DEEPBLUE

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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:	PL-AR-000042730
Product Name:	Influenza A+B & COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold)
Intended Use:	This product is used for the qualitative detection of SARS-CoV-2, influenza A and influenza B 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.
Product Model:	Cassette
REF:	COVAg+FluAB1NST-1, COVAg+FluAB1NST-2, COVAg+FluAB1NST-5, COVAg+FluAB1NST-25
EMDN:	W0105099099
Basic UDI-DI:	69520627J017LD
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 Pursuant to REGULATION (EU) 2022/1107 , ANNEX XIII COMMON SPECIFICATIONS FOR DEVICES INTENDED FOR DETECTION OR QUANTIFICATION OF MARKERS OF SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2 INFECTION
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

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

PLACE, DATE OF ISSUE: Anhui Hefei, China, June 10th, 2025

SIGNATURE: Zhang Chao

POSITION:Chairman

CE 3018

EC Declaration of Conformity

SL-CE81-COVAg+FluAB-8.1 (A/1)