



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

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