CE CE

EC Declaration of Conformity
Regarding In Vitro Diagnostic Directive (98/79/EC)

Product Designation: COVID-19 IgM-IgG Rapid Test

Model #s: 51-002-20

We herewith declare that the products listed above are in compliance with the requirements set out in the Council Directive on the harmonization of the Laws of the Member States concerning In-Vitro-Diagnostic Directive 98/79/EC. The Declaration of Conformity is issued under the sole responsibility of the manufacturer.

Conformity Assessment Procedure: Annex III (IVD 98/79/EC)

Classification of the Product:

General; Not a referred product in Annex II, List A and List B
EDMA Code: 15.04.80.90.00 - Infectious Immunology, Other Virology (Infect. Immunology), Other Viral Antigen/Antibody Detection

Applied Harmonized Standards:

EN 13640:2002	Stability Testing of in Vitro Diagnostic Reagents
EN ISO 14971 :2019	Medical devices - Application of risk management
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
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

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(Dr. Frank Wang, CEO Signature)

March 6, 2020

(Date)