

Republica Moldova
mun. Chișinău, MD-2005

str. Albișoara 64/2
tel/fax.: (373-22) 54-91-21
tel./fax: (373-22) 54-73-73



GBG-MLD SRL

Rechizitele bancare:
Cod fiscal/1003600117582
Cod TVA: /0205086
BC "MAIB" SA suc. Constantin Tanase

cod: AGRNMD2X493
Cod IBAN: MD14AG000000225184801542

Catre IMSP Spitalul Clinic Republican „Timofei Moșneaga”
In atenta grupului de lucru achizitii publice

Declarație conform cerințelor,

Prin prezenta, compania „GBG-MLD” SRL, care participă la Licitatia Publica deschisa nr.21083394/ocds-b3wdp1-MD-1687785439022, privind achizitionarea **“Reagenti si consumabile pentru dispozitivele Stat PRIME Plus – sistem inchis”**, confirmă:

- 1) Vom prezenta la livrare numar de inregistrare la AMDM (pentru produsele supuse obligatorii inregistrarii).

Director „GBG-MLD” SRL

T. Ceaicovschi_____

Către Agenția Medicamentului
și Dispozitivelor Medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale nr. 1 din 26.06.2023

Solicitantul „GBG-MLD,SRL cu sediul: mun. Chisina, str. Albisoara 64/2, tel./fax: 022 54 73 73 , e-mail cristina@gbg.md,
solicita înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii și tipuri de dispozitive medicale pentru
introducerea și punerea la dispoziție pe piață a:

57820 Stat Profile Prime Plus MicroSensor Card with COOX
57821 Stat Profile Prime Plus MicroSensor Card BUN, Creatinine
57822 Stat Profile Prime Plus MicroSensor Card with COOX (Hight Volume)
57823 Stat Profile Prime Plus Reference Cartridge
57825 Stat Profile Prime Plus Calibrator Cartridge 100 Sample
57826 Stat Profile Prime Plus Calibrator Cartridge 200 Sample
57827 Stat Profile Prime Plus Calibrator Cartridge 300 Sample
57828 Stat Profile Prime Plus Calibrator Cartridge 400 Sample
57829 Stat Profile Prime Plus Calibrator Cartridge 500 Sample
65141 Stat Profile Prime Plus Calibrator Cartridge 700 Sample
57831 Stat Profile Prime Plus Calibrator Cartridge 100 Sample with Creat/BUN
57832 Stat Profile Prime Plus Calibrator Cartridge 200 Sample with Creat/BUN
57833 Stat Profile Prime Plus Calibrator Cartridge 300 Sample with Creat/BUN
57834 Stat Profile Prime Plus Calibrator Cartridge 400 Sample with Creat/BUN
57835 Stat Profile Prime Plus Calibrator Cartridge 500 Sample with Creat/BUN
65142 Stat Profile Prime Plus Calibrator Cartridge 700 Sample with Creat/BUN
57838 Stat Profile Prime Plus Auto QC Cartridge 160 Sample
57839 Stat Profile Prime Plus Auto QC Cartridge 320 Sample
57840 Stat Profile Prime Plus Auto QC Cartridge 480 Sample
57841 Stat Profile Prime Plus Auto QC Cartridge 105 Sample with Creat/BUN
57842 Stat Profile Prime Plus Auto QC Cartridge 210 Sample with Creat/BUN
57843 Stat Profile Prime Plus Auto QC Cartridge 315 Sample with Creat/BUN
57844 Stat Profile Prime Plus Ampuled Controls BG, COOX Levels 1,2,3
57845 Stat Profile Prime Plus Ampuled Controls BG, COOX Levels 1,2,3
58379 Stat Profile Prime Plus BUN, Creatinine – Blank Sensor Card
58642 Stat Profile Prime Plus MicroSensor Card
58643 Stat Profile Prime Plus MicroSensor Card (High Volume)
61604 Stat Profile Prime Plus MicroSensor Card with COOX 100
64604 Stat Profile Prime Plus MicroSensor Card 100

Se anexează următoarele acte:

