



**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 Analyzer System including Reagents, Calibrators and Controls

Catalog Numbers: List Attached (Two Pages)

Classification: Other/General

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

Representative: William Jacques, Director of Regulatory and Quality

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 50581:2012	Technical Documentation for the Assessment of Electrical and Electronic Products with Respect to the Restriction of Hazardous Substances
EN 61010-1:2010	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
EN 61010-2:101:2015	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

Signature:

William Jacques, Director of Regulatory and Quality



Date:

Jul/24/2020

List of Catalog Items Covered:

Catalog Number	Product Name	Global Medical Device Nomenclature (GMDN) Name	GMDN Number	DIMDI EDMS Code
57400	Stat Profile Prime Plus® Analyzer	Point-of-care single channel clinical chemistry analyzer IVD	56681	21-02
59508	Stat Profile Prime Plus® Analyzer (Remanufactured)	Point-of-care single channel clinical chemistry analyzer IVD	56681	21-02
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
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
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

Catalog Number	Product Name	Global Medical Device Nomenclature (GMDN) Name	GMDN Number	DIMDI EDMS Code
55229	Nova Linearity Level 1,2,3,4	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	52860	11-50-90-01-00
56198	Linearity Standard Set G Multipack	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	52860	11-50-90-90-00
61656	Nova Linearity Creatinine/BUN/Hct Levels 1,2,3,4	Multiple blood gas/haemoximetry/electrolyte analyte IVD, control	52860	11-50-90-90-00



Product Service

Certificate

No. Q5 020747 0242 Rev. 00

Holder of Certificate: **Nova Biomedical Corporation**

200 Prospect Street
Waltham MA 02454
USA

Certification Mark:



Scope of Certificate:

Design and Development, Production, Distribution, Installation, Servicing and Technical Support of In-Vitro Diagnostic Clinical Chemistry and Hematology (Co-Oximeter) Medical Devices including Near Patient / Point of Care Analyzers, Calibrators, Controls, Reagents, Sensors, Kits used in the Detection of Blood Analytes, Electrolytes, pH, Metabolites; Self Testing and Near Patient / Point of Care In-Vitro Diagnostic Devices for the Management of Diabetes Blood Glucose, Ketone, Cholesterol and Uric Acid, including Meters, Test Strips and Controls; Self Testing In-Vitro Diagnostic Medical Devices for the Determination of the percent Hemoglobin A1c (HbA1c), Total Cholesterol, High Density Lipoprotein (HDL) Cholesterol and Triglycerides in Whole Blood, and Albumin and Creatinine in Urine including Analyzers, Test Cartridges and Controls; Contract Manufacturing of Electronic Medical Devices; Contract Manufacturing of Disposable Medical Devices; and Distribution of Lancets

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 020747 0242 Rev. 00

Report No.: 72166286

Valid from: 2021-10-29

Valid until: 2024-10-28

Date, 2021-10-29

Christoph Dicks

Head of Certification/Notified Body

Certificate

No. Q5 020747 0242 Rev. 00

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies): Nova Biomedical Corporation
165 Lexington Road, Billerica MA 01821, USA

Production of Near Patient / Point of Care, and Self-Testing Meters
for the Management of Diabetes Blood Glucose, Ketone,
Cholesterol and Uric Acid.

Nova Biomedical Corporation
39 Manning Road, Billerica MA 01821, USA

Production of Near Patient / Point of Care, and Self-Testing Test
Strips for the Management of Diabetes Blood Glucose, Ketone,
Cholesterol and Uric Acid.

Distribution of Near Patient / Point of Care, and Self-Testing Test
Strips, Meters and Controls. Distribution of Lancets.

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

Design and Development, Production, Distribution, Installation,
Servicing and Technical Support of In-Vitro Diagnostic Clinical
Chemistry and Hematology (Co-Oximeter) Medical Devices
including Near Patient / Point of Care Analyzers, Calibrators,
Controls, Reagents, Sensors, Kits used in the Detection of Blood
Analytes, Electrolytes, pH, Metabolites; Self Testing and Near
Patient / Point of Care In-Vitro Diagnostic Devices for the
Management of Diabetes Blood Glucose, Ketone, Cholesterol and
Uric Acid, including Meters, Test Strips and Controls; Self Testing
In-Vitro Diagnostic Medical Devices for the Determination of the
percent Hemoglobin A1c (HbA1c), Total Cholesterol, High Density
Lipoprotein (HDL) Cholesterol and Triglycerides in Whole Blood,
and Albumin and Creatinine in Urine including Analyzers, Test
Cartridges and Controls; Contract Manufacturing of Electronic
Medical Devices; Contract Manufacturing of Disposable Medical
Devices

