



International Certifications

Certificate of Conformity



Manufacturer

Sensing Self Pte. Ltd.

160, Robinson Road, #20-03, Singapore Business Federation Ctr, Singapore 068914.

Products

S1 Covid-19 Rapid Antigen Test Kit

S2 Covid-19 Rapid Antigen Test Kit

S4 Multiplex Covid-19 /MERS-CoV/ Influenza A/B Rapid Antigens Test Kit

Covid-19 Rapid IgG/IgM combined Antibody assay Pre-screening test Kit

Complies with the requirements applicable to Directive 98/79/EC of IVD.

This is to certify that the technical documentation as required for the device has been reviewed and found to comply with the requirements and the relevant harmonized European standards: EN ISO 14971:2019, ISO 9001:2015, ISO 13485:2016, EN 15223-1:2012, EN ISO 18113-1:2011, EN ISO 18113-4:2011, EN 13612:2002, EN 13915:2003, EN 13641:2002, EN ISO 23640:2015, EN 980:2016, EN 13640:2002

Any change of the Medical Device shall be immediately reported to EC INTERNATIONAL CERTIFICATIONS in order to examine validity of this certificate.

Certificate confirms that the product/equipment complies with the Essential Safety Requirements and Objectives of Mentioned Directive / Standard and refers to the sample(s) provided for testing / Certification.

European Authorized Representative:

Venari s.r.o

Husitská 107/3, Žižkov, 130 00 Prague 3, Czech Republic

kamil.krajnak@venari.sk

Certificate No: ECIC-2018/IVD-048

Certificate Issue Date: 10.11.2020

Certificate Expiry Date: 09.11.2023


Head of Certification



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