CE 3018

EU 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
E-mail	info@medomics-dx.com

Authorized representative information:

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

Product covered by the EU declaration of conformity:

Product name:	Eight Respiratory Pathogen Antigen Rapid Test Kit (LFIA)
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.
REF	123145-01-102,123145-02-102,123145-05-102,123145-20-102
Basic UDI-DI	697416789123145ZT
Risk class	Class C

Rule：Devices intended for self-testing are classified as class C, except for devices for the detection of

pregnancy, for fertility testing and for determining cholesterol level, and devices for the detection of glucose, erythrocytes, leucocytes and bacteria in urine, which are classified as class B (In accordance with the Rule 4(a) 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

General applicable Regulation:

The device covered by this EU declaration of conformity complies with Regulation (EC) No. 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals. All other applicable union legislations, harmonized standards, and common specifications as listed in attachment 1 (as published in the Official Journal of the European Communities) are met.

This EU Declaration of Conformity has been drafted in accordance with Article 17 of Regulation (EU) 2017/746 on the application of standards for in vitro diagnostic medical devices.

This EU declaration of conformity is issued under the sole responsibility of the manufacturer.

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

Signature: Kangjun Sun

Place: Nanjing, China **Date:** 2026-04-16

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

2. Applicable standards

No.	Standards	Title
1	EN 13612:2002	Performance evaluation of in vitro diagnostic medical devices
2	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
3	EN ISO 18113-1:2024	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions, and general requirements (ISO 18113-1:2022)
4	EN ISO 18113-4:2024	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 4: In vitro diagnostic reagents for self-testing (ISO 18113-4:2022)
5	EN ISO 23640:2015	In vitro diagnostic medical devices — Evaluation of stability of in vitro diagnostic reagents (ISO 23640:2011)
6	ISO 13485:2016	Medical devices — Quality management systems — Requirements for regulatory purposes
7	ISO 14971:2019	Medical devices — Application of risk management to medical devices
8	ISO 15198:2004	Clinical laboratory medicine — In vitro diagnostic medical devices — Validation of user quality control procedures by the manufacturer
9	ISO 15223-1:2021	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
10	ISO 20916：2019	In vitro diagnostic medical devices — Clinical performance studies using specimens from human subjects — Good study practice
11	ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
12	EN1041:2008+A1:2013	Information supplied by the manufacturer with medical devices
13	ASTM F1886/F1886M-16	Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
14	EN ISO 14644-1:2015	Cleanroom and associated controlled environments - Part 1: Classification of air cleanliness
15	EN 13532:2002	General requirements for in vitro diagnostic medical devices for self-testing

16	ISO11607-1:2006	Packaging for terminally sterilized medical devices Part 1: Requirements for materials, sterile barrier systems and packaging systems
17	ISO/TR 24971：2020	Medical devices — Guidance on the application of ISO 14971
18	ISO/TR 20416:2020	Medical devices — Post-market surveillance for manufacturers