MEDOMICS MEDICAL TECHNOLOGY Co., Ltd.
Tel / 400-915-2000 • Web / www.medomics-dx.com • E-mail / overseas@medomics-dx.com
ADD / F3, BuildingC, No.3-1XinjinhuRoad, Jiangbei New Area, Nanjing, China

SARS-CoV-2
Antigen Test Kit (LFIA)
For Self-Testing

INFECTIOUS DISEASE

Packing size:
1 pc/Box / 2 pcs/Box
5 pcs/Box / 20 pcs/Box

Storage:
2-30℃

Detection Time:
15-20 minutes

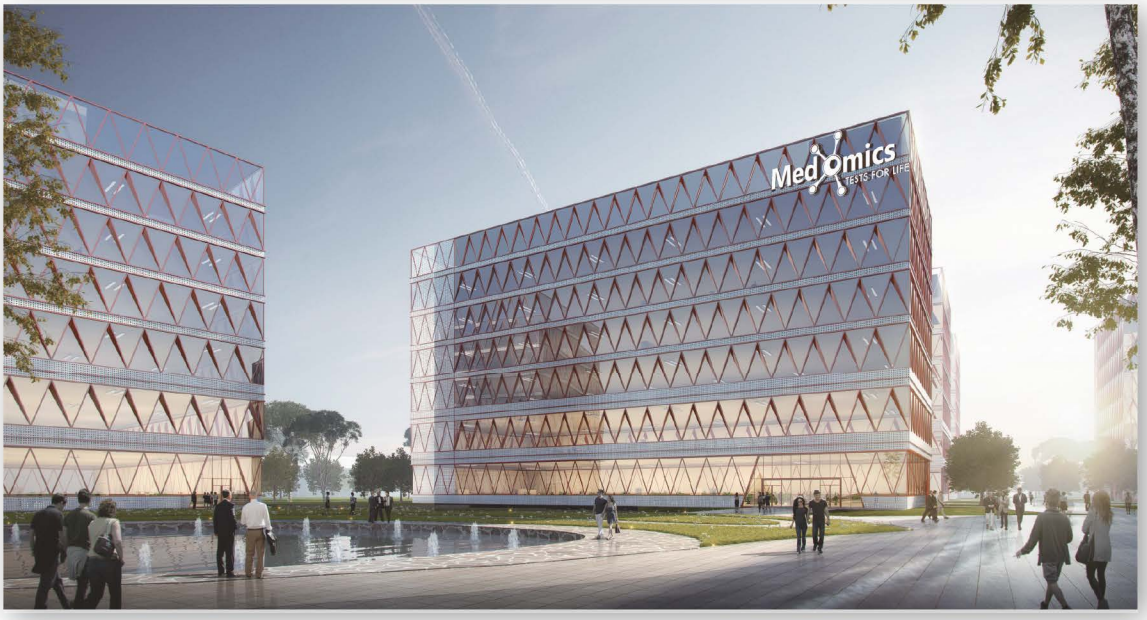
Shelf Life:
12 months

Company Profile

Jiangsu Medomics Medical Technology Co., Ltd., founded in October 2017, is located at Biotech and Pharmaceutical Valley of Jiangbei New Area, Nanjing, Jiangsu Province. It is an international high-tech enterprise driven by innovation in the area of medical devices R&D, production and sales. Medomics focuses on diagnosis of microorganisms, tumors and some rare diseases, mainly engaged in the research and development, production and sales of in vitro diagnostic reagents and automatic instruments.

At the very beginning of COVID-19 on early 2020, Medomics developed IgM/IgG antibody detecting kit with the team of Zhong Nanshan. And Medomics published the first research paper on international journal together with State Key Laboratory of Respiratory Disease (National Clinical Research Center for Respiratory Disease, Guangzhou Institute of Respiratory Health). The detecting kit was validated by CDC, Harvard Medical School and Columbia University Irving Medical Center etc. The kit has been exported to dozens of countries and areas, making great help against SARS-CoV-2.

