LABMASTER
medical devices

EU DECLARATION OF CONFORMITY

CE

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

Intended purpose:

Labmaster LUCIA™ Analyzer is a semi-automated near-patient device used in in vitro diagnostics by healthcare professionals in professional healthcare facility environment. Labmaster LUCIA™ Analyzer is used together with Labmaster LUCIA™ test for quantitative or qualitative in vitro diagnostic analysis of analytes. LUCIA Analyzer measures CECL (cathodic electrochemiluminescence) signals and calculates result of analyte based on emission signals emitted from LUCIA cassettes. LUCIA tests are purchased separately.

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 equipment

Risk Classification according to Annex VIII: A non-sterile

Conformity route:
Annex I, II and III: Self declaration

Common specifications (CS): N/A

Additionally, the product specified above meets the applicable requirements of the following:

EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
SFS-EN ISO 13485:2016/A11:2021:en	Medical devices. Quality management systems. Requirements for regulatory purposes (ISO 13485:2016)
ISO 14971:2019	Medical devices - Application of risk management to medical devices
SFS-EN ISO 14971:2019/A11:2021	Medical devices. Application of risk management to medical devices (ISO 14971:2019)
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 Kirsi-Marja Meri

Regulatory Director, Labmaster Oy

Position

Kaarina, Finland

Place

12.09.2023

Date (DD.MM.YYYY)

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