



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-i Creatinine Hospital Meter Strips, Linearity solutions, and Controls

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

Manufacturer: Nova Biomedical, Corporation
200 Prospect Street Waltham, MA 02454-9141

Representative: Dr. 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 by the manufacturer.

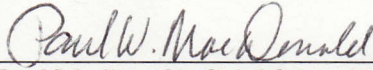
Standards Applied:

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

List of catalog #s covered:

Product Name	Catalog Number	EU Group Number (EDMS)
Nova StatSensor -i Creatinine Hospital Meter	45329	11 02 01 07
Nova StatSensor -i Creatinine Hospital Meter (Remanufactured)	45333	11 02 01 07
Nova StatSensor -i Creatinine Hospital Meter Kit	45328	11 02 01 07

Signature:


Paul MacDonald, Chief QA and RA Officer

21 July 2008
Date:

