



This is to certify that the Quality Management System of

## Nanjing Synthgene Medical Technology Co., Ltd.

**Unified Social Credit Code:** 91320114MA1X09DE0U

**Operation Address:** Building B6-2, No.9, Weidi Road, Xianlin University Town, Xianlin Street, Qixia District, Nanjing City, Jiangsu Province, China

**Registered Address:** Building B6-2, No.9, Weidi Road, Xianlin University Town, Xianlin Street, Qixia District, Nanjing City, Jiangsu Province, China

applicable to

The Manufacture of SARS-CoV-2 Nucleocapsid(N) Antigen Rapid Detection Kit (Colloidal Gold Method) and SARS-CoV-2 Virus Neutralization Test kit (Colloidal Gold Method)(Export to EU)

has been assessed and registered by NQA against the provisions of

### ISO 13485:2016

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by NQA.

Certified Clients shall accept regular surveillance assessments, the validity of certificates shall be maintained for the positive result of audit.

The information of this certificate can be checked on CNCA's website ([www.cnca.gov.cn](http://www.cnca.gov.cn))

SNQA's website: [www.snqa.com.cn](http://www.snqa.com.cn)

Managing Director

Certificate Number

**129706**

Date:

23 April 2021

Valid Until:

23 April 2024



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