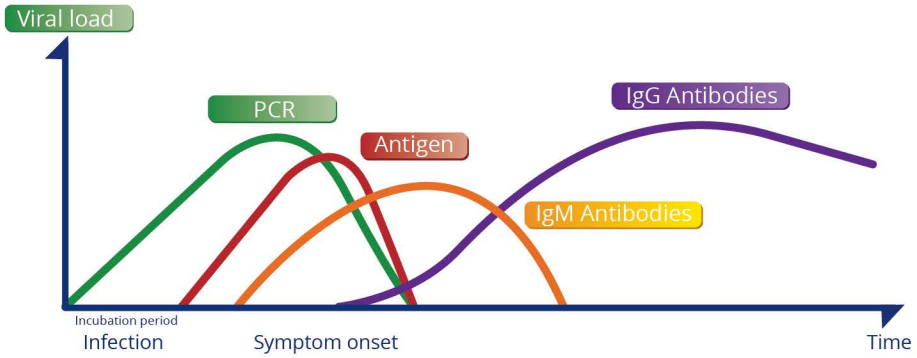
At present, Medomics's series product of SARS-CoV-2 detection have been developed according to ISO 13485 Quality system and European CE Certification.

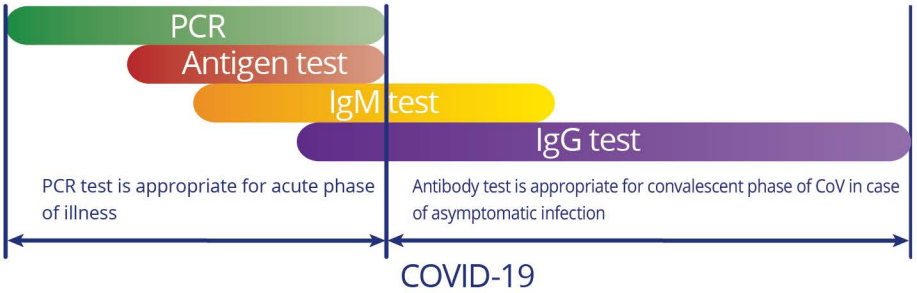


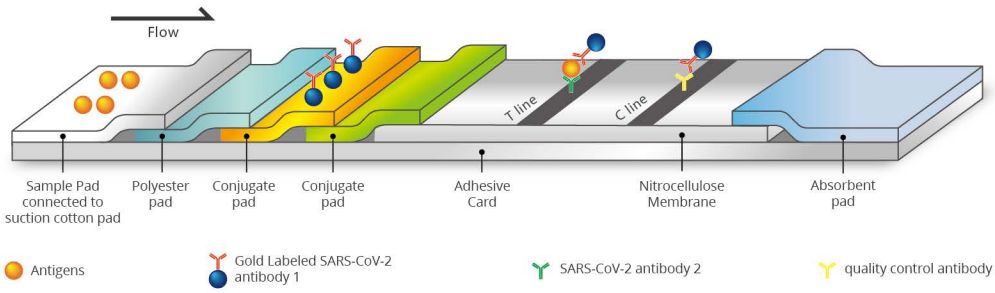
Tel / 400-915-2000 • Web / www.medomics-dx.com • E-mail / overseas@medomics-dx.com
ADD / F3, BuildingC, No.3-1XinjinhuRoad, Jiangbei New Area, Nanjing, China

Test Principle

SARS-CoV-2 Antigen Test Kit (LFIA) detects the SARS-CoV-2 nucleocapsid antigens with colloidal gold immunochromatography using a double antibody sandwich assay. The test cassette contains (1) colloidal gold-labeled anti-SARS-CoV-2 Nucleocapsid Protein antibody, (2) one detection T line and one quality control C line fixed on a nitrocellulose membrane. T line is fixed with another anti-SARS-CoV-2 Nucleocapsid Protein antibody for detecting SARS-CoV-2. The quality control antibody is fixed on the C line. When the appropriate amount of test sample treated with lysis buffer is added to the sample well of the test cassette, the sample will move forward along the test strip via capillary action. If the sample contains SARS-CoV-2 nucleocapsid antigens and concentration is higher than the limit of detection, the antigens will bind to the colloidal gold-labeled anti-SARS-CoV-2 Nucleocapsid Protein antibody.
The immune complex will be captured by another anti-SARS-CoV-2 Nucleocapsid Protein antibody immobilized on the membrane, forming a red T line and indicating a positive result for SARS-CoV-2. If the sample contains no SARS-CoV-2 nucleocapsid antigens or concentration is lower than the limit of detection, a negative result is displayed.







