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 ("RoHS2 Directive")

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

Product	**Clinical chemistry analyzer, automated**
Model	**Viva-ProE™**
Reference numbers	**6003-760** (Break-in number from 14-1301)
GMDN code	**56678**
Accessories	**See separate document 'Regulatory status of parts & accessories'**

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

The product (including all accessories) may be marketed without any restrictions within the following countries and regions:

- The Netherlands (NL);
- All other member states of the European Union (EU);
- All member states of the European Free Trade Association (EFTA) and Switzerland.

Spankeren, June 2016

A. Altink

Managing Director

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List of applied (harmonized) standards

	Standard version	Description	Tested / certified by
Safety	IEC 61010-1:2001	Safety requirements for electrical equipment for measurement, control, and laboratory use. Part 1: General requirements	DEKRA
	IEC 61010-2-010:2003	Safety requirements for electrical equipment for measurement, control and laboratory used – Part 2-010: particular requirements for laboratory equipment for the heating of material	
	IEC 61010-2-081:2001	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	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment	
	UL 61010-1 EN	Safety requirements for electrical equipment for measurement, control, and laboratory use Part1: General requirements	UL
	CAN/CSA –C22.2 No. 61010-1	Safety requirements for electrical equipment for measurement, control, and laboratory use Part1: General requirements	
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	EN ISO 13485:2012	Medical devices—Quality management systems—Requirements for regulatory purposes.	LRQA
	CAN/CSA ISO 13485:2003	Medical devices—Quality management systems—Requirements for regulatory purposes.	