

EU DECLARATION OF CONFORMITY

According to of Regulation (EU) 2017/746 on in vitro diagnostic medical devices

Name and address of the manufacturer:	BioTeke Corporation (Wuxi) Co., Ltd No. 90, Huiming Road, Huishan, Wuxi City, Jiangsu, 214000, China
SRN:	CN-MF-000007517
Trademark:	BioTeke
Name and address European Representative:	MedUnion S.L. Carrer de Tapioles, 33, 2-1, 08004, Barcelona, Spain
Trade name:	Multiple Respiratory Multipathogen Antigen Test Kit (Immunochromatographic Assay)
Product name:	Multiple Respiratory Multipathogen Antigen Test Kit (Immunochromatographic Assay)
Reference number	ICA2114-7
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-CoV2/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.
Basic UDI-DI:	697454156017LA
Classification:	Class C, rule 4a
Common specifications:	Commission Implementing Regulation (EU) 2022/1107
Conformity assessment route:	IVDR Annex IX
CE certificate No.:	

Name, address and ID of the Notified Body:

Sertio Oy
Biokatu 10, 33520 Tampere, Finland
CE 3018

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/746 on on in vitro diagnostic medical devices and the common specifications Commission Implementing Regulation (EU) 2022/1107. All supporting documentations are retained under the premises of the manufacturer.

Wuxi, 2025-5-28

Place, date

