BIOMERICA, Inc.
DECLARATION OF CONFORMITY
Rev 2 Revision Date: 21Dec20

Applicable Council Directives	IVDD 98/79/EC
Applicable Standards	BS EN ISO 13485:2016 BS EN 13612:2002 BS EN 13641:2002 BS EN ISO 14971:2012 BS EN ISO 15223-1:2016 BS EN ISO 18113-1:2011 BS EN ISO 18113-2:2011 BS EN ISO 23640:2015 BS EN 62366-1:2015
Classification (IVDD 98/79/EC)	Other Device not covered by Annex II and not for self-testing according to IVDD 98/79/EC
Conformity Assessment Route	IVDD 98/79/EC Annex III
Product Name	COVID-19 Antigen Rapid Test (Nasopharyngeal Swab)
Catalog Number	1509/1509A
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
EDMA Code:	15 70 90 08

Date CE Mark was affixed on: December 16, 2020

We, Biomerica, Inc. herewith declare that we are exclusively responsible for this declaration of conformity. We herewith declare that the above-mentioned products meet the provisions of the Council Directive IVDD 98/79/EC and Standards. All supporting documents are retained at the premises of the manufacturer.

Location: Irvine, CA

Date: 21 Dec 20

Zackary Irani-Cohen, Chief Executive Officer