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ADD / F3, BuildingC, No.3-1XinjinhuRoad, Jiangbei New Area, Nanjing, China

- One step test.
- Very high sensitivity.
- Results in 15 minutes.
- Early detection of infection.
  Detects current variants with an ongoing progrom to test against emerging variants.
- User friendly.
- A visual guide is provided for people who prefer images or where English is their second language.
- Includes software support test kit tracking, digital instructions for use, access to resources, click to call customer support, test history passport, proof of and reporting of test results to those you specify.

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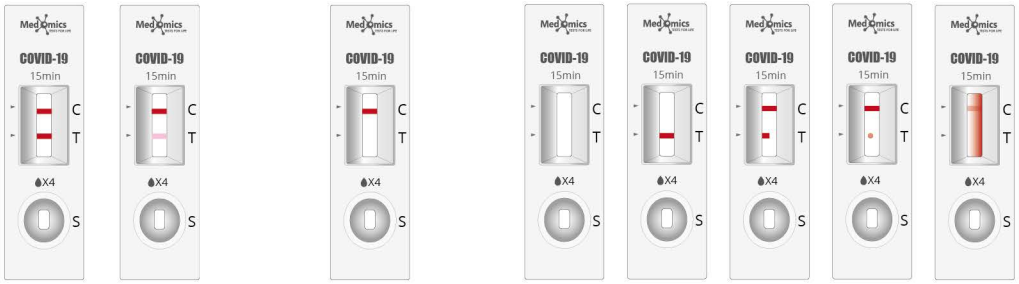
ADD / F3, BuildingC, No.3-1XinjinhuRoad, Jiangbei New Area, Nanjing, China

Intended Use

SARS-CoV-2 Antigen Test Kit (LFIA) is a colloidal gold immunochromatography for the rapid qualitative detection of SARS-CoV-2 nucleocapsid antigens present in human anterior nasal samples in vitro. The test kit is designed for use as self-testing. This test kit is intended use for individuals by 18 or older with clinical symptoms of SARS-CoV-2 infection or who are suspected of COVID-19. If the suspected individual exhibits respiratory symptoms or suspected to be infected, it is recommended to combine PCR test, clinical symptoms, prevalence and further clinical data to confirm the diagnosis.

DISPLAY OF THE RESULT / EXPECTED VALUES

Positive | Negative | Invalid



Read the results within 15-20 minutes.

A step by step guide for MEDOMICS SARS-CoV-2 Antigen Test Kit (LFIA) For Self-Testing

Operation video

Packing size:
1 pc/Box / 2 pcs/Box
5 pcs/Box / 20 pcs/Box

Storage:
2-30°C

Detection Time:
15-20minutes

Shelf Life:
12 months

QUALIFICATIONS

Australian Government
Department of Health
Therapeutic Goods Administration

File Reference: D22-5610085

Sent by email

Email: info@jense.com.au

Attention: Zhen He

Notice under section 9D of the *Therapeutic Goods Act 1989* of decision to vary ARTG inclusions for the kind of medical device

Application ID / Submission ID:	DV-2022-CR-11946-1 / DA-2022-04402-1
Sponsor:	Pale Blue Medical Trading Pty Ltd
Manufacturer:	Jiangsu Medomics Medical Technology Co Ltd
GMDN[1]:	Severe acute respiratory syndrome-associated coronavirus IVDs [CT772]
Classification:	Class 3
Device Name(s):	SARS-CoV-2 antigen Test Kit (LFIA) for Self Testing SARS-CoV-2 Antigen Test Kit (LFIA) for POCT SARS-CoV-2 Antigen Test Kit (LFIA) External quality control swab kit
ARTG Entry:	380739

As a delegate of the Secretary of the Department of Health (the Secretary), for the purposes of section 9D of the *Therapeutic Goods Act 1989* (the Act), I am writing to inform you that I have made a decision to vary the ARTG entry in relation to the abovementioned medical device.

I have decided to vary the abovementioned ARTG under subsection 9D(3D) of the Act, on the basis that the information provided for this variation does not reduce the quality, safety, or performance of the kind of medical device for the purpose for which it is intended to be used.

