NEWGENE
Bioengineering

新冠抗原检测试剂产品手册
Product Manual of COVID-19 Antigen Detection Kit

诺迦（杭州）生物工程有限公司
New Gene (Hangzhou) Bioengineering Co., Ltd.

CE CERTIFICATE – REGISTRATION LETTER

NEWGENE Bioengineering

Self-test Approval of EU

CERTIFICATE

EC Certificate No. 1434-IVDD-449/2021

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

Polish Centre for Testing and Certification certifies
that manufactured by:

New Gene (Hangzhou) Bioengineering Co., Ltd.
Room 1606, Floor 16, Building 5, 688 Bin'an Road, Changhe Street,
Binjiang District, Hangzhou City, Zhejiang Province,
P. R. China

in vitro diagnostic medical devices
for self-testing

COVID-19 Antigen Detection Kit - Nasal Swab

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 11.08.2021 to 27.05.2024

The date of issue of the Certificate: 11.08.2021

The date of the first issue of the Certificate: 11.08.2021

CE 1434

Issued under the Contract No. MD-116
Application No: 239/2021
Certificate bears the qualified signature.
Warsaw, 11.08.2021
Module A1

Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2021.08.11 09:14:18 +02'00'

Vice-President

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

CE CERTIFICATE - DOC

NEWGENE Bioengineering

CE 1434

DECLARATION OF CONFORMITY

Regarding In Vitro Diagnostic Directive (98/79/EC)

Manufacturer: New Gene (Hangzhou) Bioengineering Co., Ltd.

Address: Room 1606, Floor 16, Building 5, 688 Bin'an Road, Changhe Street, Binjiang District, Hangzhou City, Zhejiang Province, P. R. China

EC Representative: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

EC Certificate No.: 1434-IVDD-449/2021

Product Name: **COVID-19 Antigen Detection Kit – Nasal Swab**

Specification: 1Test/Box, 5Tests/Box, 25Tests/Box

Classification: Self Test (IVDD)

Conformity Assessment Procedure: Annex III (Section 6) to Directive 98/79/EC

We herewith declare that the above-mentioned products meet the requirements of In Vitro Diagnostic Directive (98/79/EC) and the following harmonized standards.

EN 23640-2015	EN 13640:2002
EN 13612:2002	EN 13641:2002
EN ISO 14971:2019	EN ISO 18113-1 2011

Signature: Mingfu Li

Name/ Position: Mingfu Li / General Manager

Date: 11/08/2021

Place: Hangzhou, Zhejiang, China

ISO 13485 CERTIFICATE

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

New Gene (Hangzhou)
Bioengineering Co., Ltd.
Room 1606,16th Floor, No.5 Building
688 Bin'an Road
Binjiang District
Hangzhou
Zhejiang
310052
China

诺迦（杭州）生物工程有限公司
中国
浙江省
杭州市
滨江区
长河街道滨安路688号
5幢16层1606室
邮编：310052

Holds Certificate No: **MD 729179**

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

Design and Development, Manufacture and Distribution of In-vitro Diagnostic Rapid Test Kit of Drug Abuse, Manufacture and Distribution of In-vitro Diagnostic Rapid Test Kit of Infectious Diseases.
药物滥用体外诊断快速检测试剂盒的设计，开发，制造和销售，传染病体外诊断快速检测试剂盒的制造和销售。

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2020-07-27
Latest Revision Date: 2020-07-27

Effective Date: 2020-07-27
Expiry Date: 2023-07-26

...making excellence a habit.™

PRODUCT INTRODUCTION

NEWGENE Bioengineering

Self-Testing

CE 1434

COVID-19 Antigen Detection Kit - Nasal Swab

No.	Components	*25 Tests/Box*	*5 Tests/Box*	*1 Test/Box*
1	Test Card	25	5	1
2	Sample Extraction Tube & Tube Cap	25	5	1
3	Sampling Swab: *for Nasal Swab*	25	5	1
4	Package Insert	1	5	1

25 Tests/Box

5 Tests/Box

1 Test/Box

EU Common List

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public health, country knowledge, crisis management
Health Security

EU health preparedness:

A common list of COVID-19 rapid antigen tests and a common standardised set of data to be included in COVID-19 test result certificates

Agreed by the Health Security Committee

This document was agreed by the HSC on 17 February 2021

Annex I

Common list of COVID-19 rapid antigen tests

A first update was agreed by the HSC on 10 May 2021; A second update was agreed by the HSC on 16 June 2021; A third update was agreed by the HSC on 7 July 2021; A fourth update was agreed by the HSC on 14 July 2021; A fifth update was agreed by the HSC on 23 July 2021.

