



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



**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
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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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