Public Summary

Summary for ARTG Entry:	372335	Emergence Technology Pty Ltd - Severe acute respiratory syndrome-associated coronavirus IVDs

ARTG entry for	Medical Device Included - IVD Class 3
Sponsor	Emergence Technology Pty Ltd
Postal Address	PO Box 420, Brunswick, VIC, 3056 Australia
ARTG Start Date	6/08/2021
Product Category	Medical Device Class 3
Status	Active
Approval Area	IVD

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.

Manufacturers

Name	Address
Assure Tech (Hangzhou) Co Ltd	Building 4 No 1418-50 Moganshan Road Gongshu District Hangzhou, Zhejiang, 310011 China

Products

1 . Severe acute respiratory syndrome-associated coronavirus IVDs

Product Type	IVD	