

# Certificate

The Certification Body of  
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**VivaChek Laboratories, Inc.**  
**913 N Market Street, Suite 200**  
**Wilmington, DE 19081**  
**USA**

has established and applies a quality management system for medical devices  
for the following scope:

**(see attachment for scope and site included)**

Proof has been furnished that the requirements specified in

## EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2018-07-06  
Certificate Registration No.: SX 60130200 0001  
An audit was performed. Report No.: 15077758 005  
This Certificate is valid until: 2021-03-15

Certification Body



Date 2018-07-06



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

**Attachment to  
Certificate**

**Registration No.:** SX 60130200 0001  
**Report No.:** 15077758 005

**Organization:** VivaChek Laboratories, Inc.  
913 N Market Street, Suite 200  
Wilmington, DE 19081  
USA

**Scope:**

Design and Development, Manufacture and Distribution of  
Blood Glucose Monitoring Systems (Blood Glucose  
Meters, Blood Glucose Test Strips and Blood Glucose  
Control Solutions), C-Reactive Protein (CRP) Test Kits

**Site included:**

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

Design and Development, Manufacture and Distribution of  
Blood Glucose Monitoring Systems (Blood Glucose  
Meters, Blood Glucose Test Strips and Blood Glucose  
Control Solutions), C-Reactive Protein (CRP) Test Kits

**Certification Body**



**Date:** 2018-07-06

