CERTIFICATE

EC Certificate No. 1434-IVDD-478/2021

EC Design-examination
Directive 98/79/EC concerning
***in vitro* diagnostic medical devices**

Polish Centre for Testing and Certification certifies
that manufactured by:

VivaChek Biotech (Hangzhou) Co., Ltd.
Level 2, Block 2, 146 East Chaofeng Rd, Yuhang Economy Development Zone, Hangzhou, Zhejiang 311100, China

in vitro diagnostic medical devices
for self-testing

The list of medical devices covered by this certificate is provided in the annex I

in terms of design documentation, comply with requirements
of Annex III (Section 6) to Directive 98/79/EC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 28.10.2021 to 27.05.2024

The date of issue of the Certificate: 28.10.2021

The date of the first issue of the Certificate: 28.10.2021

CE 1434

Issued under the Contract No. MD-91/2021
Application No: 146/2021
Certificate bears the qualified signature.
Warsaw, 28/10/2021
Module A1

Vice-President
Mgr. Anna Wyroba

ANNEX TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-IVDD-478/2021

List of medical devices covered by the certificate:

	Specification	REF
VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test	1 test/box	VCD16-10-013
	3 tests/box	VCD16-10-015
	5 tests/box	VCD16-10-014
	25 tests/box	VCD16-10-011
Verino® Pro SARS-CoV-2 Ag Rapid Test	1 test/box	VCD16-10-043
	3 tests/box	VCD16-10-045
	5 tests/box	VCD16-10-044
	25 tests/box	VCD16-10-041

CE 1434

Issued under the Contract No. MD-91/2021
Application No: 146/2021
Certificate bears the qualified signature.
Warsaw, 28/10/2021

Vice-President
mgr. Anna Wyroba

Declaration of Conformity

VivaChek Biotech (Hangzhou) Co., Ltd.
Level 2, Block 2, 146 East Chaofeng Rd., Yuhang Economy Development Zone, Hangzhou,Zhejiang, 311100, P.R.China

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

Product Name	Model
VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test	VCD16-10-013
	VCD16-10-015
	VCD16-10-014
	VCD16-10-011
Verino® Pro SARS-CoV-2 Ag Rapid Test	VCD16-10-043
	VCD16-10-045
	VCD16-10-044
	VCD16-10-041

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 Conformity Assessment Route: Annex III , section 6, and the Classification/Qualification of medical device is for self-testing

The declaration is base on the approval by the notified body

Polskie Centrum Badań i Certyfikacji S.A.ul. Puławska 469 02-844 Warszawa（PCBC）,notified under No.1434 to the EC commission.
The EC certificate No.is 1434-IVDD-478/2021

European Representative:

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Julie zhou
R.A Director
Date: Nov 10, 2021