

Certificate CN23/00004453

The management system of

# Nanjing GenScript Biotech Co., Ltd.

## Jiangsu GenScript Biotech Co., Ltd.

No. 28, Yongxi Road, Jiangning Science Zone, Nanjing City, Jiangsu Province, P.R. China

has been assessed and certified as meeting the requirements of

**ISO 13485:2016**

**EN ISO 13485:2016**

For the following activities

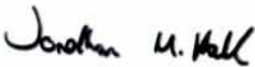
Manufacture of Proteins and Nucleic Acids used for In Vitro Diagnostic Medical Devices



This certificate is valid from 22 August 2023 until 21 August 2026 and remains valid subject to satisfactory surveillance audits.

Issue 1. Certified since 22 August 2023

Certified activities performed by additional sites are listed on subsequent pages.



Authorised by  
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Global Head - Certification Services

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**ISO 13485:2016**

**EN ISO 13485:2016**

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| Issue 1  |
| <b>Sites</b>   |
| Nanjing GenScript Biotech Co., Ltd.<br>No. 28, Yongxi Road, Jiangning Science Zone, Nanjing City, Jiangsu Province, P.R. China<br>Manufacture of Proteins used for In Vitro Diagnostic Medical Devices                                     |
| Nanjing GenScript Biotech Co., Ltd.<br>3 <sup>rd</sup> floor, Building E, No. 33, Jingyou Road, Jiangning Science Zone, Nanjing City, Jiangsu Province, P.R. China<br>Manufacture of Proteins used for In Vitro Diagnostic Medical Devices |
| Jiangsu GenScript Biotech Co., Ltd.<br>No. 39, Chunhui Road, Dingmao Subdistrict, Zhenjiang New District, Zhenjiang City, Jiangsu Province, P.R. China<br>Manufacture of Nucleic Acids used for In Vitro Diagnostic Medical Devices        |



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# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: Nanjing GenScript Biotech Co., Ltd.  
No. 28, Yongxi Road  
Jiangning Science Zone  
Nanjing City  
Jiangsu  
211100  
China

南京金斯瑞生物科技有限公司  
913201156825376724  
中国  
江苏省  
南京  
江宁科学园  
雍熙路28号  
邮编: 211100

Holds Certificate No: **MD 737430**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

The design, development, manufacture and distribution of reagent and immunoassay kits for in-vitro diagnostic detection of infectious disease. The design, development, manufacture and distribution of Antibody and Protein used for in-vitro diagnostic medical devices for the detection of infection and inflammatory, tumor markers, cardiac markers and fertility.

用于体外诊断检测传染病的试剂和免疫分析试剂盒的设计、开发、制造和分销。用于体外检测传染病、炎症、肿瘤、心肌、生育的抗体和蛋白质的设计、开发、制造和分销。

For and on behalf of BSI:

**Graeme Tunbridge, Senior Vice President Medical Devices**

Original Registration Date: 2021-02-19

Latest Revision Date: 2024-01-16

Effective Date: 2024-02-19

Expiry Date: 2027-02-18



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Certificate No: **MD 737430**

Location

Nanjing GenScript Biotech Co., Ltd.  
No. 28, Yongxi Road  
Jiangning Science Zone  
Nanjing City  
Jiangsu  
211100  
China

南京金斯瑞生物科技有限公司  
913201156825376724  
中国  
江苏省  
南京  
江宁科学园  
雍熙路28号  
邮编: 211100

Nanjing GenScript Biotech Co., Ltd.  
3/F, E Building, No.33, Jingyou Road  
Jiangning District  
Nanjing City  
Jiangsu  
211100  
China

南京金斯瑞生物科技有限公司  
913201156825376724  
中国  
江苏省  
南京市  
江宁区  
景佑路33号  
邮编: 211100

Registered Activities

Register address with provision of a business registration address for Chinese legislative purposes and the warehouse management in Building 16 of this site.

获证组织注册地址及16号楼的仓库管理活动。

The design, development, manufacture and distribution of reagent and immunoassay kits for in-vitro diagnostic detection of infectious disease. The design, development, manufacture and distribution of Antibody and Protein used for in-vitro diagnostic medical devices for the detection of infection and inflammatory, tumor markers, cardiac markers and fertility.

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

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