IMPORTANT: A (interim) grace period of 8 weeks applies whenever updates are made to Annex I, the common list of COVID-19 rapid antigen tests

New Gene (Hangzhou) Bioengineering Co., Ltd.	COVID-19 Antigen Detection Kit	Yes	98% sensitivity Nasal swab	**DE:** Positive evaluation by Paul-Ehrlich-Institut (sensitivity of 92,5% at <Ct30 and 100% at <Ct25)		DE[2]		DE[2]		1501	16 June 2021

Registration or Allowed List (Partially)

Self-test Approval in Switzerland

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Eidgenössisches Departement des Innern EDI
Bundesamt für Gesundheit BAG
Taskforce BAG Covid-19 AG Testung

Sars-CoV-2-Antigen-Schnelltests zur Eigenanwendung (Sars-CoV-2 Selbsttest)[1]
Tests rapides pour l'antigène du SARS-CoV-2 pour auto-application (autotest SARS-CoV-2)
Test rapidi dell'antigene SARS-CoV-2 per uso proprio (test autodiagnostici SARS-CoV-2)

03.09.2021

Die Schnelltests zur Eigenanwendung sind ausschliesslich für den **nasalen Abstrich** validiert und nur dementsprechend anzuwenden. Informationen bezüglich des Einsatzes der Schnelltests finden Sie auf der BAG-Webseite Covid-19-Testung. — Webseite Covid-19 Testung

Les tests rapides pour auto-application sont validés pour les **prélèvements nasaux** uniquement et ne doivent donc être utilisés qu'en conséquence. Ces informations sur l'emploi prévu des tests rapides sont disponibles sur le site web de l'OFSP Tests COVID-19. — Site internet Tests COVID-19

I test rapidi per uso proprio sono convalidati solo per i **tamponi nasali** e dovrebbero essere usati solo di conseguenza.. Le informazioni su come utilizzare i test rapidi sono disponibili sul sito internet dell'UFSP «Test COVID-19». — Sito web Test COVID-19

Hersteller Fabricant Azienda		**Antigen Schnelltest Tests rapides antigéniques Test antigenici rapidi**
Abbott Rapid Diagnostics	Germany	Panbio™ COVID-19 Antigen Self-Test
ACON Biotech (Hangzhou) Co. Ltd.	China	Flowflex SARS-CoV-2 Antigen Rapid Test (Self-Testing)
Becton, Dickinson and Company (BD)	United States	BD Kit for Rapid Detection of SARS-CoV-2
BIOSYNEX SWISS S.A.	Switzerland	BIOSYNEX Autotest antigénique COVID-19 Ag
Hangzhou AllTest Biotech Co., Ltd	China	ALLTEST SARS-CoV-2 Antigen Rapid Test (Nasal Swab)
Hangzhou AllTest Biotech Co., Ltd	China	JusChek SARS-CoV-2 Antigen Rapid Test (Nasal Swab)
New Gene (Hangzhou) Bioengineering Co., Ltd.	China	COVID-19 Antigen Detection Kit - Nasal Swab
Roche (SD BIOSENSOR)	Switzerland	SARS-CoV-2 Rapid Antigen Test Nasal
Siemens Healthineers	Germany	CLINITEST® Rapid COVID-19 Antigen Self-Test
Xiamen Boson Biotech Co., Ltd.	China	Rapid SARS-CoV-2 Antigen Test Card

