



CERTIFICATE

EC Certificate No. 1434-IVDD-455/2021

**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 01.09.2021 to 27.05.2024

The date of issue of the Certificate: 01.09.2021

The date of the first issue of the Certificate: 01.09.2021



Issued under the Contract No. MD-39/2021
Application No: 052/2021
Certificate bears the qualified signature.
Warsaw, 01.09.2021
Module A1

Vice-President

ANNEX 1 TO THE CERTIFICATE VALID ONLY WITH CERTIFICATE

No 1434-IVDD-455/2021

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



Director

Medical Device Certification Department

Issued under the Contract No. [MD-039/2021](#)
Application No: [052/2021](#)
Certificate bears the qualified signature.
Warsaw, [20.12.2021](#)