

EU DECLARATION OF CONFORMITY



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 equipment

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:

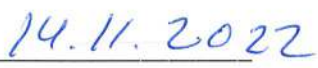
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971:2019/A11:2021	Medical devices - Application of risk management to medical devices
EN 61326-2-6 :2013	Electrical equipment for measurement, control and laboratory use - EMC requirements - 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

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