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

23/11/2021

Omnicell Pte Ltd
48 Toh Guan Road East
#04-138 Enterprise Hub
Singapore 608586

Dear Yoco Ting,

MDPSAR2021-18: EMERGENCY SUPPLY OF MEDICAL DEVICES IN SINGAPORE

Please refer to your Pandemic Special Access Route (PSAR) application submitted on 15/10/2021.
Reference No.: 61692562927e4a0013246b43
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. Omnicell 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. Omnicell 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. Omnicell Pte Ltd shall submit the results of the real-time stability studies for the medical devices once complete.

9. Omnicell Pte Ltd shall provide the electrical and electromagnetic compatibility test certificates once available.

10. Omnicell Pte Ltd shall, on an ongoing basis, work with the product owner to monitor and verify that the assay continues to be able to detect all published SARS-CoV-2 sequences. Where there is potential of false negative interpretations due to mutations affecting all targets of the assay, the impact of these mismatches to the assay shall be assessed and reported to HSA if they are expected to affect the assay.

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

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

13. 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.

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 Shaqireen d/o Kwajah Mohamed Moinuddeen, Seniour Regulatory Specialist, at Tel: 68661132 or E-mail: shaqireen_moinuddeen@hsa.gov.sg should you need further clarification.

Yours sincerely,
Sethuraman Rama (Dr)

srama

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

THE SCHEDULE

No.	Device Proprietary/Brand Name	Intended Use
1	The Cue® COVID-19 Test	The Cue COVID-19 Test is a molecular diagnostic test for the qualitative detection of nucleic acid from SARS-CoV-2 in anterior nasal (nasal) swab specimens collected with the Cue Sample Wand. The Cue COVID-19 Test is intended for use in adults (self-swabbing) or children ≥2 years of age (swabbed by

		an adult) with or without symptoms or other epidemiological reasons to suspect COVID-19. It is authorized for home use. This test will give a positive or negative result for COVID-19. The test does not differentiate between SARS-CoV and SARS-CoV-2. Results are for the identification of the SARS-CoV-2 viral RNA. Viral RNA is generally detectable in anterior nasal swab specimens during the acute phase of infection. Positive results indicate the presence of viral RNA, but clinical correlation with past medical history and other diagnostic information is necessary to determine infection status. Positive results do not rule out a bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Negative results in an asymptomatic individual are presumptive and confirmation with a molecular assay performed in a laboratory, if necessary, for patient management may be performed. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or management decisions for the individual, including infection control decisions. Negative results should be considered in the context of an individual's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19. It is important to consult your healthcare provider to discuss your results and if additional testing is necessary. The test is run using the Cue Health Monitoring System (Cue Cartridge Reader), the Cue COVID-19 Test Cartridge, the Cue Sample Wand nasal swab, and the Cue Health Mobile Application (Cue Health App) on the compatible mobile smart devices named on the Cue Health website.
2	Cue Health Monitoring System Cue Health Mobile Application Android: version 1.3.0.97	The Cue Health Monitoring System is an in vitro diagnostic medical device for use with test-specific Cue

	Apple: version 1.3.0.238	Catridge(s) and the Cue Health Mobile Application (Cue Health App) installed on a mobile smart device.

END OF PRODUCT LIST