



Self-Declaration of Conformity  
To  
Council Directive 98/79/EC  
In Vitro Diagnostic Medical Device Directive (IVDD)  
For Applying CE Mark

**Product name:** Nova StatStrip Xpress Glucose Hospital Meter,  
Glucose Test Strips, Glucose Controls  
and Glucose Linearity Solutions

**Catalog Numbers:** List Attached

**Classification:** Not listed in Annex II and are not self-test devices

**Manufacturer:** Nova Biomedical, Corp.  
200 Prospect Street  
Waltham, MA 02454-9141

**Representative:** Paul MacDonald, Chief QA and RA Officer

**European Representative:** Nova Biomedical UK  
C3-5, Evans Business Centre, Deeside Industrial Park  
Deeside, Flintshire, UK, CH5 2JZ

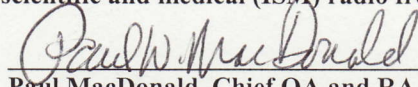
**Conformity Assessment Route:** Annex III

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.

**Standards Applied:**

ISO 13485: 2003	Quality Systems-Medical Devices- Regulatory Requirements
EN61010-2-101: 2002	Safety requirements for electrical equipment for measurement, control and laboratory use
EN61000-4-2: 1998	Electromagnetic compatibility – Testing & measurement techniques – radiated, radio-frequency, electromagnetic field immunity test
EN61000-4-3 2002	Electromagnetic compatibility (EMC)
EN61000-4-4 2000	Amendment 1. EMC
EN61000-4-8 2001	Testing and measurement techniques.. power frequency magnetic field immunity test
EN 55011:1998	Limits and methods measurement radio disturbance characteristics of industrial, scientific and medical (ISM) radio frequency equipment

**Signature:**

  
Paul MacDonald, Chief QA and RA Officer  
15 April 2008

**Date:**



List of catalog #s covered:

<b>Product Name</b>	<b>Catalog Number</b>	<b>EU Group Name/Number (EDMS)</b>	<b>EU Group Name/Number (GMDN)</b>
Nova StatStrip Glucose Test Strips, 25 per vial, 2 vials per package	42214	Blood Glucose test strip 11 70 01 01	Blood Glucose test strip 30221
Nova StatStrip Glucose Assayed Control Solution, Level 1, One bottle	41741	Diabetes Control 11 50 02 05	Glucose Control 41819
Nova StatStrip Glucose Assayed Control Solution, Level 2, One bottle	41742	Diabetes Control 11 50 02 05	Glucose Control 41819
Nova StatStrip Glucose Assayed Control Solution, Level 3, One bottle	41743	Diabetes Control 11 50 02 05	Glucose Control 41819
Nova StatStrip Glucose Linearity Kit, 5 levels, 1 bottle of each level	42173	Diabetes Control 11 50 02 05	Diabetes Control 41819
Battery for Nova StatStrip Xpress Glucose Hospital Meter	41221	Diabetes Management Hardware +Dedicated Accessories+ Software 21 07 10 01	Battery, secondary 34158
Nova StatStrip Xpress Glucose Hospital Meter Kit	43462	Diabetes Management Hardware +Dedicated Accessories+ Software 21 07 10 01*	Glucose Kit 30167
Nova StatStrip Xpress Glucose Hospital Meter	43404	Diabetes Management Hardware +Dedicated Accessories+ Software 21 07 10 01*	Glucose Kit 30167

*NOTES:*

*\*Also corresponds to 11 02 01 13 Glucose kit*