



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

Product name: Nova StatSensor Creatinine Hospital Meter Family, Strips, Linearity Solutions, and Controls

Catalog Numbers: List Attached (one page)

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 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: 2012 Medical Devices- Application of Risk Management to Medical Devices

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. Particular requirements for in vitro diagnostic (IVD) medical equipment

Signature: 
William Jacques, Director of Regulatory and Quality



Date: Jun/11/2021

List of catalog items covered:

Catalog Number	Product Name	GMDN Number	Global Medical Device Nomenclature (GMDN) Name	DIMDI EDMS Number
43272	StatSensor -i Creatinine Test Strips (Dual Pack)	53252	Creatinine IVD, reagent	11-70-01-90-00
43370	StatSensor Creatinine Test Strips	53252	Creatinine IVD, reagent	11-70-01-90-00
43921	StatSensor Creatinine Control Solution, Level 1	44699	Creatinine IVD, control	11-70-01-50-00
43922	StatSensor Creatinine Control Solution, Level 2	44699	Creatinine IVD, control	11-70-01-50-00
43923	StatSensor Creatinine Control Solution, Level 3	44699	Creatinine IVD, control	11-70-01-50-00
44037	StatSensor Creatinine Linearity Kit	44699	Creatinine IVD, control	11-70-01-50-00
44052	StatSensor Creatinine Meter with Battery and Quick Reference Guide	64382	Creatinine monitoring system IVD, point-of-care	21-01-19
45328	StatSensor -i Creatinine Hospital Meter Kit	64382	Creatinine monitoring system IVD, point-of-care	21-01-19
45333	StatSensor -i Creatinine Hospital Meter Kit (Remanufactured)	64382	Creatinine monitoring system IVD, point-of-care	21-01-19
45335	StatSensor Creatinine Hospital Meter with Quick Reference Guide- Remanufactured	64382	Creatinine monitoring system IVD, point-of-care	21-01-19
48635	StatSensor Xpress Creatinine Hospital Meter umol/L	64382	Creatinine monitoring system IVD, point-of-care	21-01-19
48727	StatSensor Xpress Creatinine Hospital Meter mg/dL	64382	Creatinine monitoring system IVD, point-of-care	21-01-19
50668	StatSensor Creatinine Meter with Battery and Quick Reference Guide	64382	Creatinine monitoring system IVD, point-of-care	21-01-19



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

This addendum covers the products listed on the Declaration of Conformity for:

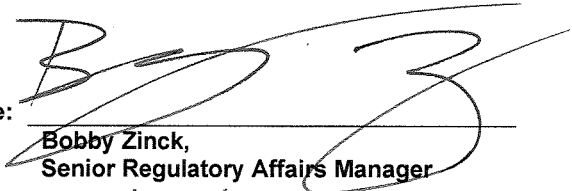
Product name: StatSensor-I Creatinine Meter and StatSensor Xpress Creatinine Meter

List of products removed and included in Declaration of Conformity according to Regulation (EU) 2017/746 of the European Parliament and of the Council In Vitro Diagnostic medical Device Regulation (IVDR):

Catalog Number	Product Name	GMDN Number	Global Medical Device Nomenclature (GMDN) Name	DIMDI EDMS Code	IVDR Declaration of Conformity
45328	StatSensor-i Creatinine Meter with Battery and Quick Reference Guide	64382	Creatinine monitoring system IVD, point-of-care	21-01-19	StatSensor-I Creatinine Meter and StatSensor Xpress Creatinine Meter
48727	StatSensor Xpress Creatinine Meter with Battery and Quick Reference Guide	64382	Creatinine monitoring system IVD, point-of-care	21-01-19	StatSensor-I Creatinine Meter and StatSensor Xpress Creatinine Meter
48635	StatSensor Xpress Creatinine Meter with Battery and Quick Reference Guide	64382	Creatinine monitoring system IVD, point-of-care	21-01-19	StatSensor-I Creatinine Meter and StatSensor Xpress Creatinine Meter
45333	StatSensor-i Crea Meter with Quick Reference Guide- Remanufactured	64382	Creatinine monitoring system IVD, point-of-care	21-01-19	StatSensor-I Creatinine Meter and StatSensor Xpress Creatinine Meter

List of products removed from this Declaration of Conformity:

Catalog Number	Product Name	GMDN Number	Global Medical Device Nomenclature (GMDN) Name	DIMDI EDMS Code	IVDR Declaration of Conformity
44052	StatSensor Creatinine Meter with Battery and Quick Reference Guide	64382	Creatinine monitoring system IVD, point-of-care	21-01-19	StatSensor Creatinine Hospital Meter Family, Strips, Linearity Solutions, and Controls 06-07-21
45335	StatSensor Creatinine Hospital Meter with Quick Reference Guide- Remanufactured	64382	Creatinine monitoring system IVD, point-of-care	21-01-19	StatSensor Creatinine Hospital Meter Family, Strips, Linearity Solutions, and Controls 06-07-21
50668	StatSensor Creatinine Meter with Battery and Quick Reference Guide	64382	Creatinine monitoring system IVD, point-of-care	21-01-19	StatSensor Creatinine Hospital Meter Family, Strips, Linearity Solutions, and Controls 06-07-21
43370	StatSensor Creatinine Test Strips	53252	Creatinine IVD, Reagent	11-70-01-90-00	StatSensor Creatinine Hospital Meter Family, Strips, Linearity Solutions, and Controls 06-07-21

Signature: 
Bobby Zinck,
 Senior Regulatory Affairs Manager

Date: 8/31/23