



Certificate of Registration

OUALITY 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

工 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,于式化学法)试剂配套使用的分析仪。

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

jany C Stade

Original Registration Date: 2020-05-29 Effective Date: 2020-07-26 Latest Revision Date: 2020-07-22 Expiry Date: 2023-07-25

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...making excellence a habit."

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. An electronic certificate can be authenticated <u>online</u>.

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