LABMASTER
medical devices

EU DECLARATION OF CONFORMITY

CE

Product:	Labmaster LUCIA™ Analyzer	Labmaster Oy
Basic UDI-DI:	6429810777LM268N	Rauhalinnantie 31, 20780 Kaarina, FINLAND
REF	LM26	SRN: FI-MF-000023942

We, as the manufacturer of the device, take sole responsibility for and hereby declare that the above mentioned product meets the provisions of the following Regulation/Directives:

EU 2017/746	Regulation on in vitro diagnostic medical devices
2014/35/EU	Directive on the making available on the market of electrical equipment designed for use within certain voltage limits
2011/65/EU	Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)
2006/42/EC	Directive on machinery
2014/53/EU	Directive on the harmonisation of the laws of the Member States relating to the making available on the market of radio equip ment

Risk Classification according to Annex VIII:

☒A non-sterile ☐B ☐C ☐D

Conformity route:

Annex I, II and III: Self declaration

Common specifications (CS):

N/A

Standards Applied:

EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971:2019/A11:2021	Medical devices - Application of risk management to medical devices
EN 61326-2-6 :2013	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
EN 55011:2016 / CISPR11 :2015	Industrial, scientific and medical equipment. Radio-frequency disturbance characteristics. Limits and methods of measurement.
SFS-EN ISO 15223-1:2021	Medical devices. Symbols to be used with information to be supplied by the manufacturer. Part 1: General requirements
SFS-EN ISO 18113-1:2011	In vitro diagnostic medical devices Information supplied by the manufacturer (labelling).Part 1: Terms, definitions and general requirements
SFS-EN ISO 18113-3:2011	In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). Part 3:In vitro diagnostic instruments for professional use

Authorised Signatory:

Name	Position	Date
	PRRC	14.11.2022

The technical documentation for the device is available from the address above.