VivaChek

# Declaration of Conformity

## Manufacturer

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

## European Representative

Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
Tel：+31644168999 E-mail：peter@lotusnl.com

## Product Name and Model

VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test VCD16

## Classification:

Other device, not in annex II, not for self-testing, not for performance evaluation.

Conformity assessment procedure: ANNEX III, 98/79/EC
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.

## 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.

Hangzhou, China, 23th Jul, 2020
Place, Date of issue

VIVACHEK BIOTECH (HANGZHOU) CO., LTD. 维策生物技术有限公司 330110006198

Elaine Huang
Regulatory Affairs Manager