



# Declaration of Conformity



**We: Vital Scientific B.V.  
Van Rensselaerweg 4  
6956 AV Spankeren/Dieren  
The Netherlands**

Declare under sole responsibility that the product indicated below (including all spares and accessories) and to which this declaration relates, conforms to the provisions of the EU Directive on *In Vitro* Diagnostic Medical Devices (98/79/EC) of the European Parliament and the Council of 27 October 1998. It is certified that this product is registered in accordance with the requirements of above mentioned EU Directive and carries the CE mark.

**Product : Clinical chemistry analyzer**  
**Model : Selectra ProM**  
**Catalog No. : 6002-400**  
**GMDN code : 56678 (Analyzer)**  
**: 56682 (Drye ISE)**

## Product classification

Products for self declaration (also referred to as: "Other Devices")

## Conformity assessment procedure

In accordance with Annex III of the IVDD

The product (including all spares and accessories) may be marketed without any restrictions within the following countries and regions:

- The Netherlands (NL)
- All member states of the European Union (EU)
- All other states that are part of the European Economic Area (EEA)

Spankeren, February 2011

A. Altink  
Managing Director

Code: 6003 - 400

Doc. no.: 510

Version: 02



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## List of applied (harmonized) standards

Applied standards		
<b>Safety</b>	IEC 61010-1:2001 Second edition	Safety requirements for electrical equipment for measurement, control, and laboratory use. Part 1: General requirements
	IEC 61010-2-081:2001 First edition	Safety requirements for electrical equipment for measurement, control, and laboratory use. Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
	IEC 61010-2-101:2002 First edition	Safety requirements for electrical equipment for measurement, control, and laboratory use. Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical devices
<b>EMC</b>	EN 61326-1:2006	Equipment for measurement, control and laboratory use
	EN 61326-2-6:2005	Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – In Vitro diagnostic (IVD) medical equipment
	EN55011:2007	Emission – class A
	EN 61000-3-2:2006	Limit for harmonic currents emissions
	EN 61000-3-3:1995 +A1:2001, +A2:2005	Limitation of voltage fluctuations and flicker
	EN 61000-4-2:1995 +A1:1998, +A2:2001	Electrostatic discharge (ESD) immunity
	EN 61000-4-3:2006	Radiated electromagnetic field immunity
	EN 61000-4-4:2004	Electrical fast transient (EFT) immunity
	EN 61000-4-5:2006	Surge transient immunity
	EN 61000-4-6:1996 +A1:2001	Conducted Radio-Frequency disturbances immunity
	EN 61000-4-11:2004	Voltage dips and interruptions immunity
<b>User Manual</b>	EN 591:2001	In vitro diagnostic systems – Requirements for user manuals for in vitro diagnostic instruments for professional use.
<b>Performance</b>	EN 13612:2003	Performance evaluation of IVD medical devices
<b>Symbols</b>	EN 980:2003	Graphical Symbols for use in the labelling of medical devices
<b>Risk analysis</b>	ISO 14971:2007	Medical devices - Application of risk management to medical devices
<b>Quality systems</b>	ISO 9001:2008	Quality systems - Model for quality assurance in design, development, production, installation and servicing.
	ISO 13485:2003	Medical devices—Quality management systems—Requirements for regulatory purposes.

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