



# CERTIFICATE

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**EC Certificate No. 1434-IVDD-189/2022**

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

Polish Centre for Testing and Certification certifies  
that manufactured by:

**Hangzhou Biotest Biotech Co., Ltd  
17#, Futai Road, Zhongtai Street, Yuhang District,  
Hangzhou, P.R. China**

in vitro diagnostic medical devices  
for self-testing

*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 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: 01.09.2021



Issued under the Contract No. MD-39/2021  
Application No: 052-2/2021  
Certificate bears the qualified signature.  
Warsaw, 23/05/2022  
Module A1

**Director  
Medical Devices Certification  
Department**



## ANNEX TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

**No 1434-IVDD-189/2022**

*List of medical devices covered by the certificate:*

| Product   | REF number | Brand           |
|---|------------|-----------------|
| COVID-19 Antigen Rapid Test Cassette (Nasal Swab) | ICOVN-C81H | RightSign       |
| COVID-19 Antigen Rapid Test Cassette (Nasal Swab) | 302282     | Sienna          |
| COVID-19 Antigen Rapid Test Cassette(Nasal Swab)  | ICOVN-C81H | ExactSign       |
| COVID-19 Antigen Rapid Test Cassette(Nasal Swab)  | ICOVN-C81H | Mr. Tellme      |
| COVID-19 Antigen Rapid Test Cassette(Nasal Swab)  | ICOVN-C81H | Tellius         |
| COVID-19 Antigen Rapid Test Cassette(Nasal Swab)  | ICOVN-C81H | SayFine         |
| COVID-19 Antigen Rapid Test Cassette(Nasal Swab)  | ICOVN-C81H | Lumiratek       |
| COVID-19 Antigen Rapid Test Cassette(Nasal Swab)  | ICOVN-C81H | Dongmeng        |
| COVID-19 Antigen Rapid Test Cassette(Nasal Swab)  | ICOVN-C81H | the One Medical |
| COVID-19 Antigen Rapid Test Cassette(Nasal Swab)  | ICOVN-C81H | Viewell         |
| COVID-19 Antigen Rapid Test Cassette(Nasal Swab)  | ICOVN-C81H | SeeRight        |



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Warsaw, 23/05/2022

**Director**  
**Medical Devices Certification**  
**Department**