



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。

jang Conada

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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...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>. Printed copies can be validated at www.bsi-global.com/ClientDirectory or telephone +86 10 8507 3000.

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