

## EC DECLARATION OF CONFORMITY

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



**Name and Address of Manufacturer:**

Labmaster Oy  
Rauhalinnantie 31  
20780 Kaarina  
FINLAND

**Product name:**

Labmaster LUCIA™ SARS-CoV-2 IgG NP Kit for Serum/Plasma Samples

**Product Code:**

LM194

**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 15223-1:2021 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:**

 CEO

Name, Position

10.02.2022

Date

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