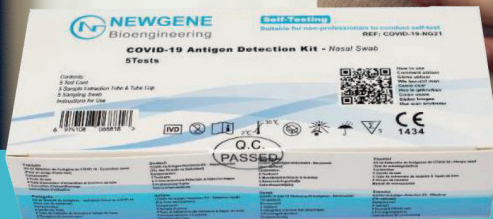




**KINGLINE**  
GMBH



# NEWGENE ANTERIOR NASAL TEST



Zertifiziert  
und Evaluiert



Zuverlässig sehr  
genaue Ergebnisse



Persönliche  
Experten-Beratung

1/4

Version: 1.0 | Freigabe: 28.11.2022

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Kingline GmbH | Am Altenbach 7 | 91341 Röttenbach



EINFACHE UND SICHERE  
ANWENDUNG



ZUVERLÄSSIG SEHR  
GENAUE ERGEBNISSE



BESONDERS FÜR KINDER,  
ÄLTERE UND MENSCHEN MIT  
BEHINDERUNG GEEIGNET



CE-1434  
ZERTIFIZIERT

## PRODUKTBILDER



Vorderansicht 1er



Vorderansicht 5er



Vorderansicht 25er



Packungsinhalt (einzel)

## DETAILINFORMATIONEN

CE-Kennzeichnung	CE-1434
Art der Probe	Anterior Nasal
Anwendungsart	Laien
LoD-Wert	0,05 ng/mL
Sensitivität/Spezifität	98,00 %/99,10 %
PEI-Werte	Cq ≤25: 100,0 % Cq 25-30: 87,0 % Cq ≥30: 20,0 % Gesamt-Sensitivität: 78,0 %
Haltbarkeit (ab Produktionsdatum)	24 Monate
Verfügbare Sprachen der Gebrauchsanweisung	Deutsch (Englisch, Spanisch, Französisch, Italienisch, Niederländisch)*

\*Abhängig von der LOT-Nummer. Nähere Infos erhalten Sie von unserem Sales Team.

## LOGISTIKDATEN

VPE	500 Stk. (1er-Packung) 1000 Stk. (5er-Packung) 1000 Stk. (25er-Packung)
VPE Gewicht	14,5 kg (1er-Packung) 11,5 kg (5er-Packung) 12 kg (25er-Packung)
VPE Maße (B x H x T)	55x54x39 cm (1er-Packung) 61,7x39,5x35 cm (5er-Packung) 52x40x48 cm (25er-Packung)
EPAL Gewicht	235 kg (1er-Packung) 200 kg (5er-Packung) 202 kg (25er-Packung)
EPAL Maße (B x H x T)	120x229x80 cm (1er-Packung) 120x226x80 cm (5er-Packung) 120x211x82 cm (25er-Packung)
Lagertemperatur	min. 2 °C; max. 30°C
Vereinzelbar	ja

## DISTRITBUTION

Hersteller	New Gene (Hangzhou) Bioengineering Co., Ltd. Room 1606, Floor 16, Building 5, 688 Bin'an Road Changhe Street, Binjiang District, Hangzhou City, Zhejiang Provinca, P.R. China
EC-REP	SUNGO Europe B.V. Olympisch Stadion 24, 1076DE, Amsterdam, Netherlands
Importeur	Kingline GmbH Am Altenbach 7 91341 Röttenbach



# 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

**CE** 1434

Anna  
Małgorzata  
Wyroba

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

Vice-President

**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: 11/08/2021

Place: Hangzhou, Zhejiang, China

