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

CE

Assure Tech

TÜVRheinland®
Certified manufacturer
according to ISO13485

No.: DOC-044