Australian Government

Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Emergence Technology Pty Ltd

for approval to supply

Severe acute respiratory syndrome-associated coronavirus IVDs

ARTG Identifier	346643
ARTG Start Date	27/10/2020
Product Category	Medical Device Included - IVD Class 3
GMDN	CT772
GMDN Term	Severe acute respiratory syndrome-associated coronavirus IVDs
Intended Purpose	The COVID-19 Antigen Rapid Test Device is an in vitro immunoassay. The assay is for the direct and qualitative detection of SARS-CoV-2 viral nucleoprotein antigens from nasopharyngeal secretions and oropharyngeal secretions. Negative results do not preclude SARS-CoV-2 viral infection. Testing results should not be the sole basis for treatment or other management decisions. This test is intended for professional use only.

Manufacturer Details	Address	Certificate number(s)
Assure Tech (Hangzhou) Co Ltd	Building 4 No 1418-50 Moganshan Road Gongshu District Hangzhou , Zhejiang , 310011 China	DV-2020-MC-27423-1

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: does not contain System(s)/Procedure Pack(s)

IVD Information

Name	Category Description
COVID-19 Antigen Rapid Test Device	Point of care testing

Product Specific Conditions

· 1. The person (the sponsor) in relation to whom the Device is included in the ARTG may only supply the Device to a. laboratories that are accredited pathology laboratories and/or b. medical practitioners who are registered under a law of a State or Territory and/or c. health care professionals in residential and aged care facilities and/or d. Commonwealth, State or Territory department of health and/or e. an agency of the Commonwealth, State or Territory acting on behalf of Commonwealth, State or Territory department of health. And within 12 months of an approval the following information will be required to