

Datum:	27/11/2023 0:00:00	<b>PRP 13 PRODUCTFILES</b>	<b>I-HACCP</b>	
			Map	2
Versie:	2			
Opgesteld door: Q-team			Controle door: QA	

<b>Reference:</b>	9002391
<b>Supplier reference:</b>	
<b>Description:</b>	COVID-19 Antigen Detection Kit-Nasal Swab 1 pc NEW GENE
<b>Barcode CU:</b>	6974108067125
<b>Barcode INNER:</b>	
<b>Barcode CARTON:</b>	

Picture:




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### **Item specifications:**

COVID-19 Antigen Detection Kit-Nasal Swab 1 pc NEW GENE

Outer sorting	20 pcs
Quantity per unit	Consist out of : 1. Sterile swab kit x 25 2. Test cassette x 25 3. Pre filled tube with extraction buffer x 25 4. Tube rack x 1 5. Instructions for use x 1
Extra comment	98% sensitivity 100% specificity 99,36% accuracy
CNK Code	4347928

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### **Packaging Outer**

<b>Quantity</b>	500
<b>Kind of outer</b>	
<b>EAN</b>	
<b>Dimensions</b>	56x45x35cm

CE 1434

## DECLARATION OF CONFORMITY

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

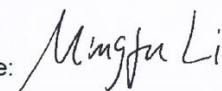
**Manufacturer:** New Gene (Hangzhou) Bioengineering Co., Ltd.  
**Address:** Room 1606, Floor 16, Building 5, 688 Bin'an Road, Changhe Street,  
Binjiang District, Hangzhou City, Zhejiang Province, P. R. China

**EC Representative:** SUNGO Europe B.V.  
**Address:** Olympisch Stadion 24, 1076DE Amsterdam, Netherlands  
**EC Certificate No.:** 1434-IVDD-476/2021

**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:   
Name/ Position: Mingfu Li / General Manager

Date: 01/12/2021

Place: Hangzhou, Zhejiang, China





# CERTIFICATE

**EC Certificate No. 1434-IVDD-476/2021**

**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

*The list of medical devices covered by this certificate is provided in the annex I*

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 01.12.2021 to 27.05.2024

The date of issue of the Certificate: 01.12.2021

The date of the first issue of the Certificate: 11.08.2021



Issued under the Contract No. MD-116/2021  
Application No: 381/2021  
Certificate bears the qualified signature.  
Warsaw, 01.12.2021  
Module A1

Anna  
Małgorzata  
Wyroba

Elektronicznie  
podpisany przez Anna  
Małgorzata Wyroba  
Data: 2021.12.01  
17:43:33 +01'00'  
Vice-President

# ANNEX 1 TO THE CERTIFICATE VALID ONLY WITH CERTIFICATE

No 1434-IVDD-476/2021

List of medical devices covered by the certificate:

Product	REF number	Brand
COVID-19 Antigen Detection Kit- Nasal swab	COVID-19-NG21	AIM-X NEWGENE
COVID-19 Antigen Detection Kit- Nasal swab	1 pcs = REF 5301 5 pcs = REF 5305  25 pcs = REF 5325	Gibson Medical
COVID-19 Antigen Detection Kit- Nasal swab	02823	Medi Concepts
COVID-19 Antigen Detection Kit- Nasal swab	COVID-19-NG21	BE HEALTHY



Anna  
Małgorzata  
Wyroba

Elektronicznie  
podpisany przez Anna  
Małgorzata Wyroba  
Data: 2021.12.01  
17:44:18 +01'00'

Vice-President

Issued under the Contract No. MD-116/2021  
Application No: 381/2021  
Certificate bears the qualified signature.  
Warsaw, 01.12.2021