Declaration of Conformity

ACON Biotech (Hangzhou) Co., Ltd.
No.210 Zhenzhong Road, West Lake District,
Hangzhou, P.R. China, 310030

We declare under our sole responsibility that the in vitro diagnostic device:

SARS-CoV-2 Antigen Rapid Test (Self-Testing)

classified as self-testing according to the Annex II of the directive 98/79/EC, meets all the provisions of the directive 98/79/EC on *in vitro* diagnostic medical devices which apply to it.

This declaration is according to Annex III.6 of the Directive and thus is based on approval by the notified body TÜV SÜD Product Service GmbH, Ridlerstraße 65 80339 MÜNCHEN, Germany, notified under No. 0123 to the EC Commission.

Authorized Representative:
MedNet GmbH
Borkstrasse 10
48163 Muenster, Germany

This declaration is valid until expiration of EC certificate
No. V9 042074 0032 Rev.00
Expiration Date: 2024-05-26

Signed this 17 day of May, 2021
in Hangzhou, China

Junny You
International Regulatory Affairs Senior Director
ACON Biotech (Hangzhou) Co., Ltd.

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07

Product Service

EC Certificate

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

No. V9 042074 0032 Rev. 00

Manufacturer:

Acon Biotech (Hangzhou) Co., Ltd.
No.210 Zhenzhong Road
West Lake District
310030 Hangzhou
PEOPLE'S REPUBLIC OF CHINA

Product: **In Vitro diagnostic devices for self testing**

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with IVDD Annex III (6). The design of the devices conforms to the requirements of this Directive. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V9 042074 0032 Rev. 00

Report No.: SH2110605

Valid from: 2021-05-14
Valid until: 2024-05-26

Date, 2021-05-14

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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EC Certificate

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

No. V9 042074 0032 Rev. 00

Model(s): **SARS-CoV-2 Antigen Rapid Test (Self-Testing)**

Facility(ies): Acon Biotech (Hangzhou) Co., Ltd.
No.210 Zhenzhong Road, West Lake District, 310030 Hangzhou,
PEOPLE'S REPUBLIC OF CHINA

Model name:	Model number:
Flowflex SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-11855
Flowflex SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118L5
Flowflex SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118T5
Flowflex SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118A5
Flowflex SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118U5
Flowflex SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118V5
Flowflex SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118Q5
Flowflex SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118M5
Flowflex SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118N5
Flowflex SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118W5
Flowflex SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118P5
Flowflex SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118Y5
Flowflex SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118Z5
Flowflex SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118R5
[redacted] SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-11853E
SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118A3E
SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118Q3E
SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118M3E
SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118P3E
SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118R3E
Quik Check SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-11857
Quik Check SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118A7
Quik Check SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118Q7
Quik Check SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118M7
Quik Check SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118P7
Quik Check SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118R7

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TÜV SÜD Product Service

EC Certificate

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

No. V9 042074 0032 Rev. 00

[redacted] SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-11853J
SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118A3J
SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118Q3J
SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118M3J
SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118P3J
SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118R3J
[redacted] SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-11853D
SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118A3D
SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118Q3D
SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118M3D
SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118P3D
SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118R3D

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