DEEPBLUE

www.dbluemedical.com

EU DECLARATION OF CONFORMITY

According to Article 17 of Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices

Manufacturer:	Anhui Deepblue Medical Technology Co., Ltd. No. 777 Jimingshan Road, High-Tech Development Zone, 230088 Hefei, Anhui, PEOPLE'S REPUBLIC OF CHINA
SRN:	CN-MF-000018785
European Representative:	Mega Eurostar Sp. z o. o. ul. Obrzeżna 5XIP/1, 02-691, Warsaw, Poland
SRN:	DE-AR-000005110
Product Name:	SARS-CoV-2 & Influenza A+B & RSV & ADV Antigen Combo Test Kit (Colloidal Gold)
Product Model:	Cassette
EMDN:	W0105099099
Basic UDI-DI:	69520627J034LD
Classification acc. to IVDR Ax. VIII:	Class C, rule 4 of IVDR Annex VIII
Conformity Assessment Procedure:	Pursuant to Regualtion (EU) 2017/746, Annex IX Chapters I, II and III
CE Certificate No.:	EU-TDA-FI-20642-800030-2025-1
Name and ID of the Notified Body:	Sertio Oy Notified Body 3018 Biokatu 10, 33520 Tampere Finland NB number: 3018 E-mail: info@sertio.fi

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices (IVDR). All supporting documentations are retained under the premises of the manufacturer.

START OF CE-MARKING: March 21th, 2025

CE 3018

PLACE, DATE OF ISSUE: Anhui Hefei, China, March 28th, 2025

SIGNATURE:

EU Declaration of Conformity

SL-CE80-CFRA-8.1 (A/1)

EU TECHNICAL DOCUMENTATION ASSESSMENT CERTIFICATE

Manufacturer:	**ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO., LTD.** No. 777 Jimingshan Road, High-Tech Development Zone, 230088 Hefei, Anhui PEOPLE'S REPUBLIC OF CHINA
Single registration number:	CN-MF-000018785
Authorized representative:	**Mega Eurostar Sp. z o. o.** Obrzeżna, 5 lok. XIP/1 02-691 Warsaw Poland
Single registration number:	PL-AR-000042730

Notified Body Sertio Oy declares that the requirements of Annex IX, Chapter II of the

REGULATION (EU) 2017/746
on In Vitro Diagnostic Devices

have been met for the products listed in this certificate.
The above mentioned manufacturer has established and maintains a technical documentation defined by Annex IX chapter II. In addition to this certificate an EU Quality Management System certificate is required before placing the listed product on the market.

Certificate validity is subject to manufacturer fulfilling the obligations arising from the Annex IX of the aforementioned regulation. Validity of the certificate is subject to following the General terms of Business by Sertio Oy and Terms of conformity assessment of IVD medical devices.

Certificate number	EU-TDA-FI-20642-800030-2025-1
Issue date	21.03.2025
Valid from	21.03.2025
Expiry date	21.03.2030

SERTIO SERTIO SERTIO SERTIO NOTIFIED BODY CE 3018

Mikko Soikkeli

Sertio Oy

Biokatu 10, 33520 Tampere, Finland

PRODUCTS

Certificate number	EU-TDA-FI-20642-800030-2025-1
Issue date	21.03.2025
Valid from	21.03.2025
Expiry date	21.03.2030

Class C for self testing

IVR 0503	Devices intended to be used to detect the presence of, or exposure to an infectious agent including sexually transmitted agents
W0105099099	Virology – RT & POC - other
Product name:	SARS-CoV-2 & Influenza A+B & RSV& ADV Antigen Combo Test Kit(Colloidal Gold)
Model:	CFRA1ST-X
Basic-UDI-DI:	69520627J034LD
Intended use:	This product is used for the qualitative detection of SARS-CoV-2, influenza A, influenza B, respiratory syncytial virus (RSV) and adenovirus antigen in human nasal swab specimens. It is a non-automated rapid test method for infection. This test is authorized for non-prescription home use with self collected anterior nasal (nares) swab samples from individuals. Individuals who test positive should seek follow up care with their physician or healthcare provider as additional testing may be necessary. Users under the age of 15 should complete the test with supervision of an adult. Both symptomatic and asymptomatic infections can be tested.