[1] Information as stated in the application

CERTIFICATE

EC Certificate No. 1434-IVDD-481/2021
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 Xinjinhuroad, Jiangbei new area, Nanjing, Jiangsu, China

in vitro diagnostic medical devices
for self-testing

SARS-CoV-2 Antigen Test Kit (LFIA)
REF: 1031-14-01, 1031-34-01, 1031-54-01

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 03.11.2021 to 27.05.2024

The date of issue of the Certificate: 03.11.2021

The date of the first issue of the Certificate: 03.11.2021

CE 1434

Issued under the Contract No. MD-82/2021
Application No: 547/2021
Certificate bears the qualified signature.
Warsaw, 03/11/2021
Module A1

Anna Małgorzata Wyroba
Vice-President
Mgr. Anna Wyroba

POLISH CENTRE FOR TESTING AND CERTIFICATION 02-844 Warsaw, 469 Putawska Street, tel. +48 22 46 45 200, e-mail:pcbc@pcbc.gov.pl

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: Jiangsu Medomics Medical Technology Co.,Ltd
F3,Building C
No.3-1 Xinjinhu road
Jiangbei new area
Nanjing
Jiangsu
210030
China

江苏美克医学技术有限公司
中国
江苏省
南京市
江北新区新锦湖路3-1号
中丹生态生命科学产业园二期
C栋3楼
邮编：210030

Holds Certificate No: MD 728732

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Design, Development, Manufacture and Distribution of immunoassay rapid diagnostic kit for the diagnosis of viral infections.
用于病毒感染诊断的免疫测定快速诊断试剂盒的设计，开发，制造和销售。

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2020-07-14
Latest Revision Date: 2020-07-14

Effective Date: 2020-07-14
Expiry Date: 2023-07-13

Page: 1 of 1

...making excellence a habit.

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
An electronic certificate can be authenticated online.
Printed copies can be validated at www.bsi-global.com/ClientDirectory or telephone +86 10 8507 3000.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: +44 845 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.

Bundesinstitut
für Arzneimittel
und Medizinprodukte

BfArM, Kurt-Georg-Kiesinger-Allee 3, D-53175 Bonn

Neucomed Deutschland GmbH
Pascal Geibl
Albert-Einstein-Str. 3
85435 Erding

ABTEILUNG Medizinprodukte
BEARBEITET VON Dr. Camilla Lambertz
TEL +49 (0)228 99 307-5372
E-MAIL Camilla.Lambertz@bfarm.de

HAUSANSCHRIFT Kurt-Georg-Kiesinger-Allee 3
53175 Bonn
TEL +49 (0)228 99 307-0
FAX +49 (0)228 99 307-5207
E-MAIL poststelle@bfarm.de
INTERNET www.bfarm.de

Bonn, den 08.06.2021
GESCHZ 5640-S-286/21

Per E-Mail: pascal.geibl@neucomed.com
Nachrichtlich:
info@rsight.nl; overseas@medomics-dx.com;
medizinprodukteanzeigeverfahren@reg-ob.bayern.de;
medizinprodukte@reg-ofr.bayern.de

Im Verfahren der erstmaligen Erteilung einer Sonderzulassung gemäß § 11 Abs. 1 MPG

5640-S-286/21	
aufgrund des Antrags vom 30.03.2021	
an	
Jiangsu Medomics Medical Technology Co., Ltd Yifeng Qin Xinjinhu-Str. 1-3, Gebäude C/F3 Jiangbei Nanjing China	„Inhaber der Sonderzulassung"
im Antragsverfahren vertreten durch	
Neucomed Deutschland GmbH Albert Einstein Str 3 85435 Erding	
für das Medizinprodukt	
SARS-CoV2 Antigen Test Kit (LFIA)	„betroffenes Medizinprodukt"
des Unternehmens	
s.o. „Inhaber der Sonderzulassung"	„Hersteller"
mit dem europäischen Bevollmächtigten gem. § 3 Ziff. 16 MPG	
R Sight B.V. Roald Dahllaan 47 5629 MC Einhoven Niederlande	„Europäischer Bevollmächtigter" und Verantwortlicher nach § 5 MPG

ergeht folgender

CERTIFICATE OF REGISTRATION

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

UL LLC®(UL) issues this certificate to the Firm named above, after assessing the Firm's quality system and finding it in compliance with:

ISO 13485:2016
EN ISO 13485:2016

Design, development, manufacture and distribution of self-testing immunoassay rapid diagnostic kits for the diagnosis of viral infection.

