EU Declaration of Conformity

ELITechGroup 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 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
6004-301	Selectra Mach5	3661540 60054 8

Product	Chemistry analyzers
EMDN code	W02010101
GMDN code	56676
Intended purpose	Automated clinical chemistry system intended for in vitro diagnostic measurements of analytes in samples derived from the human body. The system is intended for use in clinical laboratories and must be operated by qualified personnel. The system has a core module that consists of a spectrophotometric measurement system.
Risk Class	A
Product type	☒ *in vitro* diagnostic medical device ☐ accessory for an *in vitro* diagnostic medical device
SRN of manufacturer	NL-MF-000021018
Basic UDI-DI	3661540Mach-seriesTL

Spankeren, March 2023

Adriaan Intveld

Person Responsible for Regulatory Compliance (PRRC)

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 61010-2-010:2014	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 61010-2-051:2015	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-051: Particular requirements for laboratory equipment for mixing and stirring.	
	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 61326-1:2012	Electrical equipment for measurement, control, and laboratory use - EMC requirements – Part 1: General requirements	DEKRA
	IEC 61326-2-6:2012	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