

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 60147374 0001

Report No.: 15077758 008

Manufacturer: VivaChek Laboratories, Inc.

913 N Market Street, Suite 200

Wilmington, DE 19081

USA

Products: Blood Glucose Monitoring Systems (Blood Glucose

Meters, Blood Glucose Test Strips and Blood Glucose

Control Solutions)

(see attachment for site included)

Replaces Approval, Registration No.: HL 60130199 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.

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TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev. 0

Attachment to Certificate

Registration No.: Report No.:

HL 60147374 0001

15077758 008

Manufacturer:

VivaChek Laboratories, Inc.

913 N Market Street, Suite 200 Wilmington, DE 19081

USA

Site included:

12396 World Trade Drive, Suite 216, San Diego, CA 92128, USA

Date: 2020-02-27

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