Health Sciences Authority
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HSA 600:36/01

14 December 2020

HealthGroup Medical Pte Ltd
Blk 635 Veerasamy Road
#01-154
Singapore 200635

Dear Professor Lawrence Chan,

RE: STATUS OF SUPPLY OF MEDICAL DEVICES IN SINGAPORE

This letter serves to confirm that the following medical device product(s) have been issued Provisional Authorisation (MDPA2020-162) for supply in Singapore and may be exported from Singapore.

No.	Device Name	Intended Use
1	V-CODE ENCODE SARS-COV-2 Antigen Rapid Test Device (20 tests)	The SARS-COV-2 Antigen Rapid Test Device is a rapid visual immunoassay for the qualitative, presumptive detection of COVID-19 antigens from throat swabs and nasal swab specimens. It is intended to be used by professionals as a test and provides a preliminary test result to aid in the diagnosis of infection with novel Coronavirus. Any interpretation or use of this preliminary test result must also rely on other clinical findings as well as on the professional judgment of health care providers. Alternative test method(s) should be considered to confirm the test result obtained by this test. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time rule out the presence of COVID-19 viral antigens in specimen, as they may be present below the minimum detection level of the test. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

Product Owner:	HealthGroup Medical Pte Ltd Blk 635 Veerasamy Road #01-154 Singapore 200635
Manufacturing Site(s):	Zhuhai Encode Medical Engineering Co., Ltd No. 20, Honghui 2nd Road, Hongqi Industrial Zone, Jinwan District, Zhuhai, China Racer Technology Pte Ltd 28 Changi South St 1, Changi Industrial Estate Singapore 486772

2. The medical device product(s) may be supplied to the healthcare institutions, private hospitals, medical clinics or clinical laboratories licensed under the PHMC Act (Cap. 248) for use on their patients.

3. The medical device product(s) may be exported out of Singapore subject to the duties and obligations as stipulated in the Health Products Act and the Health Products (Medical Devices) Regulation 2010.

4. The confirmation above is subject to the manufacturer's activities conforming to the ISO 13485 quality system.

Yours sincerely,

DR LAKSHMIDEVI BALAKRISHNAN
REGULATORY CONSULTANT
For GROUP DIRECTOR
HEALTH PRODUCTS REGULATION GROUP
HEALTH SCIENCES AUTHORITY