



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that: VivaChek Biotech (Hangzhou) Co., Ltd.

Level 2, Block 2

146 East Chaofeng Rd.

Yuhang Economy Development Zone

Hangzhou Zhejiang 311100 China 杭州微策生物技术有限公司

中国 浙江省 杭州市 余杭区

余杭经济技术开发区 超峰东路146号2幢二楼

邮编: 311100

Holds Certificate No: MD 726764

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

Design and Development, Manufacture and Distribution of In Vitro Diagnostic Test Kits (Colloidal Gold).

设计、开发、制造和销售胶体金体外诊断试剂盒。

Cary C Stade

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2020-07-24 Effective Date: 2020-07-24 Latest Revision Date: 2020-07-24 Expiry Date: 2023-07-23

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...making excellence a habit."

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