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™ SARS-CoV-2 IgG RBD Kit for Whole Blood Samples

Product Code:
LM317

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

Risk Classification:

General IVD Medical Device according to Annex I of In Vitro Diagnostic Medical device directive 98/79/EC

Standards Applied:

EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 9001: 2015 Quality management systems — Requirements
ISO 14971:2019 Medical devices - Application of risk management to medical devices
EN ISO 18113-1:2011 In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 1: Terms, definitions and general requirements
EN ISO 18113-2:2011 In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 2: In vitro diagnostic reagents for professional use
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:

Tony CEO

Name, Position

24.05.2022

Date

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