

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

Doc. 1/1, Rev. 0

**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

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Date: 2018-07-06

