

# Certificate of Registration

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

This is to certify that: **VivaChek Biotech (Hangzhou) Co., Ltd.** 杭州微策生物技术有限公司  
Level 2, Block 2 中国  
146 East Chaofeng Rd. 浙江省  
Yuhang Economy Development Zone 杭州市  
Hangzhou 余杭区  
Zhejiang 余杭经济技术开发区  
311100 超峰东路146号2幢二楼  
China 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。

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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