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

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

Picture:

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

Packaging Outer

Quantity	500
Kind of outer	
EAN	
Dimensions	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: Mingfu Li

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

CE 1434

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

CE 1434

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