

# 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

**PRODUCTS** **COVID-19 Antigen Nasal Test Kit**

**Registration number** **NL-CA002-2021-64181**

**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:**

*EN ISO 13485:2016*

*EN ISO 14971:2019*

*EN ISO 23640:2015*

*EN 13612:2002*

*EN 13641:2002*

*IEC 62366-1:2015*

*EN ISO 18113-1:2011*

*EN ISO 15223-1:2021*

*EN 13532:2002*

*EN ISO 18113-4:2011*

*EN 13975:2003*

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

**EC Certificate No.** 1434-IVDD-078/2022

**Start of CE-Marking** 2022-04-06

Signature: 

Name of authorized signatory: Eric Ling, General Manager

 **Assure Tech**

 **CE** 1434



Certified manufacturer  
according to ISO13485

No.: DOC-271  
Version 1.1

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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

Brand name	REF.No.
Domowe Laboratorium	COV-S35002H1
	COV-S35002H2
	COV-S35002H3
	COV-S35002H4
	COV-S35002H5
	COV-S35002H6
	COV-S35002H7
	COV-S35002H8
	COV-S35002H9
	COV-S35002H10
	COV-S35002H15
	COV-S35002H20

