

# EC DECLARATION OF CONFORMITY

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

Manufacturer : Assure Tech (Hangzhou) Co., Ltd.

Address : Building 4, No. 1418-50, Moganshan Road, Gongshu District, Hangzhou, 310011 Zhejiang, P.R. China

**Product/s: COVID-19 Antigen Rapid Test Device  
COVID-19 IgG/IgM Rapid Test Device  
COVID-19 IgG/IgM Control**

**Registration number: NL-CA002-2020-52777**

Category : Other Devices (All devices except Annex II and self-testing devices)

Conformity assessment route : Declaration of Conformity IVDD Annex III

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 hereby explicitly appoint

Lotus NL B.V.

Address: Koningin Julianaplein 10,  
le Verd, 2595AA, The Hague, Netherlands

to act as our European Authorised Representative as defined in the aforementioned Directive

Signed on 2020/08/05

Place Hangzhou, China

Signature \_\_\_\_\_



Name of authorized signatory: Eric Ling, General Manager



Certified manufacturer according to ISO13485

No.: DOC-044