LABMASTER
medical devices

# EC DECLARATION OF CONFORMITY

**According to Annex III of the IVD Directive 98/79/EC**

CE

**Name and Address of Manufacturer:**

Labmaster Oy
Rauhalinnantie 31
20780 Kaarina
FINLAND

**Product name:**
Labmaster LUCIA™ MxA Kit for Whole Blood Samples

**Product Code:**
LM93

**This declaration of conformity is issued under the sole responsibility of the manufacturer.**

**Risk Classification:**

General IVD Medical Device according to Annex I Directive 98/79/EC

**Standards Applied:**

ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes

ISO 9001: 2015 Quality management systems — Requirements

ISO 14971:2019 Medical devices - Application of risk management to medical devices

ISO 18113-1:2009 In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 1: Terms, definitions and general requirements

ISO 18113-2:2009 In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 2: In vitro diagnostic reagents for professional use

ISO 15223-1:2016 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied Part 1: General requirements

**This Declaration of Conformity is signed below certifying that the requirements of Annex I and III have been met and documented.**

**Authorised Signatory:**

Tony H CEO

Name, Position

08.07.2021

Date

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

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**According to Annex III of the IVD Directive 98/79/EC**

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**Risk Classification:**

General IVD Medical Device according to Annex I Directive 98/79/EC

**Standards Applied:**

| | |
|---|---|
| EN ISO 13485:2016 | Medical devices - Quality management systems - Requirements for regulatory purposes |
| 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) |
| 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 18113-2:2024 | In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 2: In vitro diagnostic reagents for professional use applies apart from hazard pictograms to immediate labels |
| SFS-EN ISO 15223-1:2021 | Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied Part 1: General requirements |

**This Declaration of Conformity is signed below certifying that the requirements of Annex I and III have been met and documented.**

**Authorised Signatory:**

Kirsi-Marja Meri, Regulatory Director

28.11.2024
Date

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