3,4	55229
12	Prime Sensor Card CCS Comp 100	64251
13	Prime Sensor Card CCS Comp (High Volume)	55264
14	Prime Sensor Card CCS Comp	42033
15	Prime Reference Cartridge	42043
16	Prime Pump Harness	52484
17	Prime Probe S Line 100 ul	52582
18	Prime Safety Sample Port 5 Pk	52669
19	Stat Profile Critical Care Xpress Syringe Clot Catcher	38883
20	Prime Tubing L1 L2 L3	52616
21	Prime Tubing Harness ABG/CCS	52617
22	Stat Profile Prime Plus Calibrator Cartridge 100 Sample	57825
23	Stat Profile Prime Plus Calibrator Cartridge 200 Sample	57826
24	Stat Profile Prime Plus Calibrator Cartridge 300 Sample	57827
25	Stat Profile Prime Plus Calibrator Cartridge 400 Sample	57828
26	Stat Profile Prime Plus Calibrator Cartridge 500 Sample	57829
27	Stat Profile Prime Plus Calibrator Cartridge 700 Sample	65141
28	Stat Profile Prime Plus Calibrator Cartridge 100 Sample with Creat / BUN	57831
29	Stat Profile Prime Plus Calibrator Cartridge 200 Sample with Creat / BUN	57832
30	Stat Profile Prime Plus Calibrator Cartridge 300 Sample with Creat / BUN	57833
31	Stat Profile Prime Plus Calibrator Cartridge 400 Sample with Creat / BUN	57834
32	Stat Profile Prime Plus Calibrator Cartridge 500 Sample with Creat / BUN	57835
33	Stat Profile Prime Plus Calibrator Cartridge 700 Sample with Creat/BUN	65142
34	Stat Profile Prime Plus Auto QC Cartridge 160 Sample	57838
35	Stat Profile Prime Plus Auto QC Cartridge 320 Sample	57839
36	Stat Profile Prime Plus Auto QC Cartridge 480 Sample	57840

37	Stat Profile Prime Plus Auto QC Cartridge 105 Sample with Creat / BUN	57841
38	Stat Profile Prime Plus Auto QC Cartridge 210 Sample with Creat / BUN	57842
39	Stat Profile Prime Plus Auto QC Cartridge 315 Sample with Creat / BUN	57843
40	Stat Profile Prime Plus Ampuled Controls BG, COOX Levels 1, 2, 3	57844
41	Stat Profile Prime Plus Ampuled Controls Chemistry Levels 4, 5	57845
42	Stat Profile Prime Plus BUN, Creatinine - Blank Sensor Card	58379
43	Stat Profile Prime Plus MicroSensor Card™	58642
44	Stat Profile Prime Plus MicroSensor Card™ (High Volume)	58643
45	Nova Linearity Level 1,2,3,4	55229
46	Linearity Standard Set G Multipack	56198
47	Nova Linearity Creatinine/BUN/Hct Levels 1,2,3,4	61656
48	Stat Profile Prime Plus Demo Sensor Card	57815
49	Stat Profile Prime Plus Demo Sensor Card BUN, Creatinine	57816
50	Stat Profile Prime Plus Demo Calibrator Cartridge	57817
51	Stat Profile Prime Plus Demo Auto QC Cartridge	57818
52	Stat Profile Prime Plus MicroSensor Card™ BUN, Creatinine	57821
53	Stat Profile Prime Plus Reference Cartridge	57823
54	Stat Profile Prime Plus MicroSensor Card™ with COOX 100	61605
55	Stat Profile Prime Plus MicroSensor Card™ with COOX (High Volume)	61614
56	Stat Profile Prime Plus MicroSensor Card™ with COOX	61615
57	Stat Profile Prime Plus MicroSensor Card™ 100	64604
58	Prime Calibrator Cartridge ABG 600 Sample	53465
59	Prime Calibrator Cartridge ABG 500 Sample	53464
60	Prime Calibrator Cartridge ABG 400 Sample	53463
61	Prime Calibrator Cartridge ABG 300 Sample	53359
62	Prime Calibrator Cartridge ABG 200 Sample	53360
63	Prime Calibrator Cartridge ABG 100 Sample	53104
64	Prime Auto QC Cartridge ABG 100 sample	53456
65	Prime Auto QC Cartridge ABG 200 Sample	53107
66	Prime Auto QC Cartridge ABG 300 Sample	53108
67	Prime Sensor Card ABG (High Volume)	55262
68	Prime Sensor Card ABG	42031
69	Stat Profile pHox Plus L Controls Auto-Cartridge, 75	34090
70	Stat Profile pHox Plus L Controls Auto-Cartridge, 330	34091
71	Stat Profile pHox Plus L Controls Auto-Cartridge, 110	34093
72	Stat Profile pHox Plus L Calibrator Cartridge A	34085
73	Stat Profile pHox Plus L Calibrator Cartridge B	34086
74	Stat Profile pHox Plus L Calibrator Cartridge C	34087
75	Stat Profile pHox Plus L Calibrator Cartridge D	34088
76	Stat Profile pHox Plus L Control 1 2 3	34117

