EC DECLARATION OF CONFORMITY

CE

Salofa Oy
Örninkatu 15
24100 SALO, Finland

declares under our own responsibility that the product:

Salocor COVID-19 (SARS-CoV-2) IgM/IgG antibody test kit

Conforms with the provisions of the following EC Directive, including all amendents, and with national legislation implementing the directive:

Directive 98/79/EC

The following harmonized standards were applied:

EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 13485:2016	Medical devices – Quality management systems – Requirements for regulatory purposes
EN 13612:2002	Performance evaluation of in vitro diagnostic medical devices
EN 13640:2002	Stability testing of in vitro diagnostic reagents
EN 13641:2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents
EN ISO 14971:2019	Medical Devices – Application of Risk management to medical devices
EN ISO 15193:2009	In vitro diagnostic medical devices – Measurement of quantities in samples of biological origin – Requirements for content and presentation of reference measurement procedures
EN ISO 15194:2009	In vitro diagnostic medical devices - Measurement of quantities in samples of biological origin - Requirements for certified reference materials and the content of supporting documentation
EN ISO 15223-1:2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)
EN ISO 17511:2003	In vitro diagnostic medical devices – Measurement of quantities of biological origin – Metrological traceability of values assigned to calibrators and control materials
EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labeling) - 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
ISO 20916:2019	In vitro diagnostic medical devices – Clinical performance studies using specimens from human subjects – Good study practice
EN ISO 23640:2015	In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents

Salo 05.05.2020
Place, date

Christoffer Riska
Vice President Regulatory Affairs

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