

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 Laboratories, Inc.

913 N Market Street, Suite 200, Wilmington, DE, 19801, USA

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



TÜV Rheinland
(Shanghai) Co., Ltd.
10-15/F, Huatsing Building,
No.88, Lane 777,
West Guangzhong Road,
Shanghai 200072, P.R. China

Tel +86 21 6108 1188
Fax +86 21 6108 1099
+86 21 6108 1199
e-mail: info@shg.chn.tuv.com
<http://www.chn.tuv.com>

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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