PRIME PLUS / VET SHELF-LIFE & WARRANTY INFORMATION

REV: 07/2021

Stat Profile® Prime Plus and Stat Profile Prime Plus VET



DESCRIPTION		WARRANTY	SHELF LIFE
Sensors Cards			
57820	Prime-Plus Sensor Card: w/ COOx (Standard)	14 Days/200 Samples*	12 Mos
57822	Prime-Plus Sensor Card: w/ COOx (High Volume)	14 Days/400 Samples*	12 Mos
58642	Prime-Plus Sensor Card: NO COOx (Standard)	14 Days/200 Samples*	12 Mos
58643	Prime-Plus Sensor Card: NO COOx (High Volume)	14 Days/400 Samples*	12 Mos
57821	Prime-Plus: Renal Micro Sensor Card	7 Days/200 Samples*	12 Mos
58577	Prime-Plus VET- Sensor Card: w/ COOx (High Volume)	14 Days/400 Samples*	12 Mos
58578	Prime-Plus VET- Sensor Card: NO COOx (High Volume)	14 Days/400 Samples*	12 Mos
58581	Prime-Plus VET- Renal Micro Sensor Card	7 Days/200 Samples*	12 Mos
58379	Prime-Plus Sensor Card- BLANK RENAL Sensor Card: (Clinical & VET)	Free of Defects	n/a
57823	Reference Sensor- Prime-Plus (w/ W/R Pump Tubing) (CLINICAL)	Free of Defects	18 Mos
59345	Reference Sensor- Prime-Plus (w/ W/R Pump Tubing) (VET)	Free of Defects	18 Mos
Calibrators			
57825	Stat Profile Prime Plus® Calibrator Cartridge 100 Sample	100 Samples or 35 Days	18 Mos
57826	Stat Profile Prime Plus® Calibrator Cartridge 200 Sample	200 Samples or 35 Days	18 Mos
57827	Stat Profile Prime Plus® Calibrator Cartridge 300 Sample	300 Samples or 35 Days	18 Mos
57828	Stat Profile Prime Plus® Calibrator Cartridge 400 Sample	400 Samples or 35 Days	18 Mos
57829	Stat Profile Prime Plus® Calibrator Cartridge 500 Sample	500 Samples or 35 Days	18 Mos
57831	Stat Profile Prime Plus® Calibrator Cartridge 100 Sample with Creat / BUN	100 Samples or 21 Days	18 Mos
57832	Stat Profile Prime Plus® Calibrator Cartridge 200 Sample with Creat / BUN	200 Samples or 21 Days	18 Mos
57833	Stat Profile Prime Plus® Calibrator Cartridge 300 Sample with Creat / BUN	300 Samples or 21 Days	18 Mos
57834	Stat Profile Prime Plus® Calibrator Cartridge 400 Sample with Creat / BUN	400 Samples or 21 Days	18 Mos
57835	Stat Profile Prime Plus® Calibrator Cartridge 500 Sample with Creat / BUN	500 Samples or 21 Days	18 Mos
58395	Stat Profile Prime Plus® VET Calibrator Cartridge 200 Sample	200 Samples or 35 Days	18 Mos
58396	Stat Profile Prime Plus® VET Calibrator Cartridge 500 Sample	500 Samples or 35 Days	18 Mos
58405	Stat Profile Prime Plus® VET Calibrator Cartridge 200 Sample with Creat / BUN	200 Samples or 21 Days	18 Mos
58404	Stat Profile Prime Plus® VET Calibrator Cartridge 500 Sample with Creat / BUN	500 Samples or 21 Days	18 Mos
AQC Packs			
57838	Stat Profile Prime Plus® Auto QC Cartridge 160 Sample	160 Samples or 32 Days	18 Mos
57839	Stat Profile Prime Plus® Auto QC Cartridge 320 Sample	320 Samples or 32 Days	18 Mos
57840	Stat Profile Prime Plus® Auto QC Cartridge 480 Sample	480 Samples or 32 Days	18 Mos
57841	Stat Profile Prime Plus® Auto QC Cartridge 105 Sample with Creat / BUN	105 Samples or 21 Days	18 Mos
57842	Stat Profile Prime Plus® Auto QC Cartridge 210 Sample with Creat / BUN	210 Samples or 21 Days	18 Mos
57843	Stat Profile Prime Plus® Auto QC Cartridge 315 Sample with Creat / BUN	315 Samples or 21 Days	18 Mos
58406	Stat Profile Prime Plus® VET Auto QC Cartridge 160 Sample	160 Samples or 32 Days	18 Mos
58407	Stat Profile Prime Plus® VET Auto QC Cartridge 480 Sample	480 Samples or 32 Days	18 Mos
58408	Stat Profile Prime Plus® VET Auto QC Cartridge 105 Sample with Creat / BUN	105 Samples or 21 Days	18 Mos
58409	Stat Profile Prime Plus® VET Auto QC Cartridge 315 Sample with Creat / BUN	315 Samples or 21 Days	18 Mos
57844	Stat Profile Prime Plus® Ampuled Controls BG, COOX Levels 1, 2, 3	Free of Defects	12 Mos
57845	Stat Profile Prime Plus® Ampuled Controls Chemistry Levels 4,5	Free of Defects	12 Mos

57812	Stat Profile Prime Plus® VET Ampuled Controls BG, COOX Levels 1, 2, 3	Free of Defects	12 Mos
57813	Stat Profile Prime Plus® VET Ampuled Controls Chemistry Levels 4,5	Free of Defects	12 Mos

Miscellaneous:

52669	Luer Station Safety Port (5/pack) (Prime/Prime-Plus)	Free of Defects
52582	Probe/S-Line Assy : Prime/Prime-Plus	Free of Defects
49200	Printer Paper (rolls: 5/pkg) (small-style)	Free of Defects

Electro-Mechanical Components & Assemblies

***Whichever comes first.**

NOTE: THE WARRANTED USE EXPRESSED ABOVE IS ONLY VALID IF IT OCCURS

PRIOR TO THE "USE BEFORE DATE" LISTED ON THE PACKAGE LABEL.