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.

COMPANY PROFILE

New Gene (Hangzhou) Bioengineering Co., Ltd. is located in Hangzhou, China. It is a high-tech company engaged in the research, development, manufacture and distribution of biological products. It is committed to creating biological materials such as antigens and antibodies, in vitro diagnostic reagents and related devices, and also the complete industrial chain of artificial intelligence assisted diagnosis system. The product line covers a full range of in vitro diagnostic products such as immune diagnosis, molecular diagnosis, and microbiological testing. NEWGENE has profound technical accumulation and unique technological advantages in the areas of early cancer screening, rapid detection of infectious diseases, and rapid screening of geriatric diseases.

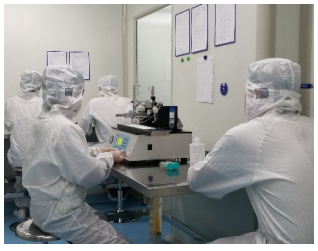
NEWGENE's manufacturing system meets GMP standards for medical devices, and is certified with ISO13485 by British BSI. Relevant in vitro diagnostic reagent products have obtained the EU CE certification. NEWGENE is also a member on the "allow list" issued by Chinese Ministry of Commerce for anti-epidemic products exporting.

At present, NEWGENE COVID-19 Antigen Detection Kit has **registered in** many countries, including ***Germany, France, Italy, Switzerland, Belgium, Portugal, Czech, Denmark, Hungary, Greece, Poland, Sweden, Moldova, Peru, Argentina, Ecuador, Kenya, Zimbabwe, Malaysia*** **etc.,** and passed the clinical **validation in** national lab in ***Germany, Switzerland, Malaysia, Ecuador, Zimbabwe etc.*** The products show good performance in sensitivity and specificity compared with international brand products and have exported to more than 50 countries and regions.










NEWGENE Bioengineering

COVID-19 Antigen Detection Kit

Multiple Sampling Methods

Nasal Swab / Nasopharyngeal Swab / Oropharyngeal Swab / Sputum (Saliva)

Multiple Packaging Specifications

25 Tests/Box, 5 Tests/Box or 1 Test/Box

Global Recognition

Registered in 20+ Countries, Exported to 50+ Countries

Multiple Usage Scenarios

Professional Use & Home Use (Self-Testing)

Fast Detection

Results in 15 minutes

Superior Performance

High Sensitivity & Specificity

Contact Info

New Gene (Hangzhou) Bioengineering Co., Ltd.
Website: www.new-gene.com
www.new-gene.net
Email: marketing@new-gene.com
24-hour Hotline: (+86) 0571-5651 5020

PRODUCT INTRODUCTION

NEWGENE Bioengineering

COVID-19 Antigen Detection Kit
(Nasal Swab Sample)

N0.	Components	*25 Tests/Box*	*5 Tests/Box*	*1Test/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	1	1

25 Tests/Box

5 Tests/Box

1 Test/Box

PRODUCT INTRODUCTION

NEWGENE Bioengineering

COVID-19 Antigen Detection Kit

(Sputum / Saliva Sample)

N0.	Components	*25 Tests/Box*	*1Test/Box*
1	Test Card	25	1
2	Sample Extraction Tube & Tube Cap	25	1
3	Paper Cup	25	1
4	Sputum Dropper	25	1
5	Package Insert	1	1

25 Tests/Box

1 Test/Box

Packaging Information

Nasopharyngeal Swab: **NPS**
Nasal Swab: **NS**
Oropharyngeal Swab: **OS**
Sputum / Saliva: **S**

25 Tests/Box

Sample	NPS	NPS+S	NS	NS+S	OS	OS+S	S
Box (mm)	230*140*80						230*120*67
Box weight (kg)	0.34	0.38	0.32	0.36	0.35	0.4	0.39
Carton (mm)	585*485*425						510*490*360
Carton weight (kg)	1.5						1.3
PCS/Box	25						
Boxes/Carton	40						
PCS/Carton	1000						
Volume/Carton	0.12CBM						0.09CBM
NW/Carton (kg)	13.6	15.2	12.8	14.4	14	16	15.6
GW/Carton (kg)	15.1	16.7	14.3	15.9	15.5	17.5	16.9

5 Tests/Box

Sample	NS	
	Size (mm)	Weight (kg)
Inner box (mm)	193*85*42	0.081
Outer box (mm)	225*197*89	0.5
Carton	470*410*470	1.3
PCS/Inner Box	5	
Inner Boxes/Outer Box	5	
PCS/Carton	500	
Volume/Carton	0.09CBM	
NW/Carton (kg)	10	
GW/Carton (kg)	11.3	

1 Test/Box

Sample	S	NS	NS+S	NPS	OS	NPS+S	OS+S
Inner box (mm)	143*83*15			170*66*15			
Inner box weight (kg)	0.026	0.027	0.03	0.024	0.028	0.028	0.032
Outer box (mm)	305*197*88			277*182*112			
Outer box weight (kg)	0.78	0.80	0.88	0.73	0.83	0.83	0.93
Carton (mm)	630*420*470			590*570*395			
Carton weight (kg)	1.8			2.2			
PCS/Inner Boxes	1						
Inner Boxes/Outer Box	25						
PCS/Carton	500						
Volume/Carton	0.13CBM			0.133CBM			
NW/Carton (kg)	15.6	16	17.6	14.6	16.6	16.6	18.6
GW/Carton (kg)	17.4	17.8	19.4	16.8	18.8	18.8	20.4

CE Certification（Notified Body 1434）

NEWGENE Bioengineering

POLSKIE CENTRUM BADAŃ I CERTYFIKACJI

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 Certification – CIBG Registration Letter

NEWGENE Bioengineering

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

> Retouradres Postbus 16114 2500 BC Den Haag

SUNGO Europe B.V.
T.a.v. de heer R. Luo
Olympisch Stadion 24
1076 DE Amsterdam

Farmatec

Bezoekadres:
Hoftoren
Rijnstraat 50
2515 XP Den Haag

T 070 340 6161

http://hulpmiddelen.farmatec.nl

Inlichtingen bij:
M. Schmitz - Konte

medische_hulpmiddelen@minvws.nl

Ons kenmerk:
CIBG-20204772

Bijlagen
-

Uw aanvraag
30 september 2020

Correspondentie uitsluitend richten aan het retouradres met vermelding van de datum en het kenmerk van deze brief.

