EC Declaration of Conformity

We: **ELITechGroup B.V.**
Van Rensselaerweg 4
6956 AV Spankeren
The Netherlands

declare under sole responsibility that the product indicated below (including all accessories) and to which this declaration relates, conforms to the provisions of:

- Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices (IVD Directive)
- 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 Directive)

It is certified that this product is registered in accordance with the requirements of above-mentioned EU Directives and carries the CE marking.

Catalogue number	Description	GTIN
6003-404	Selectra ProM™ [O/ISE/PSID]	3661540 60478 2
6003-405	Selectra ProM™ [O/PSID]	3661540 60479 9
6003-406	Selectra ProM™ [O/ISE]	3661540 60480 5
6003-407	Selectra ProM™ [O]	3661540 60481 2
6003-435	Selectra ProM™ [C/ISE/PSID/US]	3661540 60039 5
6003-439	Selectra ProM™ [LITE]	3661540 60482 9
6003-439P	Selectra ProM™ [LITE/PSID]	3661540 60483 6

Product	**Multiple clinical chemistry analyzer IVD, laboratory, automated**
GMDN code	**56676**
SRN	**NL-MF-000021018**
Accessories	**See Annex**

Product classification
As per Article 9, section 1 the products are categorized as other devices ("self-declaration").

Conformity assessment procedure
In accordance with:

- Annex III of the IVD Directive
- Article 4 of the RoHS2 Directive

Spankeren, March 2022

M.A.S.V.E. Verdaasdonk

Managing Director

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List of applied (harmonized) standards

	Standard version	Description	Tested / certified by
Safety	IEC 61010-1:2010	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements	DEKRA
	IEC 61010-2-010:2014	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 61010-2-081:2015	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 61010-2-101:2015	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 61326-1:2006	Electrical equipment for measurement, control and laboratory use - EMC requirements – Part 1: General requirements	DEKRA
	IEC 61326-2-6:2006	Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – In Vitro diagnostic (IVD) medical equipment	
Quality systems	ISO 13485:2016	Medical devices—Quality management systems—Requirements for regulatory purposes.	LRQA

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Annex – List of IVD accessories

Catalogue number	Description	GTIN
3066-155	Syringe 100 µl	3661540 60044 9
3066-156	Syringe 1 ml	3661540 60045 6
3201-019	Precision Test Solution	3661540 60042 5
3918-007	By-pass Electrode	3661540 60494 2
6002-706	Cuvette Rotor Set	3661540 60057 9