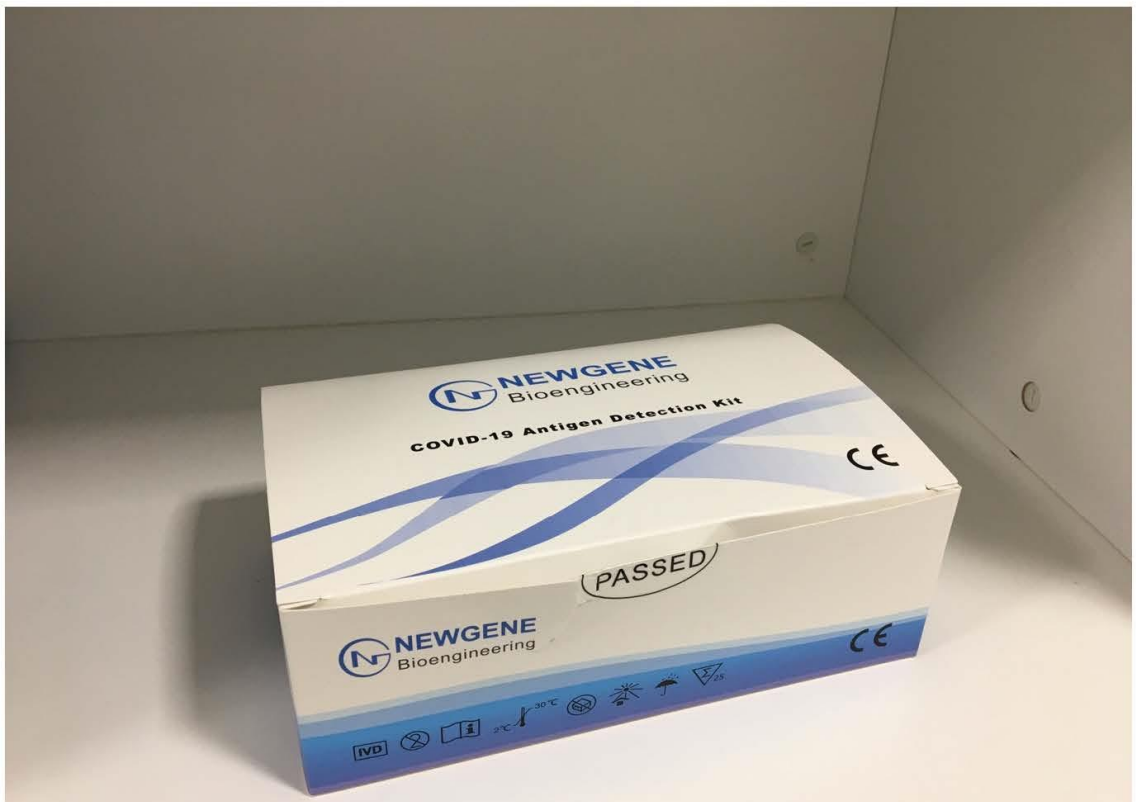
Wichtige Hinweise:
Information importante :
Avvertenza importante:

[1] Diese Liste beinhaltet SARS-CoV-2-Antigen-Schnelltest, welche die Anforderungen nach Art. 24 der Covid-19-Verordnung 3 erfüllen und zudem entweder eine CE-Zertifizierung als Produkt zur Eigenanwendung einer benannten Stelle besitzen oder eine Ausnahmebewilligung durch Swissmedic als Produkt zur Eigenanwendung besitzen.
Cette liste inclut les tests rapides pour la recherche de l'antigène du SARS-CoV-2 qui remplissent les exigences de l'art. 24 de l'ordonannce 3 COVID-19 et qui sont soit certifiés CE comme dispositif d'autotest par un organisme notifié ou qui ont une dérogation de Swissmedic pour l'auto-application.
Questo elenco comprende i test rapidi per l'antigene SARS-CoV-2 che soddisfano i requisiti dell'art. 24 dell'ordinanza 3 COVID-19 e che hanno una certificazione CE da parte di un organismo notificato come prodotto per uso proprio o un'esenzione di Swissmedic come prodotto per uso proprio.

