CERTIFICATE

EC Certificate No. 1434-IVDD-036/2022

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

Polish Centre for Testing and Certification certifies
that manufactured by:

Hangzhou 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

COVID-19 Antigen Rapid Test (Oral Fluid)

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 16.03.2022 to 27.05.2025

The date of issue of the Certificate: 16.03.2022

The date of the first issue of the Certificate: 28.05.2021

CE 1434

Issued under the Contract No. MD-136/2020
Application No: 333/2020
Certificate bears the authorized person signature.
Warsaw, 16/03/2022
Module A1

President
Aleksandra Kostrzewa

Polish Centre for Testing and Certification 469 Puławska Street, 02-844 Warsaw Poland, phone +48 22 46 45 200, e-mail: pcbc@pcbc.gov.pl

ANNEX TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-IVDD-036/2022

List of medical devices covered by the certificate:

Serial No.	Brand/Trademark	Product Name	REF. No.
1	ALLTEST	COVID-19 Antigen Rapid Test (Oral Fluid)	ICOV-802H
2	Beright	COVID-19 Antigen Rapid Test (Oral Fluid)	ICOV-802H
3	JusChek	COVID-19 Antigen Rapid Test (Oral Fluid)	ICOV-802H
4	Lambra	COVID-19 Antigen Rapid Test (Oral Fluid)	ICOV-802H
5	SCREEN CHECK TEST	COVID-19 Antigen Rapid Test (Oral Fluid)	ICOV-802H
6	Rapid Response	COVID-19 Antigen Rapid Test (Oral Fluid)	ICOV-802H
7	AllChek	COVID-19 Antigen Rapid Test (Oral Fluid)	ICOV-802H
8	RYPO	COVID-19 Antigen Rapid Test (Oral Fluid)	ICOV-802H
9	Mila	Mila Covid-19 Szybki Test Antygenowy Ze Śliny	ICOV-802H
10	Novasalus	Test Rapido per l'Antigene COVID-19 (Fluido Orale)	ICOV-802H
11	Detect	COVID-19 Antigen Rapid Test (Oral Fluid)	ICOV-802H
12	DNA DIAGNOSTIC	COVID-19 Antigen Rapid Test (Oral Fluid)	CV19OFH
13	EQL PHARMA	COVID-19 Antigen Rapid Test (Oral Fluid)	ICOV-EQL1
14	INNOVA	COVID-19 Antigen Rapid Test (Oral Fluid)	ICOV-802H
15	the one medical	COVID-19 Antigen Rapid Test (Oral Fluid)	ICOV-802H

CE 1434

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Sertio Oy
Biokatu 10
33520 Tampere
Finland

21.5.2025

Notified Body Confirmation Letter

Reference: 800081 (customer ID)

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2024/1860 amending Regulations (EU) 2017/746 as regards the transitional provisions for certain in vitro diagnostic medical devices.

This letter confirms that, Sertio Oy, a Notified Body (NB) designated against Regulation (EU) 2017/746 (IVDR) and identified by the number 3018 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of IVDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of IVDR with the following manufacturer:

Hangzhou Alltest Biotech Co.,Ltd.
#550, Yinhai Street, Hangzhou Economic & Technological Development Area
Hangzhou-310018
P.R. China

SRN Number (if available): CN-MF-000010710

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an IVDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the Directive 98/79/EC.

Table 2 identifies the devices for which an IVDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the Directive 98/79/EC.

In the case of devices covered by certificates issued under Directive 98/79/EC (IVDD) that expired after 26 May 2022 and before 09 July 2024, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under IVDR by the date of IVDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from

the applicable conformity assessment procedure in accordance with Article 54 of IVDR or Article 92 of the IVDR respectively, by the 09 July 2024 for the relevant devices. The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 110.3c of IVDR (as amended by (EU) 2024/1860), are shown below:

- 31 December 2027 for devices covered by an IVDD certificate regardless of their risk class under the IVDR
- For devices not requiring the involvement of a notified body under the IVDD, but requiring it under the IVDR and for which a declaration of conformity was drawn up prior to 26 May 2022 in accordance with Directive 98/79/EC, the following dates apply:
  - 31 December 2027, for class D devices;
  - 31 December 2028, for class C devices;
  - 31 December 2029, for class B devices and for class A devices placed on the market in sterile condition

On behalf of the Notified Body,

Mikko Soikkeli
Deputy Head of the Notified Body 3018
Notified Body 3018
Biokatu 10, 33520 Tampere, Finland
info@sertio.fi
www.sertio.fi

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Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under Directive 98/79/EC:

Device name or Basic UDI-DI (under IVDR application)	**IVDR Device classification (as proposed by the manufacturer and verified at the preapplication stage)**	**If the IVDR device is a substitute device, identification of the corresponding IVDD device**	**IVDD/ Certificate Reference(s) of the devices under IVDR application, and the NB Identification**
COVID-19 Antigen Rapid Test *Basic UDI-DI: 6970277510021PYN*	*Class C*	*N/A*	*Certificate # 1434-IVDD-036/2022; NB# 1434*
SARS-CoV-2 (COVID-19) Antigen Rapid Test *Basic UDI-DI: 6970277510013QYR*	*Class C*	*N/A*	*Certificate # 1434-IVDD-216/2022; NB# 1434*

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under Directive 98/79/EC:

Device name or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified at the preapplication stage)	If the IVDR device is a substitute device, identification of the corresponding IVDD device	IVDD/ Certificate Reference(s) of the devices under IVDR application, and the NB Identification
-	-	-	-
-	-	-	-

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
9.5.2025	800081CL-1	Initial issue
21.5.2025	800081CL-2	Transfer devices from Table 2 to Table 1 according to agreed responsibilities.