Australian Government

Department of Health

Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

APAC Security Pty Ltd

for approval to supply

Severe acute respiratory syndrome-associated coronavirus IVDs

ARTG Identifier	333341
ARTG Start Date	5/04/2020
Product Category	Medical Device Included - IVD Class 3
GMDN	CT772
GMDN Term	Severe acute respiratory syndrome-associated coronavirus IVDs
Intended Purpose	"Intended to detect the novel coronavirus SARS-CoV-2 that causes COVID-19 from symptomatic individuals at the point of care by trained health professionals (whole blood, serum, plasma, nasopharyngeal swabs and nasal swabs) and for self-testing by lay persons (nasal swabs)."

Manufacturer Details	Address	Certificate number(s)
Hangzhou Clongene Biotech Co Ltd	No 1 Yichuang Road Yuhang Sub district Yuhang District , Hangzhou , 311121 China	DV-2020-MC-04126-1

ARTG Standard Conditions

The above Medical Device Included - IVD Class 3 has been entered on the Register subject to the following conditions:

· - The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Products Covered by This Entry

1. Severe acute respiratory syndrome-associated coronavirus IVDs

This entry: contains System(s)/Procedure Pack(s)

IVD Information

Name	Category Description
COVID-19 IgG/IgM Rapid Test Cassette	Point of care testing
Clungene Covid-19 Antigen Rapid Test	Self Testing
Clungene Covid-19 Antigen Rapid Test	Point of care testing