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