



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 邮編: 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 Effective Date: 2020-07-27 Latest Revision Date: 2020-07-27 Expiry Date: 2023-07-26

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...making excellence a habit."

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