

# *nova*

## *biomedical*

### **Prohlášení o shodě s IVVD 98/79/EC**

- Název výrobku:** Stat Profile CCX Analyzátory včetně reagentů, kalibrátorů a kontrol
- Katalogová čísla:** viz seznam v příloze (3 strany)
- Klasifikace:** nepodléhají Dodatku II a nejsou prostředkem pro sebetestování
- Výrobce:** Nova Biomedical, Corp.  
200 Prospect Street  
Waltham, MA 02454-9141
- Zástupce:** Paul MacDonald, hlavní vedoucí QA a RA
- Evropský zástupce:** Nova Biomedical UK  
C3-5, Evans Business Centre, Deeside Industrial Park  
Deeside, Flintshire, UK, CH5 2JZ
- Postup vyhodnocení shody:** Dodatek IV

Nova Biomedical, Inc, prohlašuje, že uvedené výrobky jsou v souladu s ustanoveními Směrnice Rady Evropy 98/79/EC pro zdravotnické prostředky in vitro, včetně platných základních požadavků Dodatku I. Veškerá podpůrná dokumentace je uchována v sídle výrobce.

- Použité standardy:** ISO 13485: 2000  
EN41010-1/A2: 1995  
EN55011, 1991  
EN60601-1-2

**Podpis:** \_\_\_\_\_  
Paul MacDonald, hlavní vedoucí QA a RA

**Datum:** 9. prosince 2003



Declaration of Conformity  
To  
IVDD 98/79/EC

Product name: Stat Profile CCX Analyzers including Reagents, Calibrators and Controls

Catalog Numbers: List Attached (two pages)

Classification: Not subject to 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 IV

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. All supporting documentation is retained under the premises of the manufacturer.

Standards Applied: ISO 13485: 2000  
EN61010-1/A2: 1995  
EN55011, 1991  
EN60601-1-2

Signature:   
Paul MacDonald, Chief QA and RA Officer

Date: 9 Dec 2003

List of catalog #s covered:

Product Name	Catalog Number	EU Group Name	EU Group Number
Linearity Standard Set C Level 1	13519	Aqueous Standards	11 50 03 03 00
Linearity Standard Set C Level 2	13520	Aqueous Standards	11 50 03 03 00
Linearity Standard Set C Level 3	13521	Aqueous Standards	11 50 03 03 00
Linearity Standard Set C Level 4	13522	Aqueous Standards	11 50 03 03 00
Linearity Standard Set F Level 1	17461	Aqueous Standards	11 50 03 03 00
Linearity Standard Set F Level 2	17462	Aqueous Standards	11 50 03 03 00
Linearity Standard Set F Level 3	17463	Aqueous Standards	11 50 03 03 00
Linearity Standard Set F Level 4	17464	Aqueous Standards	11 50 03 03 00
Linearity Standard Set G Level 1	24877	Aqueous Standards	11 50 03 03 00
Linearity Standard Set G Level 2	24878	Aqueous Standards	11 50 03 03 00
STP pH <sub>OX</sub> and CCX SO <sub>2</sub> % Calibrator	22771	Aqueous Standards	11 50 03 03 00
tHb Calibrator CO-Ox	18100	Aqueous Standards	11 50 03 03 00
STP CCX Calibrator Cartridge 1	36253	Calibrators and Standards CC Multicomponent	11 50 03 01 00
STP CCX Calibrator Cartridge 1 with Creatinine	36254	Calibrators and Standards CC Multicomponent	11 50 03 01 00
STP CCX Calibrator Cartridge 2	36251	Calibrators and Standards CC Multicomponent	11 50 03 01 00
STP CCX Calibrator Cartridge 2 with Creatinine	36252	Calibrators and Standards CC Multicomponent	11 50 03 01 00
STP CCX Calibrator Cartridge 3	36640	Calibrators and Standards CC Multicomponent	11 50 03 01 00
STP CCX Calibrator Cartridge 4	37164	Calibrators and Standards CC Multicomponent	11 50 03 01 00
STP CCX Calibrator Cartridge 4 with Creatinine	37168	Calibrators and Standards CC Multicomponent	11 50 03 01 00
STP CCX CO-Ox Reagent Cartridge	35150	Calibrators and Standards CC Multicomponent	11 50 03 01 00
Blank Sensor ISE	37267	Electrode	
Blank Sensor Metabolites	22507	Electrode	
Blank Sensor Na/pH only	37270	Electrode	
BUN Membrane	35239	Electrode	
BUN Sensor	34966	Electrode	11 04 03 05 00
Calcium Sensor	37272	Electrode	11 04 01 02 00
Chloride Sensor	37274	Electrode	11 04 01 03 00
Creatinine Membrane	35238	Electrode	
Creatinine Sensor	35223	Electrode	11 04 03 01 00
Glucose Membrane	35236	Electrode	
Glucose Sensor	35222	Electrode	11 04 03 02 00
Lactate Membrane	35237	Electrode	
Lactate Sensor	35221	Electrode	11 04 03 04 00
Magnesium Sensor	37271	Electrode	11 04 01 05 00
PCO <sub>2</sub> Membrane	35283	Electrode	
PCO <sub>2</sub> Sensor	35286	Electrode	11 04 02 01 00
pH Sensor	37266	Electrode	11 04 02 02 00
PO <sub>2</sub> Membrane	35284	Electrode	
PO <sub>2</sub> Sensor	35285	Electrode	11 04 02 03 00
Potassium Sensor	37273	Electrode	11 04 01 06 00
Reference sensor	37269	Electrode	
SO <sub>2</sub> Sensor	21512	Electrode	11 04 02 03 00
Sodium Sensor	37264	Electrode	11 04 01 07 00

