

**EC Certificate**  
**Directive 98/79/EC Annex IV, excluding Sections 4 and 6**  
**Full Quality Assurance System**  
**In Vitro Diagnostic Medical Devices**

**Registration No.:** HL 60145622 0001

**Report No.:** 15077757 017

**Manufacturer:** VivaChek Biotech (Hangzhou)  
Co., Ltd.  
Level 2, Block 2  
146 East Chaofeng Rd.  
Yuhang Economy Development Zone  
Hangzhou  
311100 Zhejiang  
P.R. China

**Products:** In-vitro Diagnostic Self-testing Products  
  
(see attachment for products and additional site included)  
  
Replaces Approval, Registration No.: HL 60139341 0001

**Expiry Date:** 2024-05-26

The Notified Body hereby declares that the requirements of Annex IV, excluding section 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

**Effective Date:** 2020-02-27

**Date:** 2020-02-27



**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC  
concerning in vitro diagnostic medical devices with the identification number 0197.

**TÜV Rheinland  
LGA Products GmbH  
Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

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**Products:**

Blood Glucose Monitoring Systems (Blood Glucose Meters, Blood Glucose Test Strips, Blood Glucose Control Solutions); Multi-function Monitoring Systems (including Multi-function Meters; Blood Ketone Test Strips, Blood Ketone Control Solutions, Uric Acid Test Strips, Uric Acid Control Solutions, Blood Glucose Test Strips, and Blood Glucose Control Solutions)

**Site included:**

1/2/3 F, Building 1, 16 East Zhenxing Rd., Yuhang Economy Development Zone, Hangzhou, 311100 Zhejiang, China

Blood Glucose Meters, Multi-function Meters

**Date:** 2020-02-27

