CERTIFICATE

EC Certificate No. 1434-IVDD-520/2021

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

Polish Centre for Testing and Certification certifies
that manufactured by:

Vision Biyotenoloji Ar-Ge Lab Sist. San. Ve Tic. LTD. ŞTİ Merdivenkoy district dikyol street no:2-B business istanbul plaza b blok office:58 kadikoy/Istanbul Turkey

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 17.12.2021 to 27.05.2024

The date of issue of the Certificate: 17.12.2021

The date of the first issue of the Certificate: 17.12.2021

CE 1434

Issued under the Contract No. **MD-127/2021**
Application No: **122/2021**
Certificate bears the qualified signature.
Warsaw, 17/12/2021
Module A1

Director of Medical Devices
Certification Department

ANNEX TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-IVDD-520/2021

List of medical devices covered by the certificate:

VISION COVID-19 RAPID ANTIGEN TEST KIT, REF: V2004Y190
BIOESSA ANTIGEN NASAL RAPID TEST KIT, REF: ESSA001
C-EDGE COVID-19 RAPID NASAL ANTIGEN, REF: C-ERNA19
CHECK UP SARS-COV-2 NASAL ANTIGEN RAPID TEST, REF: C2104N01
MISSION COVID-19 RAPID ANTIGEN TEST KIT, REF: M01LF
NEMHESİS COVID-19 RAPID ANTIGEN TEST KIT, REF: NM01101
ORMED COVID-19 RAPID ANTIGEN TEST KIT, REF: ORM001

CE 1434

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Application No. **122/2021**
Certificate bears the qualified signature.
Warsaw, 17/12/2021

Director of Medical Devices
Certification Department