



# 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 27.10.2021 to 27.05.2024

The date of issue of the Certificate: 27.10.2021

The date of the first issue of the Certificate: 27.10.2021



Issued under the Contract No. MD-91/2021  
Application No: 146/2021  
Certificate bears the qualified signature.  
Warsaw, 27/10/2021  
Module A1

Anna  
Małgorzata  
Wyroba

Elektronicznie  
podpisany przez Anna  
Małgorzata Wyroba  
Data: 2021.10.27  
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**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



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Warsaw, 27/10/2021

**Vice-President**  
*mgr. Anna Wyroba*