4426

Authorized by

Paul Hilgeman
Director & Global Industry Leader, Medical
CMIT – Medical Regulatory

Check Certificate Status: here

File Number A28944
Certificate Number 8217.211129
Initial Issue Date November 29, 2021

Cycle Start November 29, 2021
Effective Date November 29, 2021
Expiry Date November 28, 2024

This quality system registration is included in UL's Directory of Registered Firms and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown above. By issuance of this certificate the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferable and remains the property of UL LLC.

UL LLC
333 Pfingsten Road
Northbrook, IL 60062-2096 USA

Form-ULID-000724 Issue 3.0

Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	380739 Jeninno Solutions Pty Ltd - Severe acute respiratory syndrome-associated coronavirus IVDs
ARTG entry for	Medical Device Included - IVD Class 3
Sponsor	Jeninno Solutions Pty Ltd
Postal Address	PO Box 4129, McKinnon, VIC, 3204 Australia
ARTG Start Date	13/12/2021
Product Category	Medical Device Class 3
Status	Active
Approval Area	IVD

Conditions

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Manufacturers

Name	Address
Jiangsu Medomics Medical Technology Co Ltd	F3 Building C No 3-1 Xinjinhu Road Jiangbei new area, Nanjing Jiangsu, 210030 China

Products

1 . Severe acute respiratory syndrome-associated coronavirus IVDs

Product Type	IVD	**Effective Date**	13/12/2021
GMDN	CT772 Severe acute respiratory syndrome-associated coronavirus IVDs		
Intended Purpose	SARS-CoV-2 antigen Test Kit (LFIA) is a kind of Colloidal gold immunochromatographic technology reagent. It is intended to qualitatively detect the SARS-CoV-2 virus in people having symptoms within 7 days. It is intended to be used by a health professional or a laboratory professional. It uses human anterior nasal secretion, nasopharyngeal secretion, or throat secretion for testing. It is an aid for diagnosis, and results should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection. The external quality control swab kit is intended for use as a non-viable control material to validate the SARS-CoV-2 antigen test kit (LFIA). It contains external positive quality control swab(s) and external negative quality control swab(s).		

Specific Conditions

No Specific Conditions included on Record

Public Summary

This is not an ARTG Certificate document.
The onus is on the reader to verify the current accuracy of the information on the document subsequent to the date shown.
Visit www.tga.gov.au for contact information

KEMENTERIAN KESEHATAN REPUBLIK INDONESIA
DIREKTORAT JENDERAL KEFARMASIAN DAN ALAT KESEHATAN
Jalan H.R. Rasuna Said Blok X-5 Kavling 4 - 9 Jakarta 12950
Telepon : (021) 5201590 Pesawat 2029, 8011
Faksimile : (021) 52964838 Kotak Pos : 203

GERMAS

Berdasarkan Peraturan Menteri Kesehatan R.I Nomor 62 Tahun 2017 Tentang Izin Edar Alat Kesehatan, Alat Kesehatan Diagnostik In Vitro Dan Perbekalan Kesehatan Rumah Tangga dengan ini diberikan persetujuan untuk diedarkan dengan :

NOMOR IZIN EDAR

A L A T K E S E H A T A N

KEMENKES RI AKL 20303127539

Nama Dagang / Merek	:	**MEDOMICS SARS-CoV-2 antigen Test Kits (LFIA)**
Kelompok / Kelas Resiko	:	Diagnostik *In Vitro* / B
Kategori Produk	:	Peralatan Imunologi dan Mikrobiologi
Sub Kategori	:	Pereaksi Serologi
Jenis Produk	:	Respiratory viral panel multiplex nucleic acid assay
Tipe / Ukuran	:	Tipe II
Kemasan	:	Dus, kit, isi 20 tes
Nama Produsen / Pabrikan	:	JIANGSU MEDOMICS MEDICAL TECHNOLOGY CO., LTD., China
Nama Pendaftar	:	
Atas dasar lisensi dari	:	-

