EU Declaration of Conformity

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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
6002-310	Microlab 300
6003-075	Microlab 300 LX

Product	Clinical chemistry analyzer, semi-automated
EMDN code	W02010199
GMDN code	56676
Intended purpose	Semi-automated chemistry analyzer, to be used in combination with certain reagents for *in vitro* diagnostic measurement of analytes in samples of serum, plasma, urine and aqueous standard solutions. The analyzer is designed as an ´open´ system. Most clinical chemistry tests that require a photometric measurement can be adapted for the system. The analyzer is intended for use in clinical chemistry laboratories where the workload is of low quantity. The analyzer must be operated by qualified and trained personnel.
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
Basic UDI-DI	37017008Microlab-seriesHC

Spankeren, 22-Jan-2026

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 61010-2-081:2015	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 61326-1:2020	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