

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 Nasal Test Kit**

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/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

Applicable Standards:

| | | |
|----------------------------|----------------------------|----------------------------|
| <i>EN ISO 13485:2016</i> | <i>EN ISO 14971:2019</i> | <i>EN ISO 23640:2015</i> |
| <i>EN 13612:2002</i> | <i>EN 13641:2002</i> | <i>EN ISO 15223-1:2016</i> |
| <i>EN ISO 18113-1:2011</i> | <i>EN ISO 18113-4:2011</i> | <i>EN 13532:2002</i> |
| <i>EN 13975:2003</i> | <i>IEC 62366-1:2015</i> | |

Notified Body POLISH CENTRE FOR TESTING AND CERTIFICATION, 469
Puławska Street, 02-844 Warsaw, POLAND

EC Certificate No. 1434-IVDD-517/2021

Start of CE-Marking 2021-12-10

Signature:

Name of authorized signatory: Eric Ling, General Manager

CE 1434



Certified manufacturer
according to ISO13485

No.: DOC-271
Version 1.0

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ATTACHMENT

| Brand name | Ref No. |
|-------------------|----------------|
| Ecotest | COV-S35002H1 |
| | COV-S35002H2 |
| | COV-S35002H3 |
| | COV-S35002H4 |
| | COV-S35002H5 |
| | COV-S35002H6 |
| | COV-S35002H7 |
| | COV-S35002H8 |
| | COV-S35002H9 |
| | COV-S35002H10 |
| | COV-S35002H15 |
| | COV-S35002H20 |

| Brand name | Ref. no. |
|-------------------|-----------------|
| FaStep | COV-S35002H1 |
| | COV-S35002H2 |
| | COV-S35002H3 |
| | COV-S35002H4 |
| | COV-S35002H5 |
| | COV-S35002H6 |
| | COV-S35002H7 |
| | COV-S35002H8 |
| | COV-S35002H9 |
| | COV-S35002H10 |
| | COV-S35002H15 |
| | COV-S35002H20 |

