ASSURE TECH. (HANGZHOU) CO., LTD.
Building 4, No. 1418-50, Moganshan Road, Gongshu District, Hangzhou, 310011 Zhejiang, P.R. China
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EC DECLARATION OF CONFORMITY

(No.: DOC-046)

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:

- COVID-19 & Influenza A/B Antigen Combo Rapid Test Device (Nasopharyngeal/Oropharyngeal Swab)

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

Conformity assessment route: Declaration of Conformity IVDD Annex III

Applicable Standards:

EN ISO 13485:2016	*EN 13975:2003*	*EN 13612:2002/AC:2002*
EN ISO 14971:2012	*EN ISO 15223-1:2016*	*EN ISO 18113-3:2011*
EN ISO 18113-1:2011	*EN ISO 18113-2:2011*	*EN 13641:2002*
EN ISO 23640:2015	*EN 62366-1:2015*	*EN 62366-2:2016*

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. located at Koningin Julianaplein 10, le Verd, 2595AA, The Hague, Netherlands to act as our European Authorised Representative as defined in the aforementioned Directive.

QMS certificate Registration No. SX 601450630001, Valid from 2020-04-15, Valid until 2023-02-24

Signed on 2020/08/25. Place Hangzhou, China

Represented by

Signature _____

Name of authorized signatory: Eric Ling

Position held in the company: General Manager

Seal/Stamp:

Assure Tech (Hangzhou) Co., Ltd.
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Certified manufacturer according to ISO13485

TÜVRheinland