

EC Certificate No. 1434-IVDD-446/2021

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

Polish Centre for Testing and Certification certifies that manufactured by:

TÜRKLAB Tibbi Mal. San. Tic. A.Ş.

ITOB 10017 Sokak No: 2, Tekeli – Menderes Izmir, Turkey

in vitro diagnostic medical devices for self-testing

COVID-19 Ag Home Test

The list of medical devices covered by this certificate is provided in the annex 1

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 30.07.2021 to 27.05.2024

The date of issue of the Certificate: 30.07.2021

The date of the first issue of the Certificate: 30.07.2021

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Issued under the Contract No. MD-74/2021
Application No: 114/2021
Certificate bears the qualified signature.
Warsaw, 30.07.2021
Module A1

Anna Elektronicznie podpisany przez Anna Małgorzata Wyroba Data: 2021.07.30
Wyroba 10:29:29-40:200
Vice-President



ANNEX 1 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-IVDD-446/2021

List of medical devices covered by the certificate:

Serial No.	Brand/Trademark	REF. No.	Product Name
1	Rapidan® Tester	RTCVH02001	COVID-19 Ag Home Test
2	Toyo®	TCVH02001	COVID-19 Ag Home Test
3	Info®	ICVH02001	COVID-19 Ag Home Test
4	Test It	TICVH02001	COVID-19 Ag Home Test
5	Rapidan® Tester	RTCVH02005	COVID-19 Ag Home Test
6	Toyo®	TCVH02005	COVID-19 Ag Home Test
7	Info®	ICVH02005	COVID-19 Ag Home Test
8	Test It	TICVH02005	COVID-19 Ag Home Test



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 $\label{lem:continuous} \textbf{Certificate bears the qualified signature}.$

Warsaw, 30/07/2021

Anna Małgorzata Wyroba

Elektronicznie podpisany przez Anna Małgorzata Wyroba Data: 2021.07.30 10:29:02 +02'00'

Vice - President