



TÜVRheinland®

LGA

Precisely Right.

Shanghai, 2016-09-27

To whom it may concern

This is to confirm on behalf of TÜV Rheinland LGA Products GmbH as follows:

**All the Blood Glucose Monitoring Systems listed in Appendix 1**

(Including meter, strips and control solutions)

Marketed by the legal manufacturer

**VivaChek Biotech (Hangzhou) Co., Ltd.**

Level 2, Block 2, 146 East Chaofeng Rd., Yuhang Economy Development Zone, Hangzhou, Zhejiang Province 311100, China

Fulfils all the requirements of EN ISO15197:2015. The evaluation is based on documents provided by the manufacturer for assessment.

Mr. Andreas FU  
Product Assessor, In-Vitro Diagnostics



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# Appendix 1

Precisely Right.

| Product Name                                        | Components/Model                               |                                                |                                       |
|-----------------------------------------------------|------------------------------------------------|------------------------------------------------|---------------------------------------|
| VivaChek™ Ino Blood Glucose Monitoring System       | VivaChek™ Ino Blood Glucose Meter/ VGM01       | VivaChek™ Ino Blood Glucose Test Strips/ VGS01 | VivaChek™ Ino Control Solution/ VGC01 |
| VivaChek™ Eco Blood Glucose Monitoring System       | VivaChek™ Eco Smart Blood Glucose Meter/ VGM02 | VivaChek™ Eco Blood Glucose Test Strips/ VGS01 | VivaChek™ Eco Control Solution/ VGC01 |
| VivaChek™ Fad Blood Glucose Monitoring System       | VivaChek™ Fad Blood Glucose Meter/ VGM03       | VivaChek™ Fad Blood Glucose Test Strips/ VGS02 | VivaChek™ Fad Control Solution/ VGC02 |
| VivaChek™ Ino Smart Blood Glucose Monitoring System | VivaChek™ Ino Smart Blood Glucose Meter/ VGM04 | VivaChek™ Ino Blood Glucose Test Strips/ VGS01 | VivaChek™ Ino Control Solution/ VGC01 |
| VivaChek™ Sync Blood Glucose Monitoring System      | VivaChek™ Sync Blood Glucose Meter/ VGM05      | VivaChek™ Ino Blood Glucose Test Strips/ VGS01 | VivaChek™ Ino Control Solution/ VGC01 |
| VivaChek™ Fad Smart Blood Glucose Monitoring System | VivaChek™ Fad Smart Blood Glucose Meter/ VGM07 | VivaChek™ Fad Blood Glucose Test Strips/ VGS02 | VivaChek™ Fad Control Solution/ VGC02 |

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