# 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

Digitally signed by Ceaicovschi Tudor
Date: 2023.07.26 11:05:46 EEST
Reason: MoldSign Signature
Location: Moldova

# Declaration of Conformity

## 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 labelling 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)**

## Product classification

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

## Conformity assessment procedure

In accordance with Annex III of the IVDD

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

Spankeren, February 2011

A.Altink
Managing Director

| CE | Declaration of Conformity | ELITechGroup VITAL SCIENTIFIC |
|---|---|---|

## 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 labelling 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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www.elitechgroup.com
Chamber of Commerce 09175642

To: Whom it May Concern

# Regulatory status of parts & accessories

As mentioned on the current Declarations of Conformity of our Clinical Chemistry Analyzers also the accessories conform to the provisions of the EU Directive on In Vitro Diagnostic Medical Devices (98/79/EC). This applies to the parts and accessories as mentioned in the attached list.

'IVD accessory' means an article which, whilst not being an IVD medical device, is intended specifically by its manufacturer to be used together with an IVD device to enable that IVD device to be used in accordance with its intended purpose.

ELITechGroup B.V.

Adriaan P. Intveld
Manager Quality Assurance & Regulatory Affairs

ELITechGroup
CLINICAL SYSTEMS

| Part number | Description | IVD medical device | IVD accessory | general laboratory use | spare part | supporting part |
|---|---|---|---|---|---|---|
| 1540-001 | Anti-Slip sheet | | | | | ✓ |
| 2206-007 | Cooling Liquid (1 L) | | | | | ✓ |
| 3062-021 | Sample cup (1000 pcs) | | ✓ | | | |
| 3062-033 | Sample tube 6 ml (500 pcs) | | | | | ✓ |
| 3062-040 | Water container 10 L | | | | | ✓ |
| 3062-041 | Water container 5 L | | | | | ✓ |
| 3066-155 | Syringe 100 µl | | ✓ | | | |
| 3066-156 | Syringe 1 ml | | ✓ | | | |
| 3069-040 | Keyboard Dust cover | | | | | ✓ |
| 3069-047 | Keyboard Dust cover | | | | | ✓ |
| 3070-518 | Cap holder | | | | | ✓ |
| 3070-538 | Cap rotor Left | | | | | ✓ |
| 3070-539 | Cap rotor right | | | | | ✓ |
| 3201-002 | Dichromate 8 Abs (25ml) | | ✓ | | | |
| 3365-192 | USB Stick | | | | | ✓ |
| 3374-003 | Mains cable (USA) | | | | | ✓ |
| 3374-059 | Pumpunit cable | | ✓ | | | |
| 3374-066 | Mains cable | | | | | ✓ |
| 3374-097 | Serial Null-modem cable | | | | | ✓ |
| 3374-286 | USB Extension cable | | | | | ✓ |
| 4804-038 | Reagent identification Disc | | | | | ✓ |
| 6001-826 | Diluted Waste container | | ✓ | | | |
| 6001-827 | Concentrated Waste container | | ✓ | | | |
| 6001-860 | Water container | | ✓ | | | |
| 6001-861 | Tube assy (analyser) | | ✓ | | | |
| 6001-872 | Tube assy (cooling unit) | | ✓ | | | |
| 6002-102 | Assorter unit | | | | ✓ | |
| 6002-386 | System software on CD | | ✓ | | | |
| 6002-706 | Reaction Rotor set (3 pcs) | | ✓ | | | |
| 6002-726 | System Disc | | ✓ | | | |
| 6002-817 | Bottle 30 ml (20 pcs) | | ✓ | | | |
| 6002-818 | Bottle 15 ml (20 pcs) | | ✓ | | | |
| 6002-904 | Water container 5 L | | ✓ | | | |
| 6002-910 | Assorter unit | | | | ✓ | |
| 6002-913 | External tubing | | ✓ | | | |
| 6003-074 | System software on USB stick | | ✓ | | | |
| 6003-444 | Diluted Waste Container 5 L | | ✓ | | | |
| 6003-466 | Keyboard Support option | | | | | ✓ |
| 6003-797 | CW Waste Container 2 L | | ✓ | | | |
| 6003-808 | Assorter unit | | | | ✓ | |

# CERTIFICATO N° 505SGQ05

*CERTIFICATE N° 505SGQ05*

Si certifica che il
*this is to certify that*

## Sistema di Gestione per la Qualità

*Quality Management System*

messo in atto da
*implemented by*

## APTACA S.p.A.

Via Monte Bianco, 4 – IT 20900 MONZA (MB)

nella Sede Operativa di
*Operative Unit*

Regione Monforte, 30 – IT 14053 CANELLI (AT)

