

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

Doc. 1/1, Rev. 0

**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

