

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

**Product name:** StatStrip Glucose Meter Family:  
StatStrip and StatStrip Xpress Glucose Hospital Meters, StatStrip and StatStrip Xpress Glucose and B-Ketone Hospital Meters, Glucose Test Strips, Glucose Controls, Glucose Linearity Solutions, B-Ketone Test Strips, Glucose and B-Ketone Controls and Glucose and B-Ketone Linearity Solutions

**Catalog Numbers:** List Attached

**Classification:** Other/General

**Near 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 13A, Geb. G  
64546 Mörfelden-Walldorf  
Germany

**Conformity Assessment Annex III  
Route:**

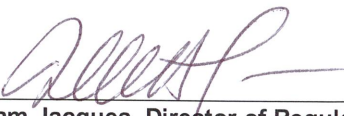
Nova Biomedical, Inc. declares that the products listed are in conformity with the provisions of the Council Directive 98/79/EC for in vitro diagnostic medical devices, including applicable essential requirements of Annex I for legal application of the CE Mark. All supporting documentation is retained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

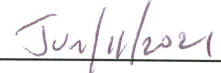
EN ISO 13485:2016	Quality Systems - Medical Devices- Regulatory Requirements
EN ISO 18113-1:2011	In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). Terms, definitions and general requirements
EN 50581:2012	Technical Documentation for the Assessment of Electrical 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. General requirements
EN 61010-2-101:2015	Safety requirements for electrical equipment for measurement, control and laboratory use. Particular requirements for in vitro diagnostic (IVD) medical equipment

**Signature:**

  
William Jacques, Director of Regulatory and Quality



**Date:**

  
Jun 14/2021

**List of Catalog Numbers covered:**

Catalog Number	Product Name	GMDN Number	Global Medical Device Nomenclature (GMDN) Name	DIMDI EDMS Code
41741	StatStrip StatStrip Xpress GLU Control Level 1	62538	Point-of-care blood glucose monitoring system IVD	11-70-01-01-00
41742	StatStrip StatStrip Xpress GLU Control Level 2	62538	Point-of-care blood glucose monitoring system IVD	11-70-01-01-00
41743	StatStrip StatStrip Xpress GLU Control Level 3	62538	Point-of-care blood glucose monitoring system IVD	11-70-01-01-00
42173	StatStrip StatStrip Xpress GLU Linearity Level 1, Level 2, Level 3, Level 4, Level 5	62538	Point-of-care blood glucose monitoring system IVD	11-70-01-01-00
42214	StatStrip StatStrip Xpress GLU - Test Strips	62538	Point-of-care blood glucose monitoring system IVD	11-70-01-01-00
42224 44993 47101 46766	StatStrip Glucose Meter with Battery and Quick Reference Guide	62538	Point-of-care blood glucose monitoring system IVD	11-70-01-01-00
42225	StatSensor StatStrip Docking Station	62644	Point-of-care blood glucose/ketone monitoring system IVD	11-70-01-90-00
43404 46799	StatStrip Xpress Glucose Meter with Battery and Quick Reference Guide	62538	Point-of-care blood glucose monitoring system IVD	11-70-01-01-00
43773 45886 47143 51707 47116	StatStrip GLU Meter with Quick Reference Guide - Remanufactured	62538	Point-of-care blood glucose monitoring system IVD	11-70-01-01-00
44321 46800	StatStrip Xpress Glucose Meter with Battery and Quick Reference Guide	62538	Point-of-care blood glucose monitoring system IVD	11-70-01-01-00
46447	StatStrip Xpress-i Glucose Meter with Battery and Quick Reference Guide	62538	Point-of-care blood glucose monitoring system IVD	11-70-01-01-00
46448	StatStrip Xpress-i Glucose Meter with Battery and Quick Reference Guide	62538	Point-of-care blood glucose monitoring system IVD	11-70-01-01-00
46945 47074	StatStrip Xpress-i GLU KET Meter with Battery and Quick Reference Guide	62644	Point-of-care blood glucose/ketone monitoring system IVD	11-70-01-90-00
46946 47073	StatStrip Xpress-i GLU KET Meter with Battery and Quick Reference Guide	62644	Point-of-care blood glucose/ketone monitoring system IVD	11-70-01-90-00
46947	StatStrip StatStrip Xpress Glu Ket Control, Level 1	62644	Point-of-care blood glucose/ketone monitoring system IVD	11-70-01-90-00
46948	StatStrip StatStrip Xpress Glu Ket Control, Level 2	62644	Point-of-care blood glucose/ketone monitoring system IVD	11-70-01-90-00
46949	StatStrip StatStrip Xpress Glu Ket Control, Level 3	62644	Point-of-care blood glucose/ketone monitoring system IVD	11-70-01-90-00
46950	StatStrip StatStrip Xpress Glu Ket Linearity, Level 1, Level 2, Level 3, Level 4, Level 5	62644	Point-of-care blood glucose/ketone monitoring system IVD	11-70-01-90-00
46951	StatStrip StatStrip Xpress KET - Test Strips	62644	Point-of-care blood glucose/ketone monitoring system IVD	11-70-01-90-00
47118 47107 50032	StatStrip GLU KET Meter with Battery and Quick Reference Guide	62644	Point-of-care blood glucose/ketone monitoring system IVD	11-70-01-90-00
47133 47117	StatStrip GLU KET Meter with Quick Reference Guide- Remanufactured	62644	Point-of-care blood glucose/ketone monitoring system IVD	11-70-01-90-00
47450	StatStrip Xpress-i GLU KET Meter MG/DL(10 EACH OF REF 47074)	62644	Point-of-care blood glucose/ketone monitoring system IVD	11-70-01-90-00
47451	StatStrip Xpress-i GLU KET Meter MMOL (10 EACH OF REF 47073)	62644	Point-of-care blood glucose/ketone monitoring system IVD	11-70-01-90-00
51994	StatSensor StatStrip Docking Station	62644	Point-of-care blood glucose/ketone monitoring system IVD	11-70-01-90-00
51995	StatSensor StatStrip Docking Station	62644	Point-of-care blood glucose/ketone monitoring system IVD	11-70-01-90-00

