EC DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices

Manufacturer: Assure Tech. (Hangzhou) Co., Ltd.
Address: Building 4, No. 1418-50, Moganshan Road, Gongshu District, Hangzhou, 310011 Zhejiang, P.R. China

Product/s: FLU A/FLU B/RSV/ADV/MP/COVID-19 Combo Test
Registration number: NL-CA002-2020-55133

Category: Other Devices (All devices except Annex II and self-testing devices)
Conformity assessment route: Declaration of Conformity IVDD Annex III excluding (6)

Applicable Standards:

EN ISO 13485:2016	*EN 13975:2003*	*EN 13612:2002/AC:2002*
EN ISO 14971:2019	*EN ISO 15223-1:2016*	*EN 13641:2002*
EN ISO 18113-1:2011	*EN ISO 18113-2:2011*	*IEC 62366-1: 2015*
EN ISO 23640:2015		

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 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 2021/11/12
Place Hangzhou, China

Signature: 

Name of authorized signatory: Eric Ling, General Manager

CE

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