EU Declaration of Conformity

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

declares under sole responsibility that the IVD medical device specified below and to which this declaration relates, conforms 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**").

This IVD medical device carries the CE-marking and is notified in accordance with the IVDR.

Catalogue number	Description	GTIN
6003-760	Viva-ProE	3661540 60035 7

Product	Clinical chemistry analyzer, automated
Basic UDI-DI	3661540Pro-series8A
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, according to Rule 5 of Annex VIII
Product type	☒ *in vitro* diagnostic medical device ☐ accessory for an *in vitro* diagnostic medical device
SRN	NL-MF-000021018

Spankeren, 28-Mar-2024

Adriaan Intveld

Person Responsible for Regulatory Compliance (PRRC)

CE	EU Declaration of Conformity	ELITechGroup EMPOWERING IVD

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	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