

EC DESIGN-EXAMINATION CERTIFICATE

Number: 2258023DE01

Directive 98/79/EC on In Vitro Diagnostic Medical Devices, Annex III (6)
(Devices for self-testing)

Manufacturer:

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

For the product

COVID-19 Antigen Saliva Test Kit

Documents, that form the basis of this certificate:

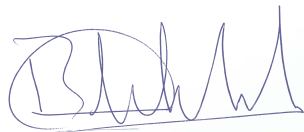
Certification Notice 2258023CN, initially dated 25 May 2022
Addendum, initially dated 25 May 2022

DEKRA hereby declares that the design of the product(s) falling within the product category mentioned above, fulfils the relevant provisions of 'Besluit in-vitro diagnostica', the Dutch transposition of the Council Directive 98/79/EC of October 27, 1998 concerning In vitro diagnostic medical devices, including all subsequent amendments, based on an examination in accordance with Annex III (6) of this Directive. The manufacturer has implemented a quality assurance system for the above mentioned product category in accordance to the provisions of Annex III (6) of Council Directive 98/79/EC of October 27, 1998 and is subject to periodical surveillance.

The necessary information and the reference to the relevant documentation, of the products concerned and the examinations and assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 26 May 2025
Issued for the first time: 25 May 2022

DEKRA Certification B.V.

A blue ink signature of B.T.M. Holtus, consisting of stylized, overlapping loops and lines.

B.T.M. Holtus
Managing Director

A blue ink signature of J.A. van Vugt, featuring a large, sweeping initial 'J' followed by a series of connected loops.

J.A. van Vugt
Certification Manager

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DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
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ADDENDUM

Belonging to certificate: 2258023DE01

1/1

EC DESIGN-EXAMINATION IN VITRO DIAGNOSTIC MEDICAL DEVICES

COVID-19 Antigen Saliva Test Kit

Issued to:

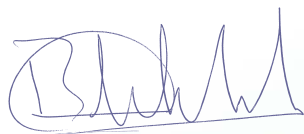
Assure Tech. (Hangzhou) Co., Ltd
Building 4, No. 1418-50, Moganshan Road, Gongshu District
310011 Hangzhou, Zhejiang
P. R. China

This certificate covers the following product(s):

- 1 test/ box
- 3 tests/ box
- 7 tests/ box
- 10 tests/ box
- 20 tests/ box

Initial date: 25 May 2022

DEKRA Certification B.V.

A blue ink signature of B.T.M. Holtus, the Managing Director of DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

A blue ink signature of J.A. van Vugt, the Certification Manager of DEKRA Certification B.V.

J.A. van Vugt
Certification Manager

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