

Declaration of Conformity

VivaChek Laboratories, Inc.

913 N Market Street, suite 200, Wilmington, DE, 19081, USA.

We declare under our sole responsibility that the *in vitro* diagnostic device:

VivaChek Ino Blood Glucose Monitoring System (Starter Kit)

classified as List B according to the Annex II of the directive 98/79/EC
meets all the provisions of the directive 98/79/EC on *in vitro* diagnostic
medical devices which apply to it

**This declaration is according to Annex IV of the Directive and thus
is based on approval by the notified body
TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431, Nürnberg,
Germany, notified under No. 0197 to the EC Commission.**

Authorized Representative:

Landlink GmbH

Dorfstrasse,2/4, Emmendingen, Germany

Tel:+ 0049 7641 9626855

Fax:+ 0049 7641 9626855

Applied harmonized standards:

**EN 376:2002, EN 12286:1998/A1:2000,12287:1999,EN ISO
13485:2012,EN 13532:2002, EN 13612:2002, EN 13640:2002, EN
13641: 2002, EN ISO 15225:2010,EN ISO 15197:2013,EN ISO
14971:2012, EN ISO 18113-5:2011, EN 980:2008, EN ISO 15223-1
2012, EN ISO 18113-4:2011,& EN ISO 17511:2003**

Signed this 11 day of August, 2017
in Wilmington, DE USA.



Rocky Zhu
Regulatory Affairs Manager
VivaChek Laboratories, Inc.

Declaration of Conformity

VivaChek Laboratories, Inc.

913 N Market Street, suite 200, Wilmington, DE, 19081, USA.

We declare under our sole responsibility that the *in vitro* diagnostic device:

VivaChek Ino Blood Glucose Meter

classified as List B according to the Annex II of the directive 98/79/EC

meets all the provisions of the directive 98/79/EC on *in vitro* diagnostic medical devices which apply to it

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Regulatory Affairs Manager
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We declare under our sole responsibility that the in vitro diagnostic device:

VivaChek Ino Blood Glucose Test Strips

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We declare under our sole responsibility that the in vitro diagnostic device:

VivaChek Ino Control Solution

classified as List B according to the Annex II of the directive 98/79/EC

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