CE

DECLARATION OF CONFORMITY

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

Manufacturer: GenaBio Diagnostics Inc
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：

- GenaBio SARS-CoV-2 Antigen Lateral Flow Test

Category：Others.

Conformity assessment route：Declaration of Conformity IVDD Annex III

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-2:2011*	*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*

We, the manufacturer, herewith 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:11/13/2020

Name of authorized signatory: Weike MO

Position held in the company: Manager

Place:MA,USA.

Seal/Stamp:

GenaBio Diagnostics Inc