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Catalog Number	Product Name	GMDN Number	Global Medical Device Nomenclature (GMDN) Name	DIMDI EDMS Code
51996	StatSensor StatStrip Docking Station	62644	Point-of-care blood glucose/ketone monitoring system IVD	11-70-01-90-00
52320	StatSensor StatStrip Docking Station	62644	Point-of-care blood glucose/ketone monitoring system IVD	11-70-01-90-00
53398	StatStrip Glucose Meter with Battery and Quick Reference Guide	62538	Point-of-care blood glucose monitoring system IVD	11-70-01-01-00
53399	StatStrip GLU Meter - Remanufactured	62538	Point-of-care blood glucose monitoring system IVD	11-70-01-01-00
53400	StatSensor StatStrip Docking Station	62644	Point-of-care blood glucose/ketone monitoring system IVD	11-70-01-90-00
53401	StatSensor StatStrip Docking Station	62644	Point-of-care blood glucose/ketone monitoring system IVD	11-70-01-90-00
53402	StatSensor StatStrip Docking Station	62644	Point-of-care blood glucose/ketone monitoring system IVD	11-70-01-90-00
53577	StatStrip Glucose Meter with Battery and Quick Reference Guide (20 EACH OF REF 53398)	62538	Point-of-care blood glucose monitoring system IVD	11-70-01-01-00
53634	StatStrip Glucose Meter with Battery and Quick Reference Guide	62538	Point-of-care blood glucose monitoring system IVD	11-70-01-01-00
53712	StatStrip GLU KET Meter with Battery and Quick Reference Guide	62644	Point-of-care blood glucose/ketone monitoring system IVD	11-70-01-90-00
53755	StatStrip GLU KET Meter with Battery and Quick Reference Guide	62644	Point-of-care blood glucose/ketone monitoring system IVD	11-70-01-90-00
54790	StatStrip GLU Meter with Battery and Quick Reference Guide (wireless option)	62538	Point-of-care blood glucose monitoring system IVD	11-70-01-01-00
54796	StatStrip GLU KET Meter with Battery and Quick Reference Guide (wireless option)	62644	Point-of-care blood glucose/ketone monitoring system IVD	11-70-01-90-00
54798	StatStrip GLU KET Meter with Battery and Quick Reference Guide (wireless option)	62644	Point-of-care blood glucose/ketone monitoring system IVD	11-70-01-90-00
56506	StatStrip Xpress 2 GLU KET Meter with Battery and Quick Reference Guide	62644	Point-of-care blood glucose/ketone monitoring system IVD	11-70-01-90-00
56508	StatStrip Xpress 2 GLU KET Meter with Battery and Quick Reference Guide	62644	Point-of-care blood glucose/ketone monitoring system IVD	11-70-01-90-00
61290	StatStrip GLU KET Meter with Battery and Quick Reference Guide	62644	Point-of-care blood glucose/ketone monitoring system IVD	11-70-01-90-00
61292	StatStrip GLU KET Meter with Battery and Quick Reference Guide	62644	Point-of-care blood glucose/ketone monitoring system IVD	11-70-01-90-00
61293	StatStrip GLU KET Meter with Battery and Quick Reference Guide	62644	Point-of-care blood glucose/ketone monitoring system IVD	11-70-01-90-00
61295	StatStrip GLU KET Meter with Battery and Quick Reference Guide	62644	Point-of-care blood glucose/ketone monitoring system IVD	11-70-01-90-00
61296	StatStrip GLU KET Meter with Battery and Quick Reference Guide	62644	Point-of-care blood glucose/ketone monitoring system IVD	11-70-01-90-00
61297	StatStrip GLU KET Meter with Battery and Quick Reference Guide	62644	Point-of-care blood glucose/ketone monitoring system IVD	11-70-01-90-00
61298	StatStrip GLU KET Meter with Battery and Quick Reference Guide	62644	Point-of-care blood glucose/ketone monitoring system IVD	11-70-01-90-00
61299	StatStrip GLU KET Meter with Battery and Quick Reference Guide	62644	Point-of-care blood glucose/ketone monitoring system IVD	11-70-01-90-00
61500	StatStrip Xpress GLU - Test Strips	62538	Point-of-care blood glucose monitoring system IVD	11-70-01-01-00
61508	StatStrip GLU KET Meter with Battery and Quick Reference Guide	62644	Point-of-care blood glucose/ketone monitoring system IVD	11-70-01-90-00
61509	StatStrip GLU KET Meter with Battery and Quick Reference Guide	62644	Point-of-care blood glucose/ketone monitoring system IVD	11-70-01-90-00