

# 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: COVID-19 Antigen Nasal Test Kit**  
**Registration number: NL-CA002-2021-59221**

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 14971:2012

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 2021/10/12

Place Hangzhou, China

Signature: \_\_\_\_\_



Name of authorized signatory: Eric Ling, General Manager