Self- Declaration of Conformity

Notificarea pentru înregistrarea dispozitivelor medicale

Declaratia pe proprie raspundere

Scrisoarea de Autorizare

Data

26.06.2023

Semnătura



Tabelul de recepționare a notificării

(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Către Agenția Medicamentului
și Dispozitivelor Medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale nr. 1 din 26.06.2023

Solicitantul „GBG-MLD,SRL cu sediul: mun. Chisina, str. Albisoara 64/2, tel./fax: 022 54 73 73 , e-mail cristina@gbg.md,
solicite înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii și tipuri de dispozitive medicale pentru
introducerea și punerea la dispoziție pe piață a:

57820 Stat Profile Prime Plus MicroSensor Card with COOX
57821 Stat Profile Prime Plus MicroSensor Card BUN, Creatinine
57822 Stat Profile Prime Plus MicroSensor Card with COOX (Hight Volume)
57823 Stat Profile Prime Plus Reference Cartridge
57825 Stat Profile Prime Plus Calibrator Cartridge 100 Sample
57826 Stat Profile Prime Plus Calibrator Cartridge 200 Sample
57827 Stat Profile Prime Plus Calibrator Cartridge 300 Sample
57828 Stat Profile Prime Plus Calibrator Cartridge 400 Sample
57829 Stat Profile Prime Plus Calibrator Cartridge 500 Sample
65141 Stat Profile Prime Plus Calibrator Cartridge 700 Sample
57831 Stat Profile Prime Plus Calibrator Cartridge 100 Sample with Creat/BUN
57832 Stat Profile Prime Plus Calibrator Cartridge 200 Sample with Creat/BUN
57833 Stat Profile Prime Plus Calibrator Cartridge 300 Sample with Creat/BUN
57834 Stat Profile Prime Plus Calibrator Cartridge 400 Sample with Creat/BUN
57835 Stat Profile Prime Plus Calibrator Cartridge 500 Sample with Creat/BUN
65142 Stat Profile Prime Plus Calibrator Cartridge 700 Sample with Creat/BUN
57838 Stat Profile Prime Plus Auto QC Cartridge 160 Sample
57839 Stat Profile Prime Plus Auto QC Cartridge 320 Sample
57840 Stat Profile Prime Plus Auto QC Cartridge 480 Sample
57841 Stat Profile Prime Plus Auto QC Cartridge 105 Sample with Creat/BUN
57842 Stat Profile Prime Plus Auto QC Cartridge 210 Sample with Creat/BUN
57843 Stat Profile Prime Plus Auto QC Cartridge 315 Sample with Creat/BUN
57844 Stat Profile Prime Plus Ampuled Controls BG, COOX Levels 1,2,3
57845 Stat Profile Prime Plus Ampuled Controls BG, COOX Levels 1,2,3
58379 Stat Profile Prime Plus BUN, Creatinine – Blank Sensor Card
58642 Stat Profile Prime Plus MicroSensor Card
58643 Stat Profile Prime Plus MicroSensor Card (High Volume)
61604 Stat Profile Prime Plus MicroSensor Card with COOX 100
64604 Stat Profile Prime Plus MicroSensor Card 100

Se anexează următoarele acte:

Self- Declaration of Conformity

Notificarea pentru înregistrarea dispozitivelor medicale

Declaratia pe proprie raspundere

Scrisoarea de Autorizare

Data

26.06.2023

Semnătura



Tabelul de recepționare a notificării

(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitant: „GBG-MLD” SRL,

cu sediul mun. Chisinau, str. Albisoara 64/2

declar pe proprie răspundere, cunoscând prevederile art. 352¹, Codul Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivului medical:

