EU TECHNICAL DOCUMENTATION ASSESSMENT CERTIFICATE

Manufacturer:	**BioTeke Corporation (Wuxi) Co., Ltd.** No. 90, Huiming Road, Huishan, Wuxi, Jiangsu, 214000 China
Single registration number:	CN-MF-000007517
Authorized representative:	**MedUnion S.L.** Carrer de Tapioles, 33, 2-1, 08004, Barcelona Spain
Single registration number:	ES-AR-000019366

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-43117-800031-2025
Issue date	30.05.2025
Valid from	30.05.2025
Expiry date	30.05.2030

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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: Multiple Respiratory Multipathogen Antigen Test Kit (immunochromatographic assay)

Model and type: ICA2114-7

Basic-UDI-DI: 697454156017LA

Intended use: This kit is only used for the in vitro qualitative detection of respiratory multipathogen antigen (SARS-CoV-2/Influenza A virus/Influenza B virus/Respiratory syncytial virus/Adenovirus) from human anterior nasal swab specimens. Multiple Respiratory Multipathogen Antigen Test Kit is an immunochromatographic double-antibody sandwich assay intended for the qualitative detection and differentiation of SARS-CoV/2/Influenza A virus/Influenza B virus/Respiratory syncytial virus/Adenovirus from individuals who are suspected of respiratory tract disease infection.

This kit is suitable for the auxiliary diagnosis of respiratory diseases. Results may serve as clinical reference only and cannot be used alone as the sole basis for diagnosing or excluding respiratory infections. The clinical diagnosis and treatment of patients should be considered in combination with their symptoms/signs, their medical history, other laboratory tests and treatment responses. Positive test result may need to be further confirmed, and negative result do not safely rule out viral respiratory infections.

Children under 18 years should be supported by an adult.

Certificate history

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Version	Date issued	Description
1	30.5.2025	Initial issue