

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: **Getein Biotech, Inc.**  
No.9 Bofu Road  
Luhe District  
Nanjing  
Jiangsu  
211505  
China

基蛋生物科技股份有限公司  
中国  
江苏省  
南京市  
六合区  
沿江工业开发区  
博富路9号  
邮编: 211505

Holds Certificate No: **MD 728432**

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

Design & Development, Manufacture and Distribution of Chemiluminescence Immunoassay, Biochemistry Assay, Point of Care Assay (including Colloidal Gold Assay, Immunofluorescence Assay, Dry Chemistry Assay). Design & Development, Manufacture and Distribution of Analyzers in use of Chemiluminescence Immunoassay, Biochemistry Assay, Point of Care Assay (including Colloidal Gold Assay, Immunofluorescence Assay, Dry Chemistry Assay).

研发, 生产和销售化学发光法试剂, 生化试剂, 即时诊断 (包括胶体金法, 免疫荧光法, 干式化学法) 试剂。

研发, 生产和销售用于化学发光法试剂, 生化试剂, 即时诊断 (包括胶体金法, 免疫荧光法, 干式化学法) 试剂配套使用的分析仪。

For and on behalf of BSI:

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

Original Registration Date: 2020-05-29

Latest Revision Date: 2020-07-22

Effective Date: 2020-07-26

Expiry Date: 2023-07-25

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