

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

CMC Medical Devices & Drugs S.L

C/Horacio Lengo Nº 18, CP 29006, Málaga, Spain

Tel: +34951214054

Fax: +34952330100

email: info@cmcmedicaldevices.com

Product Name

Multi-Drugs Saliva Rapid Test Cube

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, 23 May, 2022 Place, Date of issue

Regulatory Affairs Department