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Declaration of Conformity

Manufacturer

VivaChek Biotech (Hangzhou) Co., Ltd.

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European Representative

Lotus NL B.V.

Koningin Julianaplein 10, 1st Verd, 2595AA, The Hague, Holandsko. Phone:

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Product name and model

VivaDiagTM SARS-CoV-2 AgVCD05 rapid test

Classification:

Other equipment not listed in Annex II is not intended for self-testing and is not intended for performance evaluation.

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

We hereby declare that the above products are in accordance with COUNCIL DIRECTIVE 98/79 / EC and applicable standards. All supporting documents shall be kept by the manufacturer and the EU representative.

Commonly used standards:

DIRECTIVE 98/79 / EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 November 1998

October 1998 on in vitro diagnostic medical devices.

Hangzhou, China, July 23 ,

2020 Place, date of

publication

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Regulatory Affairs Manager

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