



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

Product name: StatStrip Glucose Hospital Meter Strips, Linearity solutions, and Controls

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

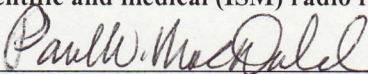
Conformity Assessment Route: Annex III

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

Date:

4/4/2008



List of catalog #s covered:

Product Name	Catalog Number	EU Group Name/Number (EDMS)	EU Group Name/Number (GMDN)
StatStrip Glucose Hospital Meter (only) with Barcode Reader	41508,44015, 44016, 44249 and 44252	Diabetes Management Hardware +Dedicated Accessories+ Software 21 07 10 01*	Glucose Kit** 30167
StatStrip Glucose Hospital Meter (includes meter, 2 batteries & quick reference guide)	42224, 44013, 44014, 44250, and 44251	Diabetes Management Hardware +Dedicated Accessories+ Software 21 07 10 01*	Glucose Kit** 30167
StatStrip Glucose Hospital Meter (only) without Barcode Reader	42290	Diabetes Management Hardware +Dedicated Accessories+ Software 21 07 10 01*	Glucose Kit** 30167
StatStrip Docking Station with AC Adapter	42225	Diabetes Management Hardware +Dedicated Accessories+ Software 21 07 10 01	Battery Charger 17115
StatStrip Glucose Test Strips	42214	Blood Glucose test strip 11 70 01 01	Blood Glucose test strip 30221
StatStrip Glucose Test Strips	43282	Blood Glucose test strip 11 70 01 01	Blood Glucose test strip 30221
StatStrip Glucose Assayed Control Solution, Level 1, One bottle	41741	Diabetes Control 11 50 02 05	Glucose Control 41819
StatStrip Glucose Assayed Control Solution, Level 2, One bottle	41742	Diabetes Control 11 50 02 05	Glucose Control 41819
StatStrip Glucose Assayed Control Solution, Level 3, One bottle	41743	Diabetes Control 11 50 02 05	Glucose Control 41819
StatStrip Glucose Linearity Kit, 5 levels, 1 bottle of each level	42173	Haematology Control and Calibrators 13 01 20 00	Haematology Control / Calibrators 30531
Battery for StatStrip Hospital Meter, 4-Pack	42215	Diabetes Management Hardware +Dedicated Accessories+ Software 21 07 10 01	Battery, secondary 34158