PUBLIC ENQUIRY - SINGAPORE MEDICAL DEVICE REGISTER (SMDR)

Device Info

Device Name:	**Acon Biotech (Hangzhou) Flowflex SARS CoV 2 Antigen Rapid Test** [ACON BIOTECH (HANGZHOU) CO., LTD]
Description:	The SARS-CoV-2 Antigen Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection the nucleocapsid protein antigen from SARS-CoV-2 in nasal and nasopharyngeal swab specimens directly from individuals who are suspected of COVID-19 by their healthcare provider within the first seven days of the onset of symptoms. The SARS-CoV-2 Antigen Rapid Test cannot be used to test specimens from asymptomatic individuals. The SARS-CoV-2 Antigen Rapid Test does not differentiate between SARS-CoV and SARS-CoV-2. The SARS-CoV-2 Antigen Rapid Test is intended for use by trained clinical laboratory personnel and individuals trained in point of care settings. SARS-CoV-2 Antigen Rapid Test is intended to be used as an aid in the diagnosis of SARS-CoV-2 infection.
Medical Specialty Area:	Immunology
Medical Device Class:	Class D medical device
Device Registration No:	DE0506284
Registration Date:	12/10/2021
Change Notification Approval Date:	Not Applicable

Product Owner

1. ACON BIOTECH (HANGZHOU) CO., LTD [ACON BIOTECH (HANGZHOU) CO., LTD] #210 ZHENZHONG ROAD, WEST LAKE DISTRICT, HANGZ...

Registrant

1. ALCOTECH PTE LTD 2 WOODLANDS SECTOR 1, WOODLANDS SPECTRUM, #01-08, SINGAPORE 738068

Models

No.	Model Name	Identifier	UDI-DI	DM-DI	Place of Manufacture
1	Flowflex(TM) SARS-CoV-2 Antigen Rapid Test	L031-11815			CHINA
2	Nasal Swab	CF 150-P 3 B			CHINA
3	Nasopharyngeal Swab	CF 150-P 2 C			CHINA

Close

Note: All device listings on the Singapore Medical Device Register (SMDR) are active. Class A medical devices are not registered in the SMDR. To retrieve Class A medical devices, please visit Class A Medical Device Database.