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EC Certificate

TÜVRheinland®

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

Notified Body
TÜV Rheinland LGA Products GmbH Zertifizierungsstelle
Fuxiu Sheng

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.

TÜVRheinland®

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev. 0

Attachment to Certificate
Registration No.: HL 60147374 0001
Report No.: 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

Notified Body

Date: 2020-02-27

Fuxiu Sheng