



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
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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。

Gary E Slack

For and on behalf of BSI:

**Gary E Slack, Senior Vice President - Medical Devices**

Original Registration Date: 2020-07-27

Effective Date: 2020-07-27

Latest Revision Date: 2020-07-27

Expiry Date: 2023-07-26

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This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.

An electronic certificate can be authenticated [online](#).

Printed copies can be validated at [www.bsi-global.com/ClientDirectory](http://www.bsi-global.com/ClientDirectory) or telephone +86 10 8507 3000.

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