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)

Digitally signed by Ceaicovschi Tudor
Date: 2025.09.29 11:57:21 EEST
Reason: MoldSign Signature
Location: Moldova

Spankeren, February 2011

MOLDOVA EUROPEANĂ

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.

Current issue date: 7 April 2025
Expiry date: 21 June 2027

Certificate identity number: 10695763

Original approval(s):
ISO 13485 - 9 June 2019

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

UKAS MANAGEMENT SYSTEMS
0001

CERTIFICAT
CERTIFICATE OF REGISTRATION
N° 10462 rev. 10

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**

DocuSigned by:
GMED SAS
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On behalf of the President
Béatrice LYS
Technical Director

cofrac
CERTIFICATION DE SYSTEMES DE MANAGEMENT
Accréditation n°4-0608
Liste des sites accrédités et portée disponible sur www.cofrac.fr

GMED_SQRS-V5-05-2013

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