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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. Obrzeżna, 5 lok. XIP/1 02-691 Warsaw Poland
SRN:	PL-AR-000042730
Product Name:	COVID-19&Influenza A+B& RSV& ADV& HMPV Antigen Combo Test Kit (LFA)
Intended Use:	This product is used for the qualitative detection of COVID-19, influenza A, influenza B, respiratory syncytial virus (RSV), adenovirus(ADV) and human metapneumovirus (HMPV) 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.
Product Model:	Cassette
REF:	CFRAH1NST-1, CFRAH1NST-2, CFRAH1NST-5, CFRAH1NST-10
EMDN:	W0105070399
Basic UDI-DI:	69520627J161LM
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

PLACE, DATE OF ISSUE: Anhui Hefei, China, April 22th, 2025

Name of Signing Person: Chao Zhang

SIGNATURE: Zhang Chao

POSITION:CHAIRMAN OF THE BOARD

CE 3018

EU Declaration of Conformity