

Part 3- Certificates

1) ISO 13485:2016



By Royal Charter

Certificate of Registration

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

<p>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</p>	<p>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</p>
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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



Page: 1 of 1

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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.

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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.

VivaChek Biotech (Hangzhou) Co., Ltd

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