Product Name	Catalog Number	EU Group Name	EU Group Number
CCX 1	35942	Medium Automated CC Analyzer	21 01 42
CCX 1 (15 tests)	36788	Medium Automated CC Analyzer	21 01 42
CCX 1+	37413	Medium Automated CC Analyzer	21 01 42
CCX 1+ (with CO-OX)	36790	Medium Automated CC Analyzer	21 01 42
CCX 2 (12 tests)	36787	Medium Automated CC Analyzer	21 01 42
CCX 2+	36791	Medium Automated CC Analyzer	21 01 42
CCX 3 (3 tests)	36963	Medium Automated CC Analyzer	21 01 42
CCX 3+	36792	Medium Automated CC Analyzer	21 01 42
CCX 4 (10 tests)	36961	Medium Automated CC Analyzer	21 01 42
CCX 4+	37677	Medium Automated CC Analyzer	21 01 42
Nova Cleaning Solution	11272	Other Clinical Chemistry (Reagents)	11 90 01
Nova CO-Oximeter Deproteinizing Solution	18098	Other Clinical Chemistry (Reagents)	11 90 01
Nova Glu/Lac Sensor Soaking Solution	13409	Other Clinical Chemistry (Reagents)	11 90 01
PCO2/TCO2 Conditioning Solution	06857	Other Clinical Chemistry (Reagents)	11 90 01
Preheater Deproteinizing Solution	12704	Other Clinical Chemistry (Reagents)	11 90 01
Performance Check Solution	17457	Other Controls Clinical Chemistry	11 50 90 90 00
STP CCX Blood Gas Auto-Cartridge 3/day	36625	Other Controls Clinical Chemistry	11 50 90 90 00
STP CCX Blood Gas Auto-Cartridge 6/day	36626	Other Controls Clinical Chemistry	11 50 90 90 00
STP CCX Blood Gas Auto-Cartridge 9/day	36627	Other Controls Clinical Chemistry	11 50 90 90 00
STP CCX Chemistry Auto-Cartridge 2/day	36628	Other Controls Clinical Chemistry	11 50 90 90 00
STP CCX Chemistry Auto-Cartridge 4/day	36629	Other Controls Clinical Chemistry	11 50 90 90 00
STP CCX Chemistry Auto-Cartridge 6/day	36630	Other Controls Clinical Chemistry	11 50 90 90 00
STP CCX Chemistry Auto-Cartridge with Creatinine 2/day	37161	Other Controls Clinical Chemistry	11 50 90 90 00
STP CCX Chemistry Auto-Cartridge with Creatinine 4/day	37162	Other Controls Clinical Chemistry	11 50 90 90 00
STP CCX Chemistry Auto-Cartridge with Creatinine 6/day	37163	Other Controls Clinical Chemistry	11 50 90 90 00
STP CCX Controls 1 2 3	35638	Other Controls Clinical Chemistry	11 50 90 90 00
STP CCX Controls 4 5	35644	Other Controls Clinical Chemistry	11 50 90 90 00
STP CCX CO-Ox Auto-Cartridge 3/day	35618	Other Controls Clinical Chemistry	11 50 90 90 00
STP CCX CO-Ox Auto-Cartridge 6/day	37609	Other Controls Clinical Chemistry	11 50 90 90 00
STP CCX CO-Ox Auto-Cartridge 9/day	37598	Other Controls Clinical Chemistry	11 50 90 90 00
STP CCX CO-Ox Controls 7 8 9	18099	Other Controls Clinical Chemistry	11 50 90 90 00
Back Up Power Supply 220/240V	33169		
Bar Code Scanner	23591		
Stat Cart: Cart Only	37223		
Stat Cart: Complete 240V	37800		