



EU Declaration of Conformity



VitalScientific B.V.
Van Rensselaerweg 4
6956 AV Spankeren
The Netherlands

declares under sole responsibility that the IVD medical devices specified below (including the listed accessories) and to which this declaration relates, conform to the provisions of:

- **Regulation (EU) 2017/746** of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU ("IVDR").
- **Directive 2006/42/EC** of the European Parliament and of the Council of 17 May 2006 on Machinery, and, amending Directive 95/16/EC ("MD").
- **Directive 2011/65/EU** of the European Parliament and of the Council of 8 June 2011 on the Restriction of the use of certain Hazardous Substances in electrical and electronic equipment, including Commission **Delegated Directive (EU) 2015/863** of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances ("RoHS").

These IVD medical devices carry the CE-marking and are notified in accordance with the IVDR.

Catalogue number	Description
6003-500	Selectra ProS [O/PSID/ISE]
6003-541	Selectra ProS [O/PSID]
6003-542	Selectra ProS [O/ISE]
6003-543	Selectra ProS [O]
6003-548	Selectra ProS [LITE]
6003-600	Selectra ProS [C/PSID/ISE/US]

Product	Clinical chemistry analyzer, automated
EMDN code	W02010101
GMDN code	56676
Intended purpose	Automated clinical chemistry system intended for use in clinical laboratories. It is intended to be used for a variety of assay methods that have been applied to spectro-photometric and electrochemical techniques. The system has two core modules: one consisting of a spectrophotometric system for measurement of analytes using spectro-photometric techniques, such as end point, rate and turbidimetric assays. The second (optional) module is an electrometer used for measurement of electrolytes.
Risk Class	A, according to Rule 5 of Annex VIII
Product type	<input checked="" type="checkbox"/> <i>in vitro</i> diagnostic medical device <input type="checkbox"/> accessory for an <i>in vitro</i> diagnostic medical device
SRN	NL-MF-000021018
Basic UDI-DI	37017008ProS-SeriesW6

Spankeren, 19-Jan-2026

Adriaan Intveld

Person Responsible for Regulatory Compliance (PRRC)



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List of applied (harmonized) standards.

	Standard (version)	Description	Tested / certified by
Safety	IEC 61010-1:2010/ AMD1:2016	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements	UL
	IEC 61010-2-010:2019	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of material	
	IEC 61010-2-101:2018	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment	
EMC	IEC 61326-1:2020	Electrical equipment for measurement, control, and laboratory use - EMC requirements – Part 1: General requirements	PHILIPS DEKRA
	IEC 61326-2-6:2020	Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – In Vitro diagnostic (IVD) medical equipment	
Quality Management System	ISO 13485:2016	Medical devices—Quality management systems—Requirements for regulatory purposes.	LRQA