

## Declaration of Conformity

### Manufacturer

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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

H. pylori Ab Rapid Test

### 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



Tracy Zhang  
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Regulatory Affairs Department

VivaChek Biotech (Hangzhou) Co., Ltd

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