PUBLIC ENQUIRY - SINGAPORE MEDICAL DEVICE REGISTER (SMDR)

Device Info

Device Name:	**Acon Biotech (Hangzhou) FLOWFLEX SARS-CoV-2 Antigen Rapid Test (Self-Testing)** [ACON BIOTECH (HANGZHOU) CO., LTD]
Description:	A rapid test for the detection of SARS-CoV-2 nucleocapsid antigens in anterior nasal swab specimens. For in vitro diagnostic use only. For self-testing.
Medical Specialty Area:	Microbiology
Medical Device Class:	Class D IVD
Device Registration No:	DE0508092
Registration Date:	15/05/2023
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 25 BUKIT BATOK CRESCENT, THE ELITIST, #09-13, SINGAPORE 658066

Models

No.	Model Name	Identifier	UDI-DI	DM-DI	Place of Manufacture
1	Flowflex SARS-CoV-2 Antigen Rapid Test(Self-Testing)	L031-118M5			CHINA
2	Flowflex SARS-CoV-2 Antigen Rapid Test(Self-Testing)	L031-118P5			CHINA
3	Flowflex SARS-CoV-2 Antigen Rapid Test(Self-Testing)	L031-118T5			CHINA
4	Flowflex SARS-CoV-2 Antigen Rapid Test(Self-Testing)	L031-118R5			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.