Medicines & Healthcare products Regulatory Agency

UK Health Security Agency

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Bcc. Medicines & Healthcare products Regulatory Agency (enforcement authority)

Dear Stakeholder,

Re: Notification of result – CTDA desktop review – COVID-19 Antigen Rapid Test Kit (Swab)

Thank you for your application for approval of a coronavirus test under the requirements that came into force on 28 July 2021 via The Medical Devices (Coronavirus Test Device Approvals) (Amendment) Regulations 2021.

I can confirm the desktop review for your product has now been completed. I can inform you that based on the information and evidence provided your application has been successful.

Your product details will be published on the register of products that have been approved under regulation 38A(5) of the Medical Devices Regulations 2002: COVID-19 test validation approved products - GOV.UK (www.gov.uk). The details published on the register will include the name and address of the registered place of business of the applicant and manufacturer; the country in which the manufacturer is established; and if there is one, the name and address of a UK Responsible Person or Authorised Representative of the manufacturer.

The approval is valid for a period of 5 years from the date of this letter.

If your test is listed on the temporary protocols (Medical Devices Regulations 2002: protocols - GOV.UK (www.gov.uk), please be advised your test will be removed from the temporary protocol list it is included under as it is added to the CTDA register of approved tests.

The MHRA, in its capacity as an enforcing authority for medical device legislation in the UK, is in copy to this letter.

Yours sincerely

CTDA Team