



**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/2015/863/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 18113-1:2024 In vitro diagnostic medical devices Information supplied by the manufacturer (labelling).Part 1: Terms, definitions and general requirements
- SFS-EN ISO 18113-3:2024 In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). Part 3:In vitro diagnostic instruments for professional use
- EN 61010-1:2010 + A1:2019 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
- EN 61010-2-101:2002 + A2:2014 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Safety requirements for in vitro diagnostic (IVD) medical equipment

**Authorised Signatory:**

  
 Name Kirsi-Marja Meri

Kaarina, Finland

**Place**

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

SOP-REG-37 Appendix 4 EN Rev2

Regulatory Director, Labmaster Oy

**Position**

  
 31.03.2025

**Date (DD.MM.YYYY)**