Ketentuan

1. Persetujuan ini adalah Persetujuan Izin Edar Dimasa Darurat Covid-19, berlaku sampai dengan 01 Desember 2022 (1 Tahun).
2. Wajib menyampaikan laporan berkala dan laporan jika ada kejadian yang tidak diinginkan akibat penggunaan Alat Kesehatan tersebut di atas sesuai ketentuan berlaku.
3. Persetujuan Izin Edar Dimasa Darurat dapat diperpanjang jika tidak ditemukan kejadian tidak diinginkan pada pemakaian.
4. Kementerian Kesehatan berhak meninjau atau mengevaluasi aspek keamanan, mutu, dan kemanfaatan apabila ditemukan bukti baru terkait Alat Kesehatan yang diterbitkan izin edarnya.
5. Apabila dikemudian hari ada pihak lain yang berhak atas merek dan/atau keagenan produk tersebut, pendaftar bersedia mengembalikan izin edar.
6. Penandaan dan informasi produk yang terlampir merupakan bagian yang tidak terpisahkan dari persetujuan izin edar ini.
7. Apabila di kemudian hari terdapat kekeliruan, maka persetujuan izin edar ini akan ditinjau kembali.

Jakarta, 01 Desember 2021

Ditandatangani Secara Elektronik Oleh :
KEMENTERIAN KESEHATAN REPUBLIK INDONESIA
a.n. Direktur Jenderal
Direktur Penilaian Alat Kesehatan dan PKRT
Ir. Sesilia Sadek, M.Kes
NIP 19621203 198503 1 004

Catatan:
- UU ITE No 11 Tahun 2007 Pasal 5 ayat 1
Informasi Elektronik dan/atau Dokumen Elektronik dan/atau hasil cetaknya merupakan alat bukti hukum yang sah.
- Dokumen ini telah ditandatangani secara elektronik menggunakan sertifikat elektronik yang diterbitkan BSrE.

KINGDOM OF SAUDI ARABIA
Saudi Food & Drug Authority

المملكة العربية السعودية
الهيئة العامة للغذاء والدواء

VISION 2030

Executive Department of Medical Devices Evaluation
Medical Devices Sector

الإدارة التنفيذية لتقويم الأجهزة الطبية
قطاع الأجهزة و المستلزمات الطبية

SFDA

إذن تسويق جهاز / مستلزم طبي
Medical Device Marketing Authorization

Issuing Date :06/1/2022	Authorization Number: MDMA-1-2022-0044	رقم الإذن	تاريخ الإصدار 03/6/1443
Expiry Date :27/5/2024	Version Number: 1	رقم الإصدار	تاريخ الانتهاء 20/11/1445
Last Version Date :06/1/2022			تاريخ آخر إصدار 03/6/1443

The Authorization is issued in accordance with the Medical Devices Law issued by Royal Decree No. (M/54) dated 6/7/1442 HA,

أصدر هذا الإذن بموجب نظام الأجهزة والمستلزمات الطبية الصادر بالمرسوم الملكي رقم (م/54) وتاريخ 6/7/1442 هـ

This authorization allows:

ME000004527
Jiangsu Medomics Medical Technology Co. Ltd.
F3, Building C,No. 3-1 Xinjinhu Road, Jiangbei New area, Nanjing, Jiangsu, China,Nanjing,210031 China

هذا الإذن يخول

To market the medical devices listed in the attached annex* in the Kingdom of Saudi Arabia

بتسويق الأجهزة / المستلزمات الطبية المحددة في القائمة المرفقة في المملكة العربية السعودية

Medical Device Description	a qualitative test that detects the presence of SARS-CoV-2	وصف الجهاز / المستلزم
Medical Device National Listing Number	MDS000004527SPDAA00001	رقم قيد الجهاز / المستلزم الطبي في السجل الوطني
Brand / Trade Name	SARS-CoV-2 Antigen Test Kit (LFIA)	الاسم التجاري

المدير التنفيذي لتقويم الأجهزة الطبية
Executive Director of Medical Devices Evaluation

عبد اللطيف بن سليمان الوعلان
Abdullatif S.Al Watban,Ph.D.

Page 1 of 1

FORM MD-15

[See sub-rule (1) of rule 36]

Licence to Import Medical Device

Licence No. : IMP/IVD/2021/000290

1. M/s Regulatory1, 34, 1st FLOOR, 6th CROSS, 6th MAIN, M S R NAGAR, MATHIKERE , Bengaluru (Bangalore) Urban, Karnataka (India) - 560054 Telephone No.: 7337811324 FAX: 7337811324 is hereby licenced to import the medical device(s) manufactured by overseas manufacturer having manufacturing site as specified below.

