



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

**Product name:** Nova StatSensor Creatinine 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

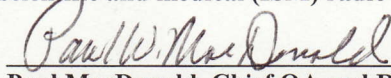
**Conformity Assessment Route:** Annex III

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:**

15 July 2008



List of catalog #s covered:

Product Name	Catalog Number	EU Group Number (EDMS)
Nova StatSensor Creatinine Hospital Meter	44011	11 02 01 07
Nova StatSensor Creatinine Hospital Meter (Remanufactured)	44069	11 02 01 07
Nova StatSensor Creatinine Hospital Meter Kit	44052	11 02 01 07
Nova StatSensor Creatinine Docking Station	42225	21 09 10 01
Nova StatSensor Creatinine Test Strips	43370	11 02 01 07
Nova StatSensor Creatinine Control Solution, Level 1	43921	11 50 02 90
Nova StatSensor Creatinine Control Solution, Level 2	43922	11 50 02 90
Nova StatSensor Creatinine Control Solution, Level 3	43923	11 50 02 90
Nova StatSensor Creatinine Linearity Kit	44037	11 50 02 90
Battery for Nova StatSensor Creatinine Hospital Meter Kit	42215	21 09 10 01