

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

杭州微策生物技术股份有限公司
中国
浙江省
杭州市
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). Design and Development, Manufacture and Distribution of In Vitro Diagnostic Test Kits (PCR).

设计、开发、制造和销售胶体金体外诊断试剂盒。

设计、开发、制造和销售PCR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

Latest Revision Date: 2021-04-28

Effective Date: 2020-07-24

Expiry Date: 2023-07-23

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Certificate No: **MD 726764**

Location

Registered Activities

VivaChek Biotech (Hangzhou) Co., Ltd.
Level 2, Block 2
146 East Chaofeng Rd.
Yuhang Economy Development Zone
Hangzhou
Zhejiang
311100
China
杭州微策生物技术股份有限公司
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杭州市
余杭经济技术开发区
超峰东路146号
2幢二楼
邮编: 311100

Design and Development, Manufacture and Distribution of In Vitro Diagnostic Test Kits (Colloidal Gold). Design and Development, Manufacture and Distribution of In Vitro Diagnostic Test Kits (PCR).
设计、开发、制造和销售胶体金体外诊断试剂盒。
设计、开发、制造和销售PCR体外诊断试剂盒。

VivaChek Biotech (Hangzhou) Co., Ltd.
1/2/3 F, Building 1
16 East Zhenxing Rd.
Yuhang Economy Development Zone
Hangzhou
Zhejiang
311100
China
杭州微策生物技术股份有限公司
中国
浙江省
杭州市
余杭经济技术开发区
振兴东路16号
1幢一、二和三楼
邮编: 311100

Distribution for PCR Diagnostic Kits.
PCR体外诊断试剂盒的销售。

Original Registration Date: 2020-07-24

Effective Date: 2020-07-24

Latest Revision Date: 2021-04-28

Expiry Date: 2023-07-23

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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 [online](#).

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

Information and Contact: BSI, John M. Keynesplein 9, 1066 EP Amsterdam The Netherlands. Tel: +31 (0) 20 3460 780

BSI Group The Netherlands B.V., registered in the Netherlands under number 33264284, at John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands
A Member of the BSI Group of Companies.

Certificate No: **MD 726764**

Location

Registered Activities

VivaChek Biotech (Hangzhou)
Co., Ltd.
F1, Building 2
26 Wuzhou Rd., Donghu Block
Yuhang Economy Development Zone
Hangzhou
Zhejiang
311199
China
杭州微策生物技术股份有限公司
中国
浙江省
杭州市
余杭经济开发区
东湖街道五洲路26号
2幢一楼
邮编: 311199

Manufacture for PCR Diagnostic Kits.
PCR体外诊断试剂盒的生产。

VivaChek Biotech (Hangzhou)
Co., Ltd.
Room 101, Building 55
650 Hongfeng Rd., Donghu Block
Yuhang Economy Development Zone
Hangzhou
Zhejiang
311199
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杭州微策生物技术股份有限公司
中国
浙江省
杭州市
余杭经济开发区
东湖街道红丰路650号
55幢101室
邮编: 311199

Design and Development for PCR Diagnostic Kits.
PCR体外诊断试剂盒的设计和开发。

Original Registration Date: 2020-07-24

Effective Date: 2020-07-24

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