



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 104507 0004 Rev. 00

Manufacturer:

ACON Laboratories, Inc.

5850 Oberlin Drive, #340
San Diego CA 92121
USA

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 104507 0004 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:V9_104507_0004_Rev.00)

Report No.:

SH2110606

Valid from:

2021-05-21

Valid until:

2024-05-26

Date,

2021-05-21

Christoph Dicks
Head of Certification/Notified Body



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

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

No. V9 104507 0004 Rev. 00

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

Facility(ies):

- ACON Laboratories, Inc.
5850 Oberlin Drive, #340, San Diego CA 92121, USA
- ACON Laboratories, Inc.
10125 Mesa Rim Road, San Diego CA 92121, USA
- ACON Laboratories, Inc.
6865 Flanders Dr., Suite B, San Diego CA 92121, USA
- AZURE Institute, Inc.
10125 Mesa Rim Road, San Diego CA 92121, USA

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 L031-118A5
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 L031-118P5
Flowflex SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118R5
Ritter Easy Check SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-11853F
Ritter Easy Check SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118A3F
Ritter Easy Check SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118V3F
Ritter Easy Check SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118Q3F
Ritter Easy Check SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118M3F
Ritter Easy Check SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118P3F
Ritter Easy Check SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118Z3F
Ritter Easy Check SARS-CoV-2 Antigen Rapid Test (Self-Testing)	REF L031-118R3F