S.No	Name and Address of Manufacturer	Name and Address of Manufacturing Site
1	Legal Manufacturing Site : M/s Jiangsu Medomics Medical Technology Co. Ltd, F3, Building C, No 3-1 Xinjinhu Road Jiangbei new Area, 210046 Nanjing, Country: China Telephone No.: 86 25 58601060 FAX: 86 25 58601060 E-Mail : chaizz@medomics-dx.com	Actual Manufacturing Site : M/s Jiangsu Medomics Medical Technology Co. Ltd, F3, Building C, No 3-1 Xinjinhu Road Jiangbei new Area, 210046 Nanjing , Country: China Telephone No.: 86 25 58601060 FAX: 86 25 58601060 E-Mail : chaizz@medomics-dx.com

3. Details of medical device(s):

S.No	Medical Device Details
1	1. Generic Name :SARS-CoV-2 Antigen Test Kit (LFIA) 2. Brand Name(if registered under the Trade Marks Act, 1999) :NA 3. Class of Medical Device :Class C 4. Shelf Life :24 Months 5. Sterile/Non-sterile:Non-Sterilized 6. Intended Use :SARS-CoV-2 antigen Test Kit (LFIA) is used to qualitatively detect SARS-CoV-2 inhuman samples in vitro. 7. Material of Construction: The test strip contains colloidal gold-labeled anti-SARS- CoV-2 Nucleocapsid Protein antibody, nitrocellulose membrane (C line fixed with goat-anti-mouse IgG polyclonal antibody, and T line fixed with another anti-SARS- CoV-2 Nucleocapsid Proteinantibody). 8. Dimension: 12*11*9 CM 9. Model No. :Type 1 - Type I test kit contains test cassettes, Sterile swabs, sampling tubes, a vital containing lysis buffer, droppers and instructions for use.,Type II - Type II test kit contains test cassettes, Sterile swabs, sampling tubes containing Individual lysis buffer, droppers and instructions for use.,Type III - Type III test kit contains test cassettes, sampling tubes, sterile swabs, buffer capsules containing Individual lysis buffer, droppers and instructions for use.

แบบ ป.ท.

ใบรับรองการประเมินเทคโนโลยีเครื่องมือแพทย์

ใบรับรองการประเมิน ที่ T 6500031

ใบรับรองการประเมินฉบับนี้ให้ไว้แก่
บริษัท ไอซายเอนซ์ เทคโนโลยี จำกัด
ผู้จดทะเบียนสถานประกอบการผลิตหรือนำเข้าเครื่องมือแพทย์ ใบจดทะเบียนที่ สน. 433/2555
เพื่อแสดงว่าเป็นผู้ผลิตหรือนำเข้าเครื่องมือแพทย์ที่ได้รับการประเมินเทคโนโลยี ตามมาตรา ๖ (๘)
แห่งพระราชบัญญัติเครื่องมือแพทย์ พ.ศ. ๒๕๕๑ สำหรับเครื่องมือแพทย์
SARS-CoV-2 Antigen Test Kit (LFIA) ยี่ห้อ Medomics

รายละเอียดเครื่องมือแพทย์ รหัสสินค้า
ขนาดบรรจุ 1 ชุดการทดสอบต่อกล่อง , 20 ชุดการทดสอบต่อกล่อง
ประเภทเพื่อการวินิจฉัยภายนอกร่างกาย ชนิดเพื่อการวินิจฉัยรายบุคคล แบบตรวจคัดกรอง
แบบตรวจหา แอนติเจนใช้โดยผู้ประกอบวิชาชีพทางการแพทย์ (Professional use only)
สิ่งส่งตรวจ Nasal swab
ชื่อและที่ตั้งของสถานที่ผลิตเครื่องมือแพทย์ในต่างประเทศ
Jiangsu Medimics Medical Technology Co., Ltd. F3, Building C, No.3-1 Xinjinhu Road,
Jiangbei New Area, Nanjing, Jiangsu, China
ณ สถานที่ผลิตหรือนำเข้าเครื่องมือแพทย์ชื่อ บริษัท ไอซายเอนซ์ เทคโนโลยี จำกัด
ตั้งอยู่เลขที่ 98/13-14 หมู่บ้านพริ้นเมียม เพลส
ตรอก/ซอย - ถนน โพธิ์แก้ว หมู่ที่ -
ตำบล/แขวง นวมินทร์ อำเภอ/เขต บึงกุ่ม
จังหวัด กรุงเทพมหานคร รหัสไปรษณีย์ 10240 โทรศัพท์ 0 2509 1623 โทรสาร 0 2509 1625
ออกให้ไว้ ณ วันที่ 20 เดือน มกราคม พ.ศ. 2565

