BioMedomics

DECLARATION OF CONFORMITY

CE

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 - 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

EU Authorized Representative: **MT Promedt Consulting GmbH**
Altenhofstrasse 80
66386 St. Ingbert
Germany

Company Name: **BioMedomics, Inc.**
Street Address: 1100 Perimeter Park Dr., Suite 104
Morrisville, NC 27560
USA

Frank Wang, Ph.D.
CEO

Signature

March 6, 2020

Date