VivaChek

Declaration of Conformity

Manufacturer

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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™ SARS-CoV-2 Ag Rapid Test VCD05

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

Julie Zhou
Regulatory Affairs Manager

VIVACHEK BIOTECH (HANGZHOU) CO., LTD. 330110006198 9