Health Sciences Authority
11 Outram Road Singapore 169078
Tel: 65 6213 0838 Fax: 65 6213 0749
Website: www.hsa.gov.sg

8 November 2021

Alcotech Pte Ltd
25 Bukit Batok Crescent
#09-13 The Elitist
Singapore 658066

Dear Tan Zhi Rong,

MDPSAR2021-12: EMERGENCY SUPPLY OF MEDICAL DEVICES IN SINGAPORE

Please refer to your Pandemic Special Access Route (PSAR) application submitted on 05 October 2021.
Reference No.: 615c09d5d106760012f2593d
Name(s) of the Emergency Medical Device: <Please refer to attached Schedule>

The Health Sciences Authority has completed the review of this application, and we wish to inform you that the information provided has demonstrated that the emergency medical device(s) in this application fulfils the conditions specified in Regulation 13C (5) (b) of the Health Product (Medical Devices) Regulations. The application is approved effective from the date of this authorisation and approved indication(s) can be found in the schedule attached.

Conditions of approval:

1. Alcotech Pte Ltd shall comply with all relevant requirements under the Health Products Act and the Health Products (Medical Devices) Regulations 2010.

2. Supply of the medical devices is subject to post-market duties and obligations as stipulated in the Health Products Act and the Health Products (Medical Devices) Regulation 2010 including reporting of adverse events arising from the use of the medical devices, reporting of Field Safety Corrective Actions and recalls related to the medical devices.

3. Alcotech Pte Ltd shall be responsible for ensuring that the quality, safety and efficacy of the medical devices are not adversely affected during storage and distribution of the medical devices.

4. Any change made to the medical device(s) in the attached schedule shall require approval from the Authority prior to supply of these medical devices, unless otherwise specified by the Authority. Failure to notify such changes to medical devices may result in suspension or cancellation of this authorisation

5. It is the responsibility of the applicant to ensure this medical device complies with any other applicable regulatory requirements of other regulatory bodies in Singapore prior to its supply (e.g. For medical devices also subject to control under the Radiation Protection Act, a licence from the Centre for Radiation Protection and Nuclear Science (CRPNS) of the National Environment Agency (NEA) may be required).

6. A record of every import and supply as required for traceability, including the date, quantity, batch/lot number of the device and details of the purchaser shall be kept and made available to HSA upon request.

7. Cold-chain condition must be maintained for temperature sensitive medical devices.

8. Alcotech Pte Ltd shall submit the results of the real-time stability studies for the medical devices once complete.

9. Alcotech Pte Ltd shall submit the results of additional clinical evaluation of the medical devices, if available.

10. Alcotech Pte Ltd shall report incidents related to any incorrect or inaccurate test results from the medical devices as and when Alcotech Pte Ltd is made aware of.

11. The registrant shall, on an ongoing basis, work with the product owner to monitor and verify that the assay continues to be able to detect SARS-CoV-2 by assessing the impact of mutations on the assay performance. Any potential false negative results from the assay due to new mutations shall be reported to HSA.

12. The devices authorised under this PSAR shall be supplied to the Ministry of Health (MOH) or to entities/facilities as directed by the MOH.

Please note that failure to adhere to any of the above conditions will invalidate this authorisation with immediate effect.

This authorisation will remain valid till **31 December 2022**.

The issuance of this authorisation shall not be construed as approval of the use(s) of this medical device. Use of this medical device may be subject to restrictions under the Private Hospitals and Medical Clinics Act, Medical Registration Act or any other applicable legislation (e.g. Radiation Protection Act).

Please contact Ong Ming Hao, Senior Regulatory Specialist, at Tel: 6866 1075 or E-mail: Ong_Ming_Hao@hsa.gov.sg should you need further clarification.

Yours sincerely,
Sethuraman Rama (Dr)

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Director, Medical Device Branch
for Group Director
Health Products Regulation Group

THE SCHEDULE

No.	Device Proprietary/Brand Name	Intended Use
1	Acon Biotech Flowflex SARS-CoV-2 Antigen Rapid Test (Self-Testing)	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.

END OF PRODUCT LIST