



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



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

REF L031-11855
REF L031-118L5
REF L031-118T5
REF L031-118A5
REF L031-118U5
REF L031-118V5
REF L031-118Q5
REF L031-118M5
REF L031-118N5
REF L031-118W5
REF L031-118P5
REF L031-118Y5
REF L031-118Z5
REF L031-118R5

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

REF L031-11853E
REF L031-118A3E
REF L031-118Q3E
REF L031-118M3E
REF L031-118P3E
REF L031-118R3E

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

REF L031-11857
REF L031-118A7
REF L031-118Q7
REF L031-118M7
REF L031-118P7
REF L031-118R7

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