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

VivaDiag™ Cardiac Troponin I Test Kit (FIA)

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

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Julie
Regulatory Affairs Department