KINGLINE
GMBH

MEDOMICS

SARS-COV-2 & INFLUENZA A/B ANTIGEN COMBO RAPID TEST KIT (LFIA)

Zertifiziert und Evaluiert

Zuverlässig sehr genaue Ergebnisse

Persönliche Experten-Beratung

sales@kingline.de | +49 (0) 9135 - 5718390

Version: 1.0 | Freigabe: 15.12.2022

Kingline GmbH | Am Altenbach 7 | 91341 Röttenbach

EINFACHE UND SICHERE ANWENDUNG

ZUVERLÄSSIG SEHR GENAUE ERGEBNISSE

SCHNELLES TESTERGEBNIS

CE-ZERTIFIZIERT (CE-1434)

PRODUKTBILDER

Vorderansicht

Packungsinhalt

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DETAILINFORMATIONEN

CE-Kennzeichnung	CE-1434
Art der Probe	Anterior Nasal
Anwendungsart	Laien-Test
LoD-Wert SARS-CoV-2	BetaCoV/JS02/human/2020: 10^1xTCID50/mL
LoD-Wert Influenza-A	A/Brisbane/02/2018 (H1N1): 10^4xTCID50/mL A/PUERTO/8/1934 (H1N1): 10^2xTCID50/mL A/Kansas/14/2017 (H3N2): 10^2xTCID50/mL A/Aichi/2/1968 (H3N2): 10^2xTCID50/mL A/Anhui/1/2013 (H7N9): 10^4xTCID50/mL
LoD-Wert Influenza-B	B/Colorado/06/2017 (Victoria): 10^0xTCID50/mL B/Phuket/3073/2013 (Yamagata): 10^2xTCID50/mL B/Chaoyang Beijing/12977/2017 (Yamagata): 10^4xTCID50/mL
Diagnostische Sensitivität SARS-CoV-2	91,28 %
Diagnostische Spezifität SARS-CoV-2	100 %
Diagnostische Sensitivität Influenza-A	92,66 %
Diagnostische Spezifität Influenza-A	100 %
Diagnostische Sensitivität Influenza-B	90,74 %
Diagnostische Spezifität Influenza-B	100 %
Haltbarkeit (ab Produktionsdatum)	24 Monate
Verfügbare Sprachen des Handbuchs	Deutsch*

*Für Verfügbarkeiten wenden Sie sich bitte an einen unserer Vertriebsmittarbeiter.

LOGISTIKDATEN

VPE	572 Stk. (1er-Packung)
VPE Gewicht	18 kg (1er-Packung)
VPE Maße (B x H x T)	50x35x60 cm (1er-Packung)
Lagertemperatur	min. 2 °C; max. 30°C
Vereinzelbar	ja

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DISTRITBUTION

Hersteller	Jiangsu Medomics Medical Technology Co., Ltd. F3, BuildingC, No. 3 - 1 Xinjinhu Road, Jiangbei New Area, Nanjing, Jiangsu
EC-REP	R Sight B.V. Road Dahllaan 47, 5629 MC, Eindhoven, The Netherlands Registrierungsnummer: 76704726 Tel: 0031640845545 E-Mail: info@rsight.nl
Importeur	Kingline GmbH Am Altenbach 7 91341 Röttenbach

CERTIFICATE

EC Certificate No. 1434-IVDD-193/2022

EC Design-examination
Directive 98/79/EC concerning
***in vitro* diagnostic medical devices**

Polish Centre for Testing and Certification certifies
that manufactured by:

Jiangsu Medomics Medical Technology Co., Ltd.
F3, Building C, No.3-1 Xinjinhu Road,
Jiangbei New Area, Nanjing, Jiangsu 210030 CHINA

in vitro diagnostic medical devices
for self-testing

SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test Kit (LFIA)
Ref. no.: 1041-14-01, 1041-24-01, 1041-34-01, 1041-54-01

in terms of design documentation, comply with requirements
of Annex III (Section 6) to Directive 98/79/EC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 24.05.2022 to 27.05.2025

The date of issue of the Certificate: 24.05.2022

The date of the first issue of the Certificate: 24.05.2022

CE 1434

Issued under the Contract No. MD-206/2021
Application No: 582/2021
Certificate bears the qualified signature.
Warsaw, 24/05/2022
Module A1

Tomasz Koeber
Elektronicznie podpisany
przez Tomasz Artur Koeber
Data: 2022.05.24 07:10:38
+02'00'

Director
Medical Device Certification
Department

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 & Influenza A/B Antigen Combo Rapid Test Kit (LFIA)

REF: 1041-14-01, 1041-24-01,1041-34-01, 1041-54-01

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

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 the sole responsibility of the manufacturer "per Requirements of decision COMMISSION REGULATION(EC) No 768/2002".

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

Signature: Zong Zhi Chai

Place: Nanjing china

Date: 2022.04.10

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) 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) MDCG 2021-21 Guidance on performance evaluation of SARS-CoV-2 in vitro diagnostic medical devices