77	Stat Profile pHOx/pHOx Ultra/Critical Care Xpress SO2 Calibrators 1 2	22771
78	Stat Profile pHOx pH Conditioning Solution	23397
79	Nova Na/pH Sensor Conditioning Solution	6856
80	Nova Glu/Lac Sensor Soaking Solution	13409
81	Stat Profile PHOX pH Conditioning Solution	23397
82	Nova Linearity Solution, Set F Level 1,2,3,4	41274
83	Stat Profile PHOX Plus L Glucose Membrane Kit	33871
84	Stat Profile PHOX Plus L Lactate Sensor	33626
85	Stat Profile PHOX Plus L Lactate Membrane Kit	33623
86	Stat Profile PHOX Plus/L/C/M W/R Pump Tubing Kit	32965
87	Stat Profile PHOX Plus/L/C/M Reference Sensor	28954
88	Stat Profile PHOX Plus/L/C/M Air Detector	28953
89	Stat Profile PHOX Plus/L/C/M Calcium Sensor	27813
90	Stat Profile PHOX Plus/L/C/M Chloride Sensor	27812
91	Stat Profile PHOX Plus/L/C/M Potassium Sensor	27811
92	Stat Profile PHOX Plus/L/C/M Sodium Sensor	27810
93	Stat Profile PHOX Plus/L/C/M Glucose Sensor	27809
94	Stat Profile PHOX Plus Sensor Module Replacement	27807
95	Stat Profile PHOX/Basic/Plus/L/C/M PCO2 Membrane Cap Kit	25048
96	Stat Profile PHOX/Basic/Plus/L/C/M Flush Fixture	24327
97	Stat Profile pHOX/Basic/Plus/L/C PCO2 Washer Removal Tool	23545
98	Stat Profile PHOX/Basic/Plus/L/C/M Thermal Paper	23298
99	Stat Profile PHOX Plus/L/C/M W/R Pump Tubing Assembly	23023
100	Stat Profile PHOX/Basic/Plus/L/C Sensor Blank	22507
101	Stat Profile pHOx Basic/Plus/L/C Waste Line Assembly	21926
102	Stat Profile PHOX/Basic/Plus/L/C PO2 Membrane Cap Kit	21795
103	Stat Profile PHOX/Basic/Plus/L/C/M PCO2 Sensor	21524
104	Stat Profile PHOX Sodium Sensor	21523
105	Stat Profile PHOX/Basic/Plus/L/C/M PH Sensor	21522
106	Stat Profile PHOX/Basic/Plus/L/C/M PO2 Sensor	21521
107	Stat Profile PHOX Reference Sensor	21520
108	Stat Profile PHOX Probe	21519
109	Stat Profile pHOx/Basic/Plus/L/C, CCX SO2 Sensor	21512
110	Stat Profile PHOX Basic/Plus/L/C Reference Line Assembly	21497
111	Probe/ S line	20629
112	Micro Sample Tube Kit	14253
113	Preheater Deproteinizing Solution	12704
114	Stat Profile Preheater Cleaning Agent	11802
115	Nova Cleaning Solution	11272
116	Nova Sensor Conditioning Solution	9458

117	Stat Profile pHox/Basic Controls 1 2 3	22763
118	Stat Profile pHox/Basic Calibrator Cartridge A	23935
119	Stat Profile pHox/Basic Calibrator Cartridge C	23936
120	Stat Profile pHox/Basic Calibrator Cartridge B	23937
121	Preheater Deproteinizing Solution	12704
122	Stat Profile pHox/pHoxBasic/BiopHox Air Detector	21513
123	Stat Profile pHox/Basic Controls Auto-Cartridge, 75	23930
124	Stat Profile PHOX/Basic Controls Auto-Cartridge. 110	23931
125	Stat Profile PHOX/Basic Controls Auto-Cartridge. 330	23933
126	Stat Profile PHOX/Basic Calibrator Cartridge D	23934
127	Stat Profile pHOX/Basic/BiopHOX W/R Pump Tubing Assembly	49846
128	Stat Profile pHOX/Basic/BiopHOX W/R Pump Tubing Kit	49847

Representative of the product owner and manufacturer

**Nova Biomedical Corporation**

Signed:

Full Name: Bradford Bullen

Position: Director, International Sales

**NOVA**  
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