



LOTUS (China UK NL USA)

## Declaration of Notification

This is to certify that, according to the COUNCIL DIRECTIVE 98/79/, Lotus NL B.V., with address at Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands, performed as the European Representative of

VivaChek Biotech (Hangzhou) Co., Ltd.  
Level 2, Block 2, 146 East Chaofeng Rd, Yuhang Economy Development Zone,  
Hangzhou, Zhejiang 311100, China  
Tel: +86-571-89182700 Fax: +86-571-89182733  
Email: info@vivachek.com www.vivachek.com

The manufacturer declares that below products meet the COUNCIL DIRECTIVE 98/79/EC and applicable standards., and has signed the EC Declaration of Conformity in agreement with ANNEX III, 98/79/EC. All supporting documentations are retained in the manufacturer and Lotus NL B.V.,

### Product Name

VivaDiag™ COVID-19 IgM/IgG rapid test

### Classification:


Others.

### General applicable standards:

DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in vitro diagnostic medical devices.

10<sup>th</sup> Mar, 2020

Date of issue

  
Peter Wei  
General Manager  
Lotus NL B.V.