57820 Stat Profile Prime Plus MicroSensor Card with COOX
57821 Stat Profile Prime Plus MicroSensor Card BUN, Creatinine
57822 Stat Profile Prime Plus MicroSensor Card with COOX (High Volume)
57823 Stat Profile Prime Plus Reference Cartridge
57825 Stat Profile Prime Plus Calibrator Cartridge 100 Sample
57826 Stat Profile Prime Plus Calibrator Cartridge 200 Sample
57827 Stat Profile Prime Plus Calibrator Cartridge 300 Sample
57828 Stat Profile Prime Plus Calibrator Cartridge 400 Sample
57829 Stat Profile Prime Plus Calibrator Cartridge 500 Sample
65141 Stat Profile Prime Plus Calibrator Cartridge 700 Sample
57831 Stat Profile Prime Plus Calibrator Cartridge 100 Sample with Creat/BUN
57832 Stat Profile Prime Plus Calibrator Cartridge 200 Sample with Creat/BUN
57833 Stat Profile Prime Plus Calibrator Cartridge 300 Sample with Creat/BUN
57834 Stat Profile Prime Plus Calibrator Cartridge 400 Sample with Creat/BUN
57835 Stat Profile Prime Plus Calibrator Cartridge 500 Sample with Creat/BUN
65142 Stat Profile Prime Plus Calibrator Cartridge 700 Sample with Creat/BUN
57838 Stat Profile Prime Plus Auto QC Cartridge 160 Sample
57839 Stat Profile Prime Plus Auto QC Cartridge 320 Sample
57840 Stat Profile Prime Plus Auto QC Cartridge 480 Sample
57841 Stat Profile Prime Plus Auto QC Cartridge 105 Sample with Creat/BUN
57842 Stat Profile Prime Plus Auto QC Cartridge 210 Sample with Creat/BUN
57843 Stat Profile Prime Plus Auto QC Cartridge 315 Sample with Creat/BUN
57844 Stat Profile Prime Plus Ampuled Controls BG, COOX Levels 1,2,3
57845 Stat Profile Prime Plus Ampuled Controls BG, COOX Levels 1,2,3
58379 Stat Profile Prime Plus BUN, Creatinine – Blank Sensor Card
58642 Stat Profile Prime Plus MicroSensor Card
58643 Stat Profile Prime Plus MicroSensor Card (High Volume)
61604 Stat Profile Prime Plus MicroSensor Card with COOX 100
64604 Stat Profile Prime Plus MicroSensor Card 100

Sunt autentice și corespund realității.

Cristina Gutu și funcția, Șef Secție,

Semnătura

Data 26.06.2015





**Self-Declaration of Conformity To European Parliament and Council Directive 98/79/EC
In Vitro Diagnostic Medical Device Directive (IVDD)**

Product name: Nova Stat Profile Prime Plus Consumables including Reagents, Calibrators and Controls

Catalog Numbers: List Attached (One Page)

Classification: Other/General

Manufacturer: Nova Biomedical Corporation
200 Prospect Street
Waltham, MA 02454 USA

Representative: John McHale, V.P. of Quality, Regulatory, and Technical Support

Authorized Representative: Nova Biomedical GmbH
Hessenring 13 A, Geb. G
64546 Mörfelden-Walldorf
Germany
Tel: +49 6105 4505-0

Conformity Assessment Route: Annex III

Nova Biomedical, Inc. declares that the products listed are in conformity with the provisions of the Council Directive 98/79/EC for in vitro diagnostic medical devices, including applicable essential requirements of Annex I for legal application of the CE Mark. All supporting documentation is retained under the premises of the manufacturer.

Nova Biomedical, Inc. declares that the electronic products listed are in conformity with the provisions of the Council Directive 2011/65/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS).

Standards Applied:

EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes

EN ISO 14971:2019 Medical devices - Application of risk management to medical devices

EN ISO 18113-1:2011 In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). Terms, definitions and general requirements

EN ISO 18113-2:2011 In vitro diagnostic medical Devices. Information supplied by the manufacturer (labelling). In vitro diagnostic reagents for professional use



Signature: _____

John McHale, V.P. of Quality, Regulatory, and Technical Support

Date: _____

4/27/23



List of Catalog Items Covered:

