



Medical Device Division, Department of Health, Government of the Hong Kong Special Administrative Region Website:www.mdd.gov.hk

表列證書 CERTIFICATE OF LISTING

表列號碼

Listing No.

220159

修訂本號碼

Revision No.

Nil

廠名、品牌及型號

Make, Brand Name and :

Model

Zhuhai Encode Medical Engineering SARS-CoV-2 Antigen Rapid Test Device

(RCD-8021, RCD-8025, RCD-80220)

儀器名稱

IVD Test Reagent/Kits, Serology, Virus, Severe Acute Respiratory Syndrome

Device Description

Coronavirus 2, Antigen

製造商

Zhuhai Encode Medical Engineering Co., LTD

Manufacturer

NO. 020, Honghui 2nd Rd, Hongqi Industrial Zone, Jinwan District, 519090

Zhuhai, PEOPLE'S REPUBLIC OF CHINA

製造地點

Zhuhai Encode Medical Engineering Co., LTD, NO. 020, Honghui 2nd Rd, Hongqi Industrial Zone, Jinwan District, 519090 Zhuhai, PEOPLE'S

Manufacturing Site

REPUBLIC OF CHINA

本地負責人

大江科技集團有限公司

Local Responsible Person

Dajiang Technology Holdings Limited

茲證明上述產品已在衞生署的「醫療儀器行政管理制度」中表列。上述本地負責人已由製造商委任,並承諾遵守「醫療 儀器行政管理制度」的規定。

This is to certify that the product described above has been listed with the Department of Health under the Medical Device Administrative Control System (MDACS). The above Local Responsible Person has been designated by the Manufacturer and has undertaken to comply with the MDACS requirements.

發出日期

16 May 2022

Date of issue

有效至 Valid until

16 May 2027

(Dr Joanna SO) or Director of Health