EU TECHNICAL DOCUMENTATION ASSESSMENT CERTIFICATE

Manufacturer:	**Jiangsu Medomics Medical Technology Co.,Ltd.** Building 01, Phase 6, No.71, Xinghui Road, Jiangbei New Area, Nanjing, 210000, Jiangsu, China
Single registration number:	CN-MF-000030226
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-06912-800035-2025-1
Issue date:	10.04.2026
Valid from:	10.04.2026
Expiry date:	31.01.2030

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Mikko Soikkeli
Sertio Oy
Biokatu 10, 33520 Tampere, Finland

PRODUCTS

Certificate number	EU-TDA-FI-06912-800035-2025-1
Issue date:	10.04.2026
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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/FluA/FluB+ADV/ RSV Antigen Combo Rapid Test Kit (LFIA)
Model: 123143-01-102, 123143-02-102, 123143-05-102, 123143-20-102, HW-5combo-2025-01, HW-5combo-2025-02, HW-5combo-2025-05, 123143-01-102-PL02, 123143-02-102-PL02, 123143-05-102-PL02, 123143-20-102-PL02, 123143-01-102-PL01, 123143-01-102-LT01, 123143-01-182, 123143-02-182, 123143-05-182, 123143-20-182, 123143-01-182-01
Basic-UDI-DI: 697416789123143ZP
Intended use: SARS-CoV-2/FluA/FluB+ADV/RSV Antigen Combo Rapid Test Kit (LFIA) is an immunochromatography based one step in vitro test. It is designed for the qualitative detection of the SARS-CoV-2 virus, Influenza A virus, Influenza B virus, Adenovirus and Respiratory syncytial virus in human anterior nasal swab samples. The test results are used for the auxiliary diagnosis of respiratory pathogen infections and are suitable for people with clinical symptoms such as fever, sore throat, cough, runny nose. The test kit is designed for use as self-testing. This test kit can be used independently by individuals who are 18 or older. For those under the age of 18, it should be operated or supervised by an adult. This test kit is not used in combination with other equipment and is not automated.

Class C for self testing

IVR 0301 Devices intended to be used in screening, diagnosis, staging or monitoring of cancer
W0102160202 PSA-RT & POC
Product name: Prostate Specific Antigen (PSA) test kit (LFIA)
Model: 012103-01-142, 012103-02-142, 012103-05-142, 012103-20-142
Basic-UDI-DI: 697416789099PY
Intended use: The Prostate-Specific Antigen (PSA) Test Kit is a rapid test strip method (LFIA, lateral flow immunoassay) intended for the qualitative detection of total PSA in fingertip whole blood. Total PSA includes both free PSA and PSA in a complex form (such as PSA-ACT,PSA bound to α1-antichymotrypsin). This kit is intended to aid to diagnosis of suspected benign prostatic hyperplasia (BPH) or prostate cancer in males aged 45 years and above who present with clinical symptoms such as frequent urination, urgency, and dysuria. This kit is not automated. It is intended for lay users without training, qualification or experience. The kit is designed for self-testing.

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: Eight Respiratory Pathogen Antigen Rapid Test Kit (LFIA)

Model: 123145-01-102, 123145-02-102, 123145-05-102, 123145-20-102

Basic-UDI-DI: 697416789123145ZT

Intended use: Eight Respiratory Pathogen Antigen Rapid Test Kit (LFIA) is an immunochromatography based one step in vitro test. It is designed for the differentiation and qualitative detection of the SARS-CoV-2 virus, Influenza A virus, Influenza B virus, Adenovirus, Respiratory syncytial virus, Parainfluenza virus, Human rhinovirus, metapneumovirus in human anterior nasal swab samples. The test results are used for the auxiliary diagnosis of respiratory pathogen infections, and are suitable for people with clinical symptoms such as fever, sore throat, cough, runny nose. The test kit is designed for use as self-testing. This test kit can be used independently by individuals who are 18 or older. For those under the age of 18, it should be operated or supervised by an adult. This test kit is not used in combination with other equipment and is not automated.

Certificate history

Certificate number EU-TDA-FI-06912-800035-2025-1
Issue date: 10.04.2026
Valid from: 10.04.2026
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Version	Date issued	Description
1	31.01.2025	Initial certificate
2	24.04.2025	Supplemented with class D devices: HW-5combo-2025-01, HW-5combo-2025-02, HW-5combo-2025-05, 123143-01-102-PL02, 123143-02-102-PL02, 123143-05-102-PL02, 123143-20-102-PL02, 123143-01-102-PL01
3	27.05.2025	Down-classification of the devices from class D to class C.
4	06.06.2025	Change of Basic UDI-DI due to down-classification from class D to C.
5	08.07.2025	Supplemented with class C device: 123143-01-102-LT01
6	7.11.2025	Supplemented with class C device brand variants: - Rapicheck 123143-01-182, 123143-02-182, 123143-05-182, 123143-20-182, - 2SAN 5 in 1 Self-Test Covid-19 + Flu A + Flu B + ADV + RSV brand variant of models 123143-01-102, 123143-02-102, 123143-05-102
7	20.02.2026	Supplemented with class C self-testing device: - Prostate Specific Antigen (PSA) test kit (LFIA) 012103-01-142, 012103-02-142, 012103-05-142, 012103-20-142
8	12.03.2026	Supplemented the previously certified class C device (basic UDI-DI 697416789123143ZP) with a Co-Test brand variant: - REF 123143-01-182-01
9	10.04.2026	Supplemented with class C self-testing device: - Eight Respiratory Pathogen Antigen Rapid Test Kit (LFIA) 123145-01-102, 123145-02-102, 123145-05-102, 123145-20-102