# EC DECLARATION OF CONFORMITY

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

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

EUROPEAN: Lotus NL B.V.
Address: Koningin Julianaplein 10,
leVerd, 2595AA,The Hague, Netherlands

**PRODUCT:** **COVID-19 Antigen Saliva Test Kit**
**Registration number** **NL-CA002-2022-72296**
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 14971:2012* | *EN ISO 23640:2015* |
| *EN 13612:2002* | *EN 13641:2002* | *EN ISO 15223-1:2015* |
| *EN ISO 18113-1:2011* | *EN ISO 18113-4:2011* | *EN 13532:2002* |
| *EN 13975:2003* | *EN 62366:2008* | |

**Notified Body** DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O.

**EC Certificate No.** 2258023DE01

**Start of CE-Marking** 2022-05-25

Signature:

Name of authorized signatory: Eric Ling,General Manager

CE 0344

Certified manufacturer
according to ISO13485

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