CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices.

Manufacturer: Genabio LLC

Address:303 Wyman Street,Suite 300 Waltham,MA02451,USA

European Representative: Lotus NL B.V.

Contact person: Peter E-mail: peter@lotusnl.com

Address: Koningin Julianaplein 10,1e Verd,2595AA,The Hague,Netherlands.

In Vitro Diagnostic Directive:

- SARS-CoV-2 IgM/IgG (GICA)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III.

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

We, the manufacturer, here declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In Vitro Diagnostic Medical Devices.

We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on: 04/28/2020

Name of authorized signatory: Weike MO

Position held in the company: Manager

Place:MA,USA

Seal/Stamp:

Genabio LLC