EC DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III, 6

MANUFACTURER: **Assure Tech. (Hangzhou) Co., Ltd.**
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EUROPEAN: Lotus NL B.V.
Address: Koningin Julianaplein 10,
leVerd, 2595AA,The Hague, Netherlands

PRODUCT: **COVID-19 & Influenza A/B Antigen Nasal Test Kit**
Registration number **NL-CA002-2022-71261**
CATEGORY: Self-testing devices

CONFORMITY ASSESSMENT ROUTE: Annex III (Section 6) to Directive 98/79/EC

We,the Manufacturer, herewith declare with sole responsibility
that our product/s mentioned above meet/sthe 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

Applicable Standards:

EN ISO 13485:2016	*EN ISO 14971:2019*	*EN ISO 23640:2015*
EN 13612:2002	*EN 13641:2002*	*EN ISO 15223-1:2016*
EN ISO 18113-1:2011	*EN ISO 18113-4:2011*	*EN 13532:2002*
EN 13975:2003	*IEC 62366-1:2015*	

Notified Body CeCert Sp. Zo.o, ul. Żurawia 32/34, 00-515 Warszawa

EC Certificate No. CeCert/081/W/E.2

Start of CE-Marking 2022-05-10

Signature:

Name ofauthorized signatory: Eric Ling,General Manager

CE 2934

Certified manufacturer
according to ISO13485

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