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# 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 accoding 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**

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**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.

REPUBLICA MOLDOVA, mun. CHIŞINĂU S.R.L. "PHARMONY" IDNO 1015600025123 SOCIETATEA CU RĂSPUNDERE LIMITATĂ

Regulatory Affairs Manager
VivaChek Laboratories, Inc.