VivaChek

Declaration of Conformity

Manufacturer

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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

Multiplex Respiratory Antigen Rapid Test
10 in 1: SARS-CoV-2/Influenza A+B/HPIV/RSV/Adenovirus/MP/HMPV/Rhinovirus/SP

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

Julie Zhou
Regulatory Affairs Director