Provisional Authorisation for COVID-19 Tests

Annlicant	Sinch Medical Pte Ltd
Applicant	Silicii Medicai Ple Llu
Name of test	2019-nCOV/COVID-19 IgG/IgM Rapid Test
	Device
Intended purpose (As per manufacturer's information for use)	The 2019-nCOV/COVID-19 IgG/IgM Rapid test Device is a rapid chromatographic immunoassay for the qualitative detection of IgG & IgM antibody of Coronavirus Disease 2019 in human whole blood, serum, or plasma. The results from this test is not to be used for confirmatory testing or as sole basis for diagnosis.
Date of Provisional Authorisation	28 May 2020