

BIOMERICA, Inc.
DECLARATION OF CONFORMITY
Rev 8 Revision Date: 18Mar20

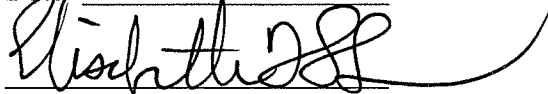
Applicable Council Directives	IVD Directive 98/79/EC
Standards to which conformity is declared	EN ISO 13485: 2016
Classification (IVD Directive 98/79/EC) Conformity Assessment Route	Other Device Annex III
Product Name Catalog Number	COVID-19 IgG/IgM Rapid Test 1507A
Manufacturer Name Manufacturer Address	Biomerica, Inc. 17571 Von Karman Avenue Irvine, CA 92614, USA
European Representative Address	MDSS GmbH Schiffgraben 41 30175 Hannover, Germany Tel: 49-511-62628630 Fax: 49-511-62628633
Certification Body Address	LNE/G-MED 1 rue Gaston Boissier 75724 Paris Cedex 15 France
EDMA Code:	15 70 90 90

Date CE Mark was affixed on: March 13, 2020

We, the undersigned, hereby declare, under our sole responsibility, that the above-mentioned products conform to the specified Directives and Standards. All supporting documents are retained at the premises of the manufacturer.

Location: Irvine, CA

Date: 18 Mar 20



Elisabeth Laderman
VP, Development and Quality