สำนักงานคณะกรรมการอาหารและยา
กระทรวงสาธารณสุข
ผู้อนุญาต

República Argentina - Poder Ejecutivo Nacional
Las Malvinas son argentinas

Certificado - Redacción libre

Número:

Referencia: EX-2021-86180222- -APN-DGA#ANMAT

CERTIFICADO DE AUTORIZACIÓN E INSCRIPCIÓN

PRODUCTOS PARA DIAGNÓSTICO IN VITRO

EX-2021-86180222- -APN-DGA#ANMAT

La Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT) certifica que, de acuerdo con lo solicitado por la firma se autoriza la inscripción en el Registro Nacional de Productores y Productos de Tecnología Médica (RPPTM), de un nuevo producto médico para diagnóstico in vitro con los siguientes datos identificatorios característicos:

NOMBRE COMERCIAL: SARS-CoV-2 Antigen Test Kit (LFIA)

INDICACIÓN DE USO: El Kit de prueba de antígenos SARS-CoV-2 (LFIA) es una inmunocromatografía de oro coloidal para la detección cualitativa rápida de antígenos de nucleocápside del SARS-CoV-2 presentes en muestras nasales anteriores humanas in vitro. El kit de prueba está diseñado para su uso como autotest. Este kit de prueba está destinado a personas mayores de 18 años con síntomas clínicos de infección por SARS-CoV-2 o sospechosas de COVID-19.

FORMA DE PRESENTACIÓN: Envases por 1 determinación individual conteniendo: 1 casete de prueba (en una bolsa de papel de aluminio con desecante), 1 tubo tampón de lisis, 1 hisopo estéril, 1 tapón gotero, 1 Bolsa de bioseguridad y las instrucciones de uso.

PERIODO DE VIDA ÚTIL Y CONDICIONES DE CONSERVACIÓN: 24 (VENTICUATRO) meses desde la fecha de elaboración, conservado entre 2°C-30°C.

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION
Civic Drive, Filinvest Corporate City, Alabang, Muntinlupa City

CERTIFICATION

To Whom This May Concern:

This is to certify that the **SARS-CoV-2 Antigen Test Kit (LFIA) Medomics (NL-CA002-2020-53182)** manufactured by: Jiangsu Medomics medical technology Co., Ltd – F3, BuildingD, No.3-1 XinjinhuRoad, Jiangbei New Area, Nanjing, Jiangsu, China has complied with all the requirements for the special certification of COVID-19 Diagnostic Kits. The product has a Product Registration from Ministry of Health, Welfare and Sport of Netherlands. With this approval, the company is required to indicate in the product label or in the accompanying product insert the following statement:

"This product is strictly for medical professional use only and not intended for personal use. The administration of the test and the interpretation of the results should be done by a trained health professional. The result of this test should not be the sole basis for the diagnosis; confirmatory testing is required"

This certification is issued upon the request of with business address at Unit 702 Common Goal Tower, Finance St. Cor. Industry St., Madrigal Business Park, Ayala Alabang, Muntinlupa City for whatever legal purpose this may serve.

This certificate cannot be used for advertising purposes in whatever medium and neither can this certificate be construed as an endorsement by the Center for Device Regulation, Radiation Health, and Research.

Done this 23rd November 2020 at Alabang, Muntinlupa City.

BY AUTHORITY OF THE DIRECTOR GENERAL

MARIA CECILIA C. MATIENZO
Officer-in-Charge
Center for Device Regulation, Radiation Health, and Research

Not valid without FDA Seal

Seq No. : 110620198537
Amount : PhP 510.00
Date : 06 November 2020
SC-COVID19-2020-767
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m/cb

FDA-0475113