Declaration of Conformity

VivaChek Biotech (Hangzhou) Co., Ltd.
Level 2, Block 2, 146 East Chaofeng Rd., Yuhang Economy Development Zone, Hangzhou,Zhejiang, 311100, P.R.China

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

VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test

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 Conformity Assessment Route: Annex III , section 6, and the Classification/Qualification of medical device is for self-testing

The declaration is base on the approval by the notified body

Polskie Centrum Badań i Certyfikacji S.A.ul. Puławska 469 02-844 Warszawa (PCBC) ,notified under No.1434 to the EC commission.
The EC certificate No.is 1434-IVDD-478/2021

European Representative:

Lotus NL B.V.
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Date: Oct 28, 2021
Julie zhou
R.A Director

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