



## 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 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

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: 6003-500

Doc. no.: 510

Version: 02

	<h1 style="text-align: center;">Declaration of Conformity</h1>	
-----------------------------------------------------------------------------------	----------------------------------------------------------------	-------------------------------------------------------------------------------------

## 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
	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.

Code: 6003-500	Doc. no.: 510	Version: 02
----------------	---------------	-------------

# Certificate of Approval

This is to certify that the Management System of:

**VitalScientific B.V.**

Van Rensselaerweg 4, 6956 AV Spankeren, The Netherlands

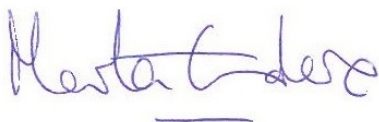
has been approved by LRQA to the following standards:

**ISO 13485:2016**

Approval number(s): ISO 13485 – 00020722

**The scope of this approval is applicable to:**

Design, development and manufacturing of clinical chemistry analyzers and contract manufacturing of ion-selective electrodes (ISE) and erythrocyte sedimentation rate (ESR) analyzers.



**Marta Escudero**

Regional Director, Europe

Issued by: LRQA Limited



**GMED certifie que le système de management de la qualité développé par**  
*GMED certifies that the quality management system developed by*

**VitalScientific**

**Zone industrielle**  
**61500 SEES FRANCE**

**pour les activités**  
*for the activities*

**Conception, production, contrôle et commercialisation de produits de chimie cliniques  
pour le diagnostic in vitro. Validation de la combinaison réactifs et automates.**  
**Distribution d'automates et de produits de chimie cliniques pour le diagnostic in vitro.**

*Design, production, control and sales of clinical chemistry products intended to be used  
for in vitro diagnostics. Validation of the combination reagents and analyzers.*  
*Distribution of clinical chemistry analyzers and products for in vitro diagnostics.*

**réalisées sur le(s) site(s) de**  
*performed on the location(s) of*

**VitalScientific,**  
**Zone industrielle - 61500 SEES - FRA**

**est conforme aux exigences des normes internationales**  
*complies with the requirements of the international standards*

**NF EN ISO 13485 : 2016**

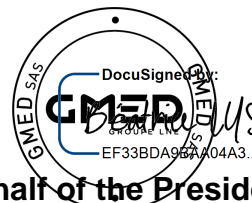
**Début de validité / Effective date** **May 21st, 2025 (included)**

**Valable jusqu'au / Expiry date :** **July 27th, 2026 (included)**

**Etabli le / Issued on :** **May 21st, 2025**



Accréditation n°4-0608  
Liste des sites accrédités  
et portée disponible sur  
[www.cofrac.fr](http://www.cofrac.fr)



**On behalf of the President**  
**Béatrice LYS**  
**Technical Director**

GMED N° 10462-10

Ce certificat est délivré selon les règles de certification GMED / This certificate is issued according to the rules of GMED certification

Modifie le certificat 10462-9

**GMED • Société par Actions Simplifiée au capital de 300 000 € • Organisme Notifié/Notified Body n° 0459**  
**Siège social : 1, rue Gaston Boissier - 75015 Paris • Tél. : 01 40 43 37 00 • [gmed.fr](http://gmed.fr)**