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## Provisional Authorisation for COVID-19 Tests

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| <i>Applicant</i>  | Breathonix Pte Ltd   |
| <i>Name of test</i>   | BreFence Go COVID-19 Breath Test System  |
| <i>Intended purpose (As per manufacturer's information for use)</i> | <p><i>The BreFence Go COVID-19 Breath Test System is a real-time, non-invasive breath test intended for the qualitative detection of volatile organic compounds (VOCs) in human breath specimens by their mass-to-charge ratio (m/z). The VOCs of interest are unique to the COVID-19 and the body's response to the disease in individuals suspected of infection by the SARS-CoV-2 virus by healthcare providers.</i></p> <p><i>Positive results indicate the presence of COVID-19 infection, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses.</i></p> <p><i>Negative results should be treated as presumptive, although they do not rule out COVID-19 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19, and confirmed with a molecular assay, if necessary, for patient management.</i></p> <p><i>BreFence Go COVID-19 Breath Test System is intended for use in clinical laboratories, clinical settings, hospitals or other point-of-care settings by personnel trained to the operation of the system.</i></p> |
| <i>Date of Provisional Authorisation</i>                            | 17 May 2021  |

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