



CERTIFICATE

EC Certificate No. 1434-IVDD-429/2021

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

Polish Centre for Testing and Certification certifies
that manufactured by:

**Hangzhou AllTest Biotech Co., Ltd,
#550,Yinhai Street Hangzhou Economic & Technological
Development Area, Hangzhou, 310018, 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 07.06.2021 to 27.05.2024

The date of issue of the Certificate: 07.06.2021

The date of the first issue of the Certificate: 28.05.2021



Issued under the Contract No. MD-136/2020
Application No: 333/2020a
Certificate bears the qualified signature.
Warsaw, 07.06.2021
Module A1

Anna
Małgorzata
Wyroba
Elektronicznie
podpisany przez Anna
Małgorzata Wyroba
Data: 2021.06.08
16:53:30 +02'00'
Vice-President



ANNEX 1 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-IVDD-429/2021

List of medical devices covered by the certificate:

Product	REF Number	Brand
COVID-19 Antigen Rapid Test (Oral Fluid)	ICOV-802H	ALLTEST
COVID-19 Antigen Rapid Test (Oral Fluid)	ICOV-802H	Beright
COVID-19 Antigen Rapid Test (Oral Fluid)	ICOV-802H	JusChek
COVID-19 Antigen Rapid Test (Oral Fluid)	ICOV-802H	Lambra
COVID-19 Antigen Rapid Test (Oral Fluid)	ICOV-802H	SCREEN CHECK TEST
COVID-19 Antigen Rapid Test (Oral Fluid)	ICOV-802H	Rapid Response



Issued under the Contract No. **MD-136/2021**
Application No: **333/2020a**
Certificate bears the qualified signature.
Warsaw, 07/06/2021

Anna
Małgorzata
Wyroba

Vice-President

Elektronicznie
podpisany przez Anna
Małgorzata Wyroba
Data: 2021.06.08
16:52:41 +02'00'



Certificate

No. Q5 095123 0007 Rev. 03

Holder of Certificate: **Hangzhou AllTest Biotech Co., Ltd.**

550#, Yin Hai Street
Hangzhou Economic and Technological Development Area
310018 Hangzhou
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Hangzhou AllTest Biotech Co., Ltd.
550#, Yin Hai Street, Hangzhou Economic and Technological
Development Area, 310018 Hangzhou, PEOPLE'S REPUBLIC OF
CHINA

Certification Mark:



Scope of Certificate:

Design and Development, Production and Distribution of In Vitro Diagnostic Kit for Obstetrics and Gynecology, Infectious Disease, Drug of Abuse, Vitamin, Special Protein, Oncology, Cardiology and Biochemistry, and Digital test for pregnancy and ovulation. Home use, Clinical Laboratory use and Near Patient In-vitro Diagnostic Devices and the related POCT analyzer.

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH20106401

Valid from: 2020-09-25

Valid until: 2023-09-24

Date, 2020-08-05

Christoph Dicks

Head of Certification/Notified Body

Pro-med COVID-19 Antigen Rapid Detection Kit	Pro-med (Beijing) Technology Co., Ltd.
Covid-19 Antigen Rapid Test (Oral fluid)	Hangzhou AllTest Biotech Co., Ltd.
Novel Coronavirus (COVID-19) Antigen Rapid Test Kit	Qingdao AIBO Diagnostic CO., LTD.
Rapid SARS-CoV-2 Antigen Test (Colloidal Gold)	InTec Products, Inc.
2019-nCoV Antigen Test Kit	Chongqing M&D Biotechnology Co. Ltd.
Synthgene Neues Coronavirus (SARS-CoV-2) Antigen-Schnellerkennungs kit (Collate Gold-Methode)	Nanjing Synthgene Medical Technology Co., Ltd.
Joysbio SARS-CoV-2 Antigen rapid test kit - PRO (Colloidal Gold)	JOYSBIO (Tianjin) Biotechnology Co., Ltd.
SureScreen COVID-19 Antigen Rapid	SureScreen Diagnostics Ltd.
2019-nCoV Ag Test (Latex Chromatography Assay)	Innovita (Tangshan) Biological Technology Co., LTD.
SARS-CoV-2 Antigen Test Kit (Lateral Flow Assay)	Wuxi Biohermes Bio & Medical Technology Co., Ltd.
SARS-CoV-2 Spike Protein Test Kit (Fluorescence Immunoassay)	Shenzhen Microprofit Biotech Co., Ltd
Zijian SARS-CoV-2 (COVID-19) Antigen Rapid Detection Kit (Lateral Flow Method)	Shen Zhen Zi Jian Biotechnology Co., Ltd.
New Coronavirus (COVID-19) Antigen Rapid Test	Anhui Formaster Biosci Co., Ltd
Sienna COVID-19 Antigen-Schnelltestkassette (Nasenabstrich)	Hangzhou Biotest Biotech Co., Ltd
SARS-CoV-2 Antigen Rapid Detection Kit (LFA)	Acro Diagnostics Co., Ltd
SARS-CoV-2 Antigen Test Cassette	Jiangsu Mole Bioscience Co., Ltd
SARS-CoV-2-Antigen-Schnelltestgerät	Hangzhou Funworld Biotech. Co., Ltd
COVID-19 Antigen Test Kit	Beijing Homa Biological Engineering Co., Ltd.
InstantSure Covid-19 Ag CARD	Suzhou Soochow University SAIER IMMUNO BIOTECH Co., Ltd.
KaiBILI COVID-19 Antigen Pro	Hangzhou Genesis Biodetection & Biocontrol Co., Ltd.
SARS-Cov-2-Antigen-Schnelltest-Karte	BioDetect (Xiamen) Biotechnology Co., Ltd
Neuartiges Coronavirus (2019-nCoV) Antigendetektionsreagenz (immunochromatographischer Assay)	Zhongxiu Science and Technology Co., Ltd
Virusee® SARS-CoV-2 Antigen Rapid Test (Colloidal Gold) (Saliva/Swab)	Genobio Pharmaceutical Co., Ltd.
SARS-CoV-2 Ag Rapid Test	BioMaxima S.A.
SARS-Cov-2 Nucleocapsid(N) Antigen Rapid Test Cassette	Hangzhou Zheda Dixun Biological Gene Engineering CO. Ltd.
SARS-CoV-2 Antigen Rapid Test	Nantong Egens Biotechnology
Convergys® COVID-19 Rapid Antigen Test	Convergent Technologies
INVBIO One Step Diagnostic Rapid Test Cassette	Innovation Biotech (Beijing) Co. LTD
SARS-CoV-2 Antigen Rapid Test Kit (Immunochromatography)	Shenzhen Huaree Technology Co., Ltd
Dräger Antigen Test SARS-CoV-2	Dräger Safety AG & Co. KGaA
LionRun™ SARS-CoV-2 Antigen Rapid Test Kit (Lateral Flow Immunoassay)	Shanghai Liangrun Biomedicine Technology Co., Ltd.
SARS-CoV-2 Antigen Saliva Rapid Test Kit	Shenzhen Huaree Technology Co., Ltd
SARS-CoV-2 Antigen Assay Kit by Latex Immunochromatography method	Sichuan Xincheng Biological Co., LTD
COVID-19 Schnelltestgerät	Jiangsu Well Biotech Co., Ltd.