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	28.04.2026
Valid from	28.04.2026
Expiry date	21.03.2030

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Elina Tuomola
Sertio Oy
Biokatu 10, 33520 Tampere, Finland

PRODUCTS

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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, CFRA1ST-1, P120101, CFRA1NST-5B, CFRA1NST-10B, CFRA1NST-2N
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.

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: Influenza A+B & COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold)
Model: COVAg+FluAB1NST-X, COVAg+FluAB1NST-1, COVAg+FluAB1NST-2, CF1NST-5B, CF1NST-10B, CF1NST-2N
Basic-UDI-DI: 69520627J017LD
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.

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: COVID-19 (SARS-CoV-2) Antigen Test Kit(Colloidal Gold
Model: SL030101NST-X
Basic-UDI-DI: 69520627J012L3
Intended use: This product is used for the qualitative detection of SARS-CoV-2 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.

IVR 0503 Devices intended to be used to detect the presence of, or exposure to an infectious agent including sexually transmitted agents
W0105010401 H. Pylori Antigen Detection
Product name: H.Pylori Antigen Test Kit
Model: HPAg1FEST-X, HPAg4FEST-X, HPAg2FEST-X
Basic-UDI-DI: 69520627J016LB
Intended use: This product is used for the qualitative detection of Helicobacter pylori antigen in human fecal specimens. It is a non-automated rapid test designed for infection diagnosis, specifically to aid in diagnosing Helicobacter pylori infection in individuals. The test is authorized for non-prescription home use with self-collected fecal specimens.

IVR 0503 Devices intended to be used to detect the presence of, or exposure to an infectious agent including sexually transmitted agents
W0105070399 Multiple Viruses – Multiplex Assays - Other
Product name: COVID-19 & Influenza A+B & RSV & ADV & HMPV Antigen Combo Test Kit (LFA)
Model: CFRAH1NST-X
Basic-UDI-DI: 69520627J161LM
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.