



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 Laboratories, Inc.

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

Fulfills 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

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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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