Datum: 1 oktober 2020
Betreft: aanmelding In-vitro diagnostica

Geachte heer Luo,

Op 30 september 2020 ontving ik uw notificatie krachtens artikel 4, eerste lid van het Nederlandse Besluit in-vitro diagnostica (BIVD) om onder de bedrijfsnaam New Gene (Hangzhou) Bioengineering Co., Ltd. met Europees gemachtigde SUNGO Europe B.V. onderstaande producten als in-vitro diagnostica op de Europese markt te brengen.

De producten staan geregistreerd als in-vitro diagnostica onder nummer:

COVID-19 / Influenza A / Influenza B Detection Kit
(geen merknaam) (NL-CA002-2020-53701)
COVID-19 Antibody / Antigen Detection Kit
(geen merknaam) (NL-CA002-2020-53700)
COVID-19 Antigen Detection Kit
(geen merknaam) (NL-CA002-2020-53699)
COVID-19 Neutralizing Antibody Detection Kit
(geen merknaam) (NL-CA002-2020-53702)
Novel Coronavirus Ribonucleic Acid Detection Kit
(geen merknaam) (NL-CA002-2020-53698)

Hiermee heeft u voldaan aan uw verplichting op grond van artikel 4, BIVD.

In alle verdere correspondentie betreffende bovenvermelde producten verzoek ik u deze nummers te vermelden. Aan deze nummers kunnen geen verdere rechten ontleend worden, ze dienen alleen om de notificatie administratief te vergemakkelijken.

De registratie van in-vitro diagnostica als medisch hulpmiddel op grond van de Classificatiecriteria (Bijlage II) bij Richtlijn 98/79/EG betreffende medische hulpmiddelen voor in-vitro diagnostiek is onderhevig aan mogelijke revisies van Europese regelgeving inzake de classificatie van medische hulpmiddelen en aan voortschrijdend wetenschappelijk inzicht (zie artikel artikel 10, eerste lid van Richtlijn 98/79/EG).

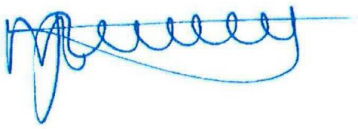
Notificatie van in-vitro diagnostische medische hulpmiddelen impliceert dat de fabrikant, New Gene (Hangzhou) Bioengineering Co., Ltd. de CE-conformiteitsmarkering heeft aangebracht op de desbetreffende producten alvorens deze in een EU-lidstaat in de handel te brengen. Zodoende garandeert SUNGO Europe B.V. dat de in-vitro diagnostica voldoen aan de essentiële eisen zoals opgenomen in bijlage I bij Richtlijn 98/79/EG (en in het daarmee corresponderende onderdeel 1 bij het besluit)

Volledigheidshalve wijzen wij u erop dat een in-vitro diagnosticum moet voldoen aan de eisen uit het BIVD. Het BIVD is gebaseerd op Richtlijn voor in-vitro diagnostiek, 98/79/EG. Met name wijzen wij u op de Nederlandse-taaleis zoals deze in Nederland geldt, de eisen voor het ter beschikking houden van de technische documentatie en de plicht tot het hebben van een Post Marketing Surveillance- en vigilantiesysteem.

Tot slot merk ik op dat met uw notificatie - de administratieve notificatie als fabrikant - en deze brief geen sprake is van een oordeel over de status of kwalificatie van uw product: notificering betekent niet dat daadwerkelijk sprake is van een in-vitro diagnosticum in de zin van de onderhavige wet- en regelgeving. In voorkomende gevallen kan de Inspectie Gezondheidszorg en Jeugd (IGJ), belast met het toezicht op de naleving van het bij of krachtens de wet bepaalde, een standpunt innemen over de status van een product, waarbij het volgens vaste jurisprudentie uiteindelijk aan de nationale rechter is om te bepalen of een product onder de definitie van in-vitro diagnosticum valt.

De Minister voor Medische Zorg en Sport,
namens deze,

Afdelingshoofd
Farmatec



Dr. M.J. van de Velde

CE Certification – Declaration of Conformity

NEWGENE Bioengineering

CE

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

Product Name: COVID-19 Antigen Detection Kit

Product Code: COVID-19-NG08

Specification: 25Tests/Box 1Test/Box

Classification: Others (IVDD)

Conformity Assessment Procedure: Annex III of In Vitro Diagnostic 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 980:2016	EN 13641:2002
EN ISO 14971:2019	EN ISO 18113-1 2011
EN 13612:2002	EN ISO 18113-4 2011

On behalf of SUNGO Europe office, I confirmed we are EU REP of the company who issue this document.

Sungo global service

Signature:

Name/ Position: Mingfu Li / General Manager

Date: 29/09/2020

Place: Hangzhou, Zhejiang, China

Authorized Signature (S)

ISO 13485 Certification

bsi.

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.™

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