

## 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



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