Evaluation Report (Nasal Swab)

Validation protocol for the

Newgene bioengineering COVID-19 Rapid Antigen Test



Testing laboratory:
Molecular Diagnostic Laboratory
Via Petrini 2
CH-6900 Lugano
Switzerland

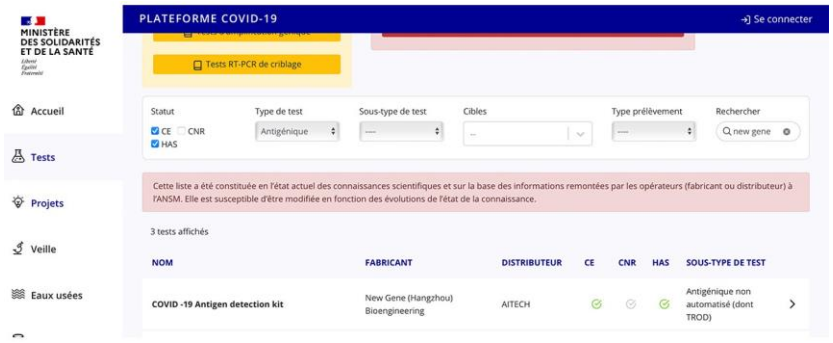
Discussion and Conclusion.

In conclusion, the Newgene antigen detection test is highly precise and accurate (**100% specificity and 95.1% sensitivity**), it is non-invasive and mimics the PCR results very closely where PCR is considered the golden standard technique. The device can easily be operated and used by non-medically trained personnel, does not need a laboratory setting and could be intended for regular use by regular people.

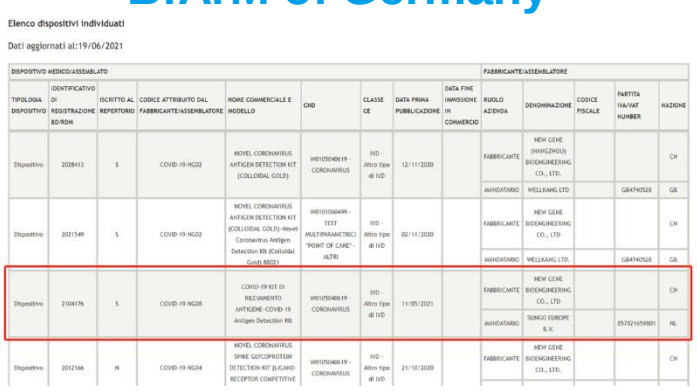
Lugano, June 18th 2021.
Dr. G. Soldati
CEO
Molecular Diagnostic Laboratory
Via Petrini 2
CH-6900 Lugano, Switzerland

Registration or Allowed List (Partially)

