



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, MA 02451, 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 ELISA assay kit

Category : Others.

Conformity assessment route : Declaration of Conformity IVDD Annex III

Applicable Standards:

ISO 13485:2016

ISO 14971:2019

EN ISO 18113-1:2011

EN ISO 18113-2:2011

EN 13641:2002

ISO 15223-1:2016

EN 13612:2002

ISO 23640:2015

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

Place: MA, USA.

Name of authorized signatory: Weike MO

Position held in the company: Manager

Seal/Stamp:

GenaBio Diagnostics Inc