



# CERTIFICATE

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**EC Certificate No. 1434-IVDD-200/2022**

**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 1 and 2*

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 23.05.2022 to 27.05.2025

The date of issue of the Certificate: 23.05.2022

The date of the first issue of the Certificate: 28.10.2021



Issued under the Contract No. MD-91/2021  
Application No: 146/2021  
Certificate bears the qualified signature.  
Warsaw, 23/05/2022  
Module A1

**Director  
Medical Device Certification  
Department**



# ANNEX 1 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

**No 1434-IVDD-200/2022**

*List of medical devices covered by the certificate:*

Product Name: VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test			
Specification	REF. No.	Specification	REF. No.
1 test/box	VCD16-10-013	1 test/bag	VCD16-10-01A
3 tests/box	VCD16-10-015	3 tests/bag	VCD16-10-01C
5 tests/box	VCD16-10-014	5 tests/bag	VCD16-10-01D
6 tests/box	VCD16-10-016	6 tests/bag	VCD16-10-01E
7 tests/box	VCD16-10-017	7 tests/bag	VCD16-10-01F
10 tests/box	VCD16-10-018	10 tests/bag	VCD16-10-01G
15 tests/box	VCD16-10-019	15 tests/bag	VCD16-10-01H
20 tests/box	VCD16-10-012	20 tests/bag	VCD16-10-01J
25 tests/box	VCD16-10-011	25 tests/bag	VCD16-10-01K

Product Name: Verino® Pro SARS-CoV-2 Ag Rapid Test			
Specification	REF. No.	Specification	REF. No.
1 test/box	VCD16-10-043	1 test/bag	VCD16-10-04A
3 tests/box	VCD16-10-045	3 tests/bag	VCD16-10-04C
5 tests/box	VCD16-10-044	5 tests/bag	VCD16-10-04D
6 tests/box	VCD16-10-046	6 tests/bag	VCD16-10-04E
7 tests/box	VCD16-10-047	7 tests/bag	VCD16-10-04F
10 tests/box	VCD16-10-048	10 tests/bag	VCD16-10-04G
15 tests/box	VCD16-10-049	15 tests/bag	VCD16-10-04H
20 tests/box	VCD16-10-042	20 tests/bag	VCD16-10-04J
25 tests/box	VCD16-10-041	25 tests/bag	VCD16-10-04K



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Warsaw, 23/05/2022

**Director**  
**Medical Device Certification Department**



## ANNEX 2 TO THE CERTIFICATE

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**No 1434-IVDD-200/2022**

*List of medical devices covered by the certificate:*

Product Name: Vacsure® Pro SARS-CoV-2 Ag Rapid Test			
Specification	REF. No.	Specification	REF. No.
1 test/box	VCD16-10-053	1 test/bag	VCD16-10-05A
3 tests/box	VCD16-10-055	3 tests/bag	VCD16-10-05C
5 tests/box	VCD16-10-054	5 tests/bag	VCD16-10-05D
6 tests/box	VCD16-10-056	6 tests/bag	VCD16-10-05E
7 tests/box	VCD16-10-057	7 tests/bag	VCD16-10-05F
10 tests/box	VCD16-10-058	10 tests/bag	VCD16-10-05G
15 tests/box	VCD16-10-059	15 tests/bag	VCD16-10-05H
20 tests/box	VCD16-10-052	20 tests/bag	VCD16-10-05J
25 tests/box	VCD16-10-051	25 tests/bag	VCD16-10-05K

Product Name: Rapid Gold Pro SARS-CoV-2 AG Test			
Specification	REF. No.	Specification	REF. No.
RGP-01S	1 test/box	RGP-01SS	1 Test/bag
RGP-03S	3 tests/box	RGP-10S	10 tests/box
RGP-05S	5 tests/box	RGP-25S	25 tests/box



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**Medical Device Certification Department**