

## **Declaration of Conformity**

Manufacturer:

VivaChek Biotech (Hangzhou) Co., Ltd

Address:

Level 2, Block 2, 146 East Chaofeng Rd,

Yuhang Economy Development Zone, Hangzhou, Zhejiang 311100, China

European Representative:

Lotus NL B.V.

Address:

Koningin Julianaplein 10, 1e Verd, 2595AA, the Hague,

Netherlands.

Tel:

+31644168999

E-mail:

peter@lotusnl.com

Products:

VivaDiag POCT Analyzer

VIM01/VIM1000

Classification (Article 9, 98/79/EC): Others

Conformity Assessment procedure:

98/79/EEC ANNEX III

We hereby declare that the above mentioned products meet the COUNCIL DIRECTIVE 98/79/EC and applicable Standards. All supporting documentations are retained in the manufacturer and EU representative.

Hangzhou, China, 27<sup>th</sup> Feb, 2020 Place, Date of issue

> Regulatory Affairs Manager aChek Biotech (Hangzhou) Co., Ltd