



## 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.*

**Signature:**

*Mingfu Li*

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

**Date:** 29/09/2020

**Place:** Hangzhou, Zhejiang, China



*Authorized Signature (S)*

*Authorized Signature (S)*



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



Page: 1 of 1

...making excellence a habit.™