è conforme alla norma
*is in compliance with the standard*

**UNI EN ISO 9001-2015 (ISO 9001-2015)**

per i seguenti Processi
*concerning the following kinds of Processes*

**Gestione della fabbricazione ed immissione in commercio di tamponi sterili per il prelievo di campioni biologici in orifizi naturali e in ambito chirurgico. Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi. Gestione della fabbricazione ed immissione in commercio di dispositivi medici invasivi in relazione agli orifizi del corpo in Classe I Sterile. Fabbricazione di dispositivi medici invasivi in relazione agli orifizi del corpo in Classe I Sterile. Commercializzazione di dispositivi medici e diagnostici in vitro. Commercializzazione di articoli da laboratorio**

*Management of the manufacturing and placing on the market of sterile tampons for sampling of biological specimens in natural orifice and in surgical field. Design and manufacturing of diagnostic medical devices for laboratories of analysis. Management of the manufacturing and placing on the market of invasive medical devices with respect to body orifices (class I sterile). Manufacturing of invasive medical devices with respect to body orifices (class I sterile). Marketing of medical and diagnostic devices in vitro. Marketing of laboratory articles.*

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la certificazione in vigore applicabili.
*This Certificate shall satisfy the requirements established in the Rules for the certification in force applicable.*
In caso di discordanza tra le lingue utilizzate nella traduzione del contenuto del presente certificato, fare riferimento alla lingua italiana
*In cases of discrepancy between the languages used in the translation of the content of this certificate, please refer to the Italian language*

L'AMMINISTRATORE DELEGATO
*MANAGING DIRECTOR*

Dr. Ing. Roberto Cusolito

| Data di Prima Emissione<br>*First Issue Date* | Data di Prima Emissione ITALCERT<br>*First Issue Date ITALCERT* | Data di Rinnovo<br>*Renewal Date* | Data di Scadenza<br>*Expiration Date* |
|---|---|---|---|
| 1998-07-23 | 2011-10-30 | 2020-10-30 | 2023-10-29 |

Settore IAF 14 - 29

SGQ N° 023A
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
*Signatory of EA, IAF and ILAC Mutual Recognition Agreements*

ITALCERT S.r.l. | Viale Sarca, 336 – 20126 Milano (MI) | tel. +39 0266104876 | fax. +39 0266101479 | www.italcert.it | italcertsrl@legalmail.it

# CERTIFICATO N° 505DM07

*CERTIFICATE N° 505DM07*

Si certifica che il
*this is to certify that*

## Sistema di Gestione per la Qualità

*Quality Management System*

messo in atto da
*implemented by*

## APTACA S.p.A.

Via Monte Bianco, 4 – IT 20900 MONZA (MB)

nella Sede Operativa di
*Operative Unit*

**Regione Monforte, 30 – IT 14053 CANELLI (AT)**

è conforme alla norma
*is in compliance with the standard*

**UNI CEI EN ISO 13485-2016 (ISO 13485-2016)**

per i seguenti Processi
*concerning the following kinds of Processes*

**Gestione della fabbricazione e immissione in commercio di tamponi sterili per il prelievo di campioni biologici in orifizi naturali e in ambito chirurgico. Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi. Gestione della fabbricazione ed immissione in commercio di dispositivi medici invasivi in relazione agli orifizi del corpo in Classe I Sterile. Fabbricazione di dispositivi medici invasivi in relazione agli orifizi del corpo in Classe I Sterile. Commercializzazione di dispositivi medici e diagnostici in vitro.**

*Management of the manufacturing and placing on the market of sterile tampons for sampling of biological specimens in natural orifice and in surgical field. Design and manufacturing of diagnostic medical devices for laboratories of analysis. Management of the manufacturing and placing on the market of invasive medical devices with respect to body orifices (class I sterile). Manufacturing of invasive medical devices with respect to body orifices (class I sterile). Marketing of medical and diagnostic devices in vitro.*

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L'AMMINISTRATORE DELEGATO
*MANAGING DIRECTOR*

Dr. Ing. Roberto Cusolito

| Data di Prima Emissione<br>*First Issue Date* | Data di Prima Emissione ITALCERT<br>*First Issue Date ITALCERT* | Data di Rinnovo<br>*Renewal Date* | Data di Scadenza<br>*Expiration Date* |
|---|---|---|---|
| 2007-10-30 | 2011-10-30 | 2020-10-30 | 2023-10-29 |

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# CERTIFICATE

This is to certify that

## Powertronix Inc.

1120 Chess Drive
Foster City, CA 94404
United States of America

has implemented and maintains a **Quality Management System**.

Scope:
The Design and Manufacture of Power, Distribution and Specialty Transformers & Power Solutions.

Through an audit, documented in a report, it was verified that the management system fulfills the requirements of the following standard:

## ISO 9001 : 2015

| | |
|---|---|
| Certificate registration no. | 10002386 QM15 |
| Date of original certification | 2007-06-01 |
| Date of revision | 2022-02-07 |
| Date of certification | 2021-03-20 |
| Valid until | 2024-03-19 |

**DQS Inc.**

Brad McGuire
Managing Director

Accredited Body: DQS Inc., 1500 McConnor Parkway, Suite 400, Schaumburg, IL 60173 USA