EU Declaration of Conformity

ELITechGroup
EMPOWERING IVD

ELITechGroup B.V.
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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 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	GTIN
6003-760	Viva-ProE®	3661540 60035 7

Product	Chemistry analyzers
EMDN code	W02010101
GMDN code	56676
Intended purpose	Automated clinical chemistry analyzer intended for use in clinical laboratories. It is intended to be used for a variety of assay methods that have been applied to spectrophotometric techniques.
Risk Class	A
Product type	☒ *in vitro* diagnostic medical device ☐ accessory for an *in vitro* diagnostic medical device
SRN	NL-MF-000021018
Basic UDI-DI	3661540Pro-series8A

Spankeren, March 2023

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	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	
	UL 61010-1	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1. General requirements	UL
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