Catalog Number	Product Name	Global Medical Device Nomenclature (GMDN) Name	GMDN Number	DIMDI EDMS Code
57820	Stat Profile Prime Plus MicroSensor Card™ with COOX ✓	Point-of-care single channel clinical chemistry analyzer IVD	56681	21-02
57821	Stat Profile Prime Plus MicroSensor Card™ BUN, Creatinine ✓	Point-of-care single channel clinical chemistry analyzer IVD	56681	21-02
57822	Stat Profile Prime Plus MicroSensor Card™ with COOX (High Volume) ✓	Point-of-care single channel clinical chemistry analyzer IVD	56681	21-02
57823	Stat Profile Prime Plus Reference Cartridge ✓	Point-of-care single channel clinical chemistry analyzer IVD	56681	21-02
57825	Stat Profile Prime Plus Calibrator Cartridge 100 Sample ✓	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	52859	11-04-04-03-00
57826	Stat Profile Prime Plus Calibrator Cartridge 200 Sample ✓	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	52859	11-04-04-03-00
57827	Stat Profile Prime Plus Calibrator Cartridge 300 Sample ✓	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	52859	11-04-04-03-00
57828	Stat Profile Prime Plus Calibrator Cartridge 400 Sample ✓	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	52859	11-04-04-03-00
57829	Stat Profile Prime Plus Calibrator Cartridge 500 Sample ✓	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	52859	11-04-04-03-00
65141	Stat Profile Prime Plus Calibrator Cartridge 700 Sample ✓	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	52859	11-04-04-03-00
57831	Stat Profile Prime Plus Calibrator Cartridge 100 Sample with Creat / BUN ✓	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	52859	11-04-04-03-00
57832	Stat Profile Prime Plus Calibrator Cartridge 200 Sample with Creat / BUN ✓	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	52859	11-04-04-03-00
57833	Stat Profile Prime Plus Calibrator Cartridge 300 Sample with Creat / BUN ✓	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	52859	11-04-04-03-00
57834	Stat Profile Prime Plus Calibrator Cartridge 400 Sample with Creat / BUN ✓	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	52859	11-04-04-03-00
57835	Stat Profile Prime Plus Calibrator Cartridge 500 Sample with Creat / BUN ✓	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	52859	11-04-04-03-00
65142	Stat Profile Prime Plus Calibrator Cartridge 700 Sample with Creat / BUN ✓	Multiple blood gas/haemoximetry/electrolyte analyte IVD, calibrator	52859	11-04-04-03-00
57838	Stat Profile Prime Plus Auto QC Cartridge 160 Sample ✓	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	52860	11-50-90-01-00
57839	Stat Profile Prime Plus Auto QC Cartridge 320 Sample ✓	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	52860	11-50-90-01-00
57840	Stat Profile Prime Plus Auto QC Cartridge 480 Sample ✓	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	52860	11-50-90-01-00
57841	Stat Profile Prime Plus Auto QC Cartridge 105 Sample with Creat / BUN ✓	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	52860	11-50-90-01-00
57842	Stat Profile Prime Plus Auto QC Cartridge 210 Sample with Creat / BUN ✓	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	52860	11-50-90-01-00
57843	Stat Profile Prime Plus Auto QC Cartridge 315 Sample with Creat / BUN ✓	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	52860	11-50-90-01-00
57844	Stat Profile Prime Plus Ampuled Controls BG, COOX Levels 1, 2, 3 ✓	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	52860	11-50-90-01-00
57845	Stat Profile Prime Plus Ampuled Controls Chemistry Levels 4,5 ✓	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	52860	11-50-90-01-00
58379	Stat Profile Prime Plus BUN, Creatinine - Blank Sensor Card ✓	Point-of-care single channel clinical chemistry analyzer IVD	56681	21-02
58642	Stat Profile Prime Plus MicroSensor Card™ ✓	Point-of-care single channel clinical chemistry analyzer IVD	56681	21-02
58643	Stat Profile Prime Plus MicroSensor Card™ (High Volume) ✓	Point-of-care single channel clinical chemistry analyzer IVD	56681	21-02
61604	Stat Profile Prime Plus MicroSensor Card™ with COOX 100 ✓	Point-of-care single channel clinical chemistry analyzer IVD	56681	21-02
64604	Stat Profile Prime Plus MicroSensor Card™ 100 ✓	Point-of-care single channel clinical chemistry analyzer IVD	56681	21-02





August 4, 2022

To: Medicines and Medical Devices Agency

We, Nova Biomedical Corporation, reputable manufacturer of Prime Plus Analyzers, With headquarters located at 200 prospect Street, Waltham, MA 02454, USA, assign "GBG-MLD" SRL, having a registered office at Str. Albisoara 64/2, Chisinau MD -2005, Moldova, as our **Authorized representative** in correspondence with the conditions of LAW No. 102 from 09.06.2017 regarding medical devices.

