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
BS-IVDR-099

Product Service

EU Technical Documentation Assessment Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices, Annex IX, Chapter II (Class D Devices)

No. V70 042074 0033 Rev. 00

Manufacturer:

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

SRN Manufacturer - CN-MF-000006977

Authorized Representative:

MedNet EC-REP GmbH
Borkstraße 10, 48163 Münster, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has drawn up and presented a Technical Documentation according to Annex II and III of the Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices. Details on devices covered by the Technical Documentation are described on the following page(s).
The Report referenced below summarizes the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX, Chapter II, of this regulation with a positive result. In order to maintain this certificate, the manufacturer shall submit Periodic Safety Update Reports at least annually to the notified body TÜV SÜD Product Service GmbH. Verification of manufactured class D devices according to Annex IX Sections 4.12 and 4.13 is applicable. In order to place the devices on the market with CE-marking, an EU Quality Management System Certificate pursuant to Annex IX Chapters I and III is necessary in addition to this EU Technical Documentation Assessment Certificate. All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V70 042074 0033 Rev. 00

Report No.: SH2310603

Valid from: 2024-07-24
Valid until: 2029-07-23

Marta Carnielli
Head of Certification IVD

Issue date: 2024-07-24

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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No. V70 042074 0033 Rev. 00

Classification:	Class D
Device Group:	W0105040619 - CORONAVIRUS
Basic UDI-DI:	6921756499990035X8
Intended Purpose:	The SARS-CoV-2 Antigen Rapid Test is a lateral flow test for the qualitative detection of the nucleocapsid antigen from SARS-CoV-2 in anterior nasal swab specimens directly from individuals suspected of COVID-19 within the first seven days of the onset of symptoms. The test can also test specimens from individuals without symptoms. The SARS-CoV-2 Antigen Rapid Test is intended to be used for self-testing by lay users as an aid to diagnosis of SARS-CoV-2 infection. Children under 14 years should be supervised by an adult.
Device(s):	Flowflex SARS-CoV-2 Antigen Rapid Test (Self-Testing), REF L031-118M5-201, L031-118T5-201, L031-118P5-201, L031-118Y5-201, L031-118R5-201 Hughes SARS-CoV-2 Antigen Rapid Test (Self-Testing), REF L031-118M3E-201, L031-118P3E-201

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The validity of this certificate depends on conditions and/or is limited to the following:	- none -

Revision History:

Rev.	Dated	Report	Description
00	2024-07-24	SH2310603	Initial issuance

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