CE 3018

Declaration of Conformity

Manufacturer information:

Name:	Jiangsu Medomics Medical Technology Co., Ltd.
Address:	Building 01, Phase 6, No.71, Xinghui Road, Jiangbei New Area, Nanjing, 210000, Jiangsu, P.R. China
Tel.:	025-58601060
SRN:	CN-MF-000030226
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Authorized representative information:

Name:	Mega Eurostar Sp. z o. o.
Address:	ul. Obrzeżna 5XIP/1, 02-691, Warsaw, Poland

Product covered by the EC declaration of conformity:

Product name:	SARS-CoV-2/FluA/FluB+ADV/RSV Antigen Combo Rapid Test Kit (LFIA)
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.
REF	123143-01-102,123143-02-102,123143-05-102,123143-20-102
Basic UDI-DI	697416789100NQ

Risk class: Class D

Rule： Devices intended to be used for the detection of the presence of, or exposure to, a transmissible agent that causes a life threatening disease with a high or suspected high risk of propagation (In accordance with the Rule 1 set out in Annex VIII of REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

Notified body:

Name: SERTIO Oy
Identification number: 3018

Conformity Assessment Procedure: Annex IX, Chapter I+Chapter II (4.4-4.8,5.1)+Chapter III

General applicable Regulation:

According to Art.17 of Regulation 2017/746(EU) on in vitro diagnostic medical devices Standard Applied: All other applicable union legislations, harmonized standards and common specification (published in the Official Journal of the European Communities)

This declaration of conformity is issued under Commission Implementing Regulation (EU) 2022/1107 of 4 July 2022, laying down common specifications for certain class D in vitro diagnostic medical devices in accordance with Regulation (EU) 2017/746 of the European Parliament and of the Council".

Name: Kangjun Sun **Function or Title:** Person Responsible for Regulatory Compliance

Signature:

Place: Nanjing **Date:** 2025-01-24

Issue on behalf of Jiangsu Medomics Medical Technology Co., Ltd.

Attachment 1

References to other union legislations, standards and common specification (if applicable）

Applied

1. Laws, Regulations and Standards

No.	Standards	Title
1	(EU) 2017/746 IVDR	Regulation (EU) 2017/746 on in vitro diagnostic medical devices
2	Regulation (EC) No 1907/2006	Concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
3	Regulation (EU) 2022/1107	Commission Implementing Regulation (EU) 2022/1107 of 4 July 2022, laying down common specifications for certain class D in vitro diagnostic medical devices in accordance with Regulation (EU) 2017/746 of the European Parliament and of the Council

2. Applicable standards

No.	Standards	Title
1	EN 13612:2002	Performance evaluation of in vitro diagnostic medical devices
2	IEC 62366-1:2020	Medical devices – Part 1 Application of usability engineering to medical devices
3	EN ISO 17511:2021	In vitro diagnostic medical devices. Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples
4	EN ISO 18113-1:2011	In Virto diagnostic medical devices-Information supplied by the manufacturer(Labelling)-Part 1: Terms, definitions and general requirements (ISO 18113-1:2009)
5	EN ISO 18113-4:2012	In Virto diagnostic medical devices-Information supplied by the manufacturer(Labelling)-Part 4: In vitro diagnostic reagents for self-testing (ISO 18113-4:2009)
6	EN ISO 23640:2015	In vitro diagnostic medical devices — Evaluation of stability of in vitro diagnostic reagents (ISO 23640:2011)
7	ISO 13485:2016	Medical devices — Quality management systems — Requirements for regulatory purposes
8	ISO 14971:2019	Medical devices — Application of risk management to medical devices
9	ISO 15198:2004	Clinical laboratory medicine — In vitro diagnostic medical devices — Validation of user quality control procedures by the manufacturer
10	ISO 15223-1:2021	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
11	ISO 20916：2019	In vitro diagnostic medical devices — Clinical performance studies using specimens from human subjects — Good study practice
12	ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
13	EN1041:2008+A1:2013	Information supplied by the manufacturer with medical devices
14	ASTM F1886/F1886M-16	Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection

15	EN ISO 14644-1:2015	Cleanroom and associated controlled environments - Part 1: Classification of air cleanliness
16	EN 13532:2002	General requirements for in vitro diagnostic medical devices for self-testing
17	EN ISO 23640:2015	In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents
18	EN 13640-2002	Stability testing of in vitro diagnostic reagents
19	ISO11607-1:2006	Packaging for terminally sterilized medical devicesPart 1: Requirements for materials, sterile barrier systems and packaging systems
20	ISO/TR 24971：2020	Medical devices — Guidance on the application of ISO 14971
21	ISO/TR 20416:2020	Medical devices — Post-market surveillance for manufacturers

3 Guidance documents

No.	Standards	Title
1	GLSI EP 25-A	Evaluation of Stability of in Vitro Diagnostic Regents;Approved Guideline
2	GLSI EP 12-A2	User Protocol for Evaluation of Qualitative Test Performance;Approved Guideline-Second Edition
3	GLSI EP15-A	User Demostration of Performance for Precision and Accuracy;Approved Guideline
4	MDCG 2022-2	Guidance on general principles of clinical evidence for In Vitro Diagnostic medical devices (IVDs)
5	CLSI EP07	Interference Testing in Clinical Chemistry, 3rd Edition
6	CLSI EP17	Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures, 2nd Edition
7	CLSI EP18	Risk Management Techniques to Identify and Control Laboratory Error Sources, 2nd Edition
8	CLSI EP37Ed1E	Supplemental Tables for interference Testing in Clinical Chemistry, 1st Edition