We declare that the company mentioned above is authorized to register, notify, renew, or modify the registration of medical devices on the territory of the Republic of Moldova.

This Letter of Authorization shall remain in effect until the earlier (a) August 3, 2023, or (b) Nova's written revocation of this Letter of Authorization. To the extent that any other letter of Authorization has been previously issued by Nova for the use within Kazakhstan, this Letter of Authorization supersedes and nullifies any such other letter of authorization. Any renewal or extension of this Letter of Authorization must be in writing and executed by a director or officer of Nova.

Place: Waltham, MA

Date: August 4, 2022

Signed:

Bradford Bullen

Senior Manager, International Sales

Nova Biomedical Corporation



Nova Biomedical, 200 Prospect Street, Waltham, MA 02454-9141 U.S.A. Tel: 781-894-0800
www.novabiomedical.com

№	Numărul de catalog (referință)*	Denumire generică (denumirea dispozitivului)	GMDN
1	57820	Stat Profile Prime Plus MicroSensor Card with COOX	56681
2	57821	Stat Profile Prime Plus MicroSensor Card BUN, Creatinine	56681
3	57822	Stat Profile Prime Plus MicroSensor Card with COOX (High Volume)	56681
4	57823	Stat Profile Prime Plus Reference Cartridge	56681
5	57825	Stat Profile Prime Plus Calibrator Cartridge 100 Sample	52859
6	57826	Stat Profile Prime Plus Calibrator Cartridge 200 Sample	52859
7	57827	Stat Profile Prime Plus Calibrator Cartridge 300 Sample	52859
8	57828	Stat Profile Prime Plus Calibrator Cartridge 400 Sample	52859
9	57829	Stat Profile Prime Plus Calibrator Cartridge 500 Sample	52859
10	65141	Stat Profile Prime Plus Calibrator Cartridge 700 Sample	52859
11	57831	Stat Profile Prime Plus Calibrator Cartridge 100 Sample with Creat/BUN	52859
12	57832	Stat Profile Prime Plus Calibrator Cartridge 200 Sample with Creat/BUN	52859
13	57833	Stat Profile Prime Plus Calibrator Cartridge 300 Sample with Creat/BUN	52859
14	57834	Stat Profile Prime Plus Calibrator Cartridge 400 Sample with Creat/BUN	52859
15	57835	Stat Profile Prime Plus Calibrator Cartridge 500 Sample with Creat/BUN	52859
16	65142	Stat Profile Prime Plus Calibrator Cartridge 700 Sample with Creat/BUN	52859
17	57838	Stat Profile Prime Plus Auto QC Cartridge 160 Sample	52860
18	57839	Stat Profile Prime Plus Auto QC Cartridge 320 Sample	52860
19	57840	Stat Profile Prime Plus Auto QC Cartridge 480 Sample	52860
20	57841	Stat Profile Prime Plus Auto QC Cartridge 105 Sample with Creat/BUN	52860
21	57842	Stat Profile Prime Plus Auto QC Cartridge 210 Sample with Creat/BUN	52860
22	57843	Stat Profile Prime Plus Auto QC Cartridge 315 Sample with Creat/BUN	52860
23	57844	Stat Profile Prime Plus Ampuled Controls BG, COOX Levels 1,2,3	52860
24	57845	Stat Profile Prime Plus Ampuled Controls BG, COOX Levels 1,2,3	52860
25	58379	Stat Profile Prime Plus BUN, Creatinine – Blank Sensor Card	56681
26	58642	Stat Profile Prime Plus MicroSensor Card	56681
27	58643	Stat Profile Prime Plus MicroSensor Card (High Volume)	56681
28	61604	Stat Profile Prime Plus MicroSensor Card with COOX 100	56681
29	64604	Stat Profile Prime Plus MicroSensor Card 100	56681

