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HSA 600:36/01

28 July 2020

All Eights (Singapore) Pte Ltd
6 Harper Road #03-02 / #06-07,
Leong Huat Building,
Singapore 369674

Dear Jocelyn Koh,

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 (MDPA2020-101) for supply in Singapore and may be exported from Singapore.

No.	Device Name	Intended Use
1	StrongStep® Novel Coronavirus (SARS-CoV-2) Multiplex Real-Time PCR Kit (500190)	This product is intended to be used to achieve qualitative detection of SARS-CoV-2 viral RNA extracted from nasopharyngeal swabs, oropharyngeal swabs, sputum and BALF from patients in association with an RNA extraction system and the designated PCR platforms listed above. The kit is intended for use by laboratory trained personnel.

Product Owner: Nanjing Liming Bio-Products Co., Ltd.
No. 12 Huayuan Road, Nanjing, Jiangsu,
210042 P.R. China.

Manufacturing Site: Nanjing Liming Bio-Products Co., Ltd.
No. 12 Huayuan Road, Nanjing, Jiangsu,
210042 P.R. 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

