

# 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  
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310052  
China

诺迦（杭州）生物工程有限公司  
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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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