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

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

TÜV®

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

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

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
Hughes SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-11853E
Hughes SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118A3E
Hughes SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118Q3E
Hughes SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118M3E
Hughes SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118P3E
Hughes 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

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

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

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

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

DIAQUICK SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-11853J
DIAQUICK SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118A3J
DIAQUICK SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118Q3J
DIAQUICK SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118M3J
DIAQUICK SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118P3J
DIAQUICK SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118R3J
Swiss Point of care SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-11853D
Swiss Point of care SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118A3D
Swiss Point of care SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118Q3D
Swiss Point of care SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118M3D
Swiss Point of care SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118P3D
Swiss Point of care SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118R3D

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

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

TÜV®