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TÜVRheinland®

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 60101067 0001

Report No.: 15077758 001

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)

Expiry Date: 2020-03-15

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: 2015-04-24

Date: 2015-04-24

Notified Body
S. Liu

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.