# EC DECLARATION OF CONFORMITY

CE

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

declares under our own responsibility that the product:

**Sienna™ COVID-19 Antigen Rapid Test Cassette (Nasopharyngeal Swab)**
**(Gold Colloidal)**

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:

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|---|---|
| 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 25.09.2020
Place, date

Christoffer Riska
Vice President Regulatory Affairs

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