# 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 XL** |
| **Catalog No.** | **: 6002-600** |
| **GMDN code** | **: 56678 (Analyzer)** |
| | **: 56682 ( Dry 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

Digitally signed by Ceaicovschi Tudor
Date: 2024.10.03 16:44:22 EEST
Reason: MoldSign Signature
Location: Moldova

| CE | Declaration of Conformity | ELITechGroup VITAL SCIENTIFIC |
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## List of applied (harmonized) standards

| Applied standards | | |
|---|---|---|
| **Safety** | 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 |
| **EMC** | 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 |
| **User Manual** | EN 591:2001 | In vitro diagnostic systems – Requirements for user manuals for in vitro diagnostic instruments for professional use. |
| **Performance** | EN 13612:2003 | Performance evaluation of IVD medical devices |
| **Symbols** | EN 980:2003 | Graphical Symbols for use in the labeling of medical devices |
| **Risk analysis** | ISO 14971:2007 | Medical devices - Application of risk management to medical devices |
| **Quality systems** | 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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**Product : Clinical chemistry analyzer**
**Model : Selectra ProS**
**Catalog No. : 6003-500**
**GMDN code : 56678 (Analyzer)**
**: 56682 ( Dry ISE)**

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| | 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 |
| **EMC** | 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 |
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| | EN 61000-3-3:1995 +A1:2001, +A2:2005 | Limitation of voltage fluctuations and flicker |
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