

# EC DECLARATION OF CONFORMITY



**Salofa Oy**  
Örninkatu 15  
24100 SALO, Finland

declares under our own responsibility that the product:

**Sienna™ COVID-19 IgG/IgM Rapid Test Cassette**

Conforms with the provisions of the following EC Directive, including all amendments,  
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 18113-2:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use

Salo 27.04.2020  
Place, date

  
Christopher Riska  
Vice President Regulatory Affairs