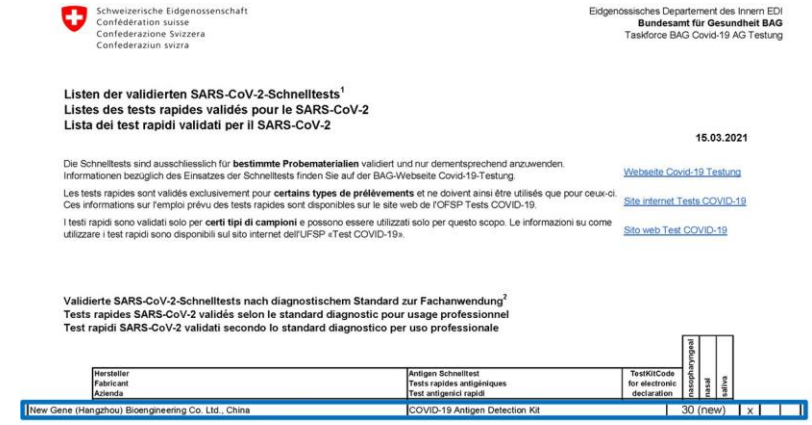
BfArM of Germany



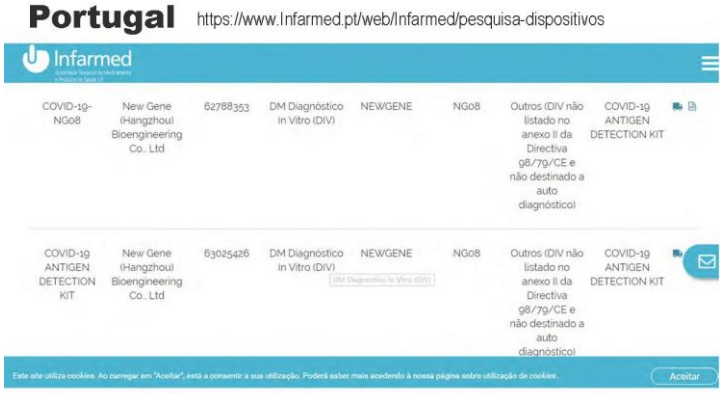
ANSM of France



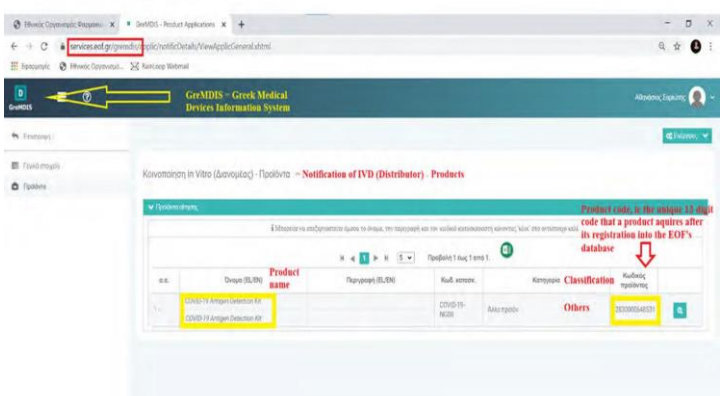
Italy



Switzerland



Portugal



Greece

Žádost o notifikaci zdravotnického prostředku

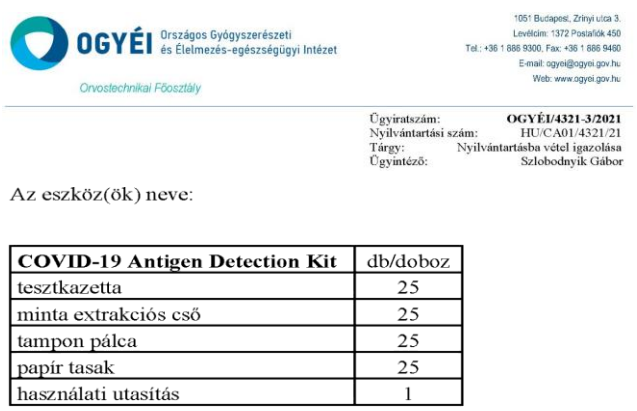
Žadatel

Registrační číslo:	054535
Název:	Markmed s.r.o.
IČ:	02478170
Ulice:	Kubánské náměstí 1391
Obec:	Praha
PSČ:	10000
Stát:	Česká republika

Identifikace zdravotnického prostředku

Druh zdravotnického prostředku:	Diagnostický zdravotnický prostředek in vitro
Typ evidence zdravotnického prostředku:	Notifikace dle § 33
Činnost:	Distributor
Obchodní název zdravotnického prostředku:	Novel Coronavirus Spike Glycoprotein Detection Kit (Ligand-receptor Competitive Chromatography)
Jedná se o příslušenství?	Ne
Jedná se o soupravu/systém zdravotnických prostředků?	Ne
Míra zdravotního rizika zdravotnického prostředku:	IVD A

Czech



COVID-19 Antigen Detection Kit	db/doboz
tesztkazetta	25
minta extrakciós cső	25
tampon pálca	25
papír tasak	25
használati utasítás	1

A gyártó neve: New Gene (Hangzhou) Bioengineering Co.Ltd.
A gyártó kódja: CN/000000053699
A meghatalmazott képviselő neve: Sungo Europe B.V.
A meghatalmazott képviselő kódja: NL/492381971
A forgalmazó neve: Biosan Egészségügyi Kereskedelmi és Szolgáltató Kft.
A forgalmazó kódja: HU/10331701-2-41

Hungary