**Health Sciences Authority**
11 Outram Road Singapore 169078
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HSA 600:36/01

15 July 2020

Hi-Beau Group
37 Ubi Crescent
Singapore 408586

Dear Edith Chin,

**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 (MDPA2020-98) for supply in Singapore and may be exported from Singapore.

| No. | Device Name | Intended Use |
|---|---|---|
| 1 | SAVANT™ New Coronavirus (SARS-CoV-2) N Protein Detection Kit (Fluorescence Immunochromatography) (10, 50, 100 pieces test kit)<br><br>Fluorescence Immunoassay chromatography analyser (Savant-100) | The kit is used for qualitative detection of new coronavirus nucleocapsid (N) antigen from the SARS-CoV-2 in oropharyngeal swab aspirate specimens collected from individuals suspected of COVID-19 by their healthcare providers.<br><br>Results are for the detection of new coronavirus (SARS-CoV-2) N Protein, which is generally detectable in oropharyngeal swab specimens during the acute phase of infection. Positive results are indicative of active infection with SARS-CoV-2; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status.<br><br>Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. All the agencies within Singapore and its territories are required to report all positive results to the appropriate public health authorities.<br><br>Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information. |

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|---|---|
| Product Owner: | Beijing Savant Biotechnology Co. Ltd<br>14# 4F, No. 2 Kechuang East 5th Street<br>Tongzhou District , 101111 Beijing<br>People's Republic of China |
| Manufacturing Site: | Beijing Savant Biotechnology Co. Ltd<br>14# 4F, No. 2 Kechuang East 5th Street<br>Tongzhou District , 101111 Beijing<br>People's Republic of China |

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 CHRISTOPHER LAM
SENIOR REGULATORY SPECIALIST
*For* GROUP DIRECTOR
HEALTH PRODUCTS REGULATION GROUP
HEALTH SCIENCES AUTHORITY