

CE 1434

EC Declaration of Conformity

Manufacturer information:

Name: Jiangsu Medomics Medical Technology Co., Ltd.

Address: F3, Building C, No.3-1 Xinjinhu road, Jiangbei new area, Nanjing, Jiangsu, China

Authorized representative information:

Name: R Sight B.V.

Address: Roald Dahllaan 47, 5629 MC, Eindhoven.The Netherlands

Product covered by the EC declaration of conformity:

Product name: SARS-CoV-2 Antigen Test Kit (LFIA)

REF: 1031-14-01, 1031-34-01, 1031-54-01

Risk class: IVD for self-testing(In accordance with the rule set out in Annex III of DIRECTIVE 98/79/EC-IVDD)

Notified body:

Name: The Polish Center for Testing and Certification

Identification number: 1434

Conformity Assessment Procedure: Annex III, section 6

General applicable Regulation:

DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in vitro diagnostic medical devices

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

Standard Applied:

All other applicable union legislations, harmonized standards and common specification (published in the Official Journal of the European Communities)

Name: Zongzhi Chai **Function or Title:** Management Representative

Signature:

Place:

Date:

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

File ID: 1031-DOC-01

Version: A/2

Attachment 1

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

- 1) EN ISO13485:2016 Medical devices - Quality management systems- Requirements for regulatory purposes
- 2) EN ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
- 3) EN ISO 14971:2012 Medical devices - Application of risk management to medical devices
- 4) ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- 5) EN ISO 11135:2014+A1:2019 Sterilization of health care products - Ethylene oxide - Requirements for development, validation and routine control of a sterilization process for medical devices
- 6) EN ISO 11607-1:2020: Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
- 7) EN ISO 11607-2:2020: Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
- 8) ISTA-2A:2011: Series Partial Simulation Performance Test Procedure (Packaged - Products 150lb (68kg) or less)
- 9) ASTM F1886/F1886M-16 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
- 10) EN1041:2008+A1:2013 Information supplied by the manufacturer with medical devices
- 11) EN ISO 14644-1:2015 Cleanroom and associated controlled environments - Part 1: Classification of air cleanliness
- 12) EN ISO 11737-1:2018 Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products
- 13) EN ISO 11737-2:2018 Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
- 14) EN 62366-1:2015 Medical devices - Application of usability engineering to medical devices
- 15) EN ISO 18113-1:2011 In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). Terms, definitions and general requirements
- 16) EN ISO 18113-4:2011 In vitro diagnostic medical Devices. Information supplied by the manufacturer (labelling). In vitro diagnostic reagents for self-testing
- 17) EN 13532:2002 General requirements for in vitro diagnostic medical devices for self-testing

- 18) EN ISO 23640:2015 In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents
- 19) EN 13640-2002 Stability testing of in vitro diagnostic reagents
- 20) EN 592-2002 Instructions for use for in vitro diagnostic instruments for self-testing
- 21) EN ISO 13612:2002 Performance evaluation of in vitro diagnostic medical devices
- 22) EN ISO 14155:2011 Clinical investigation of medical devices for human subjects Good clinical practice
- 23) MEDDEV 2.7.1 Rev.4 GUIDELINES ON MEDICAL DEVICES
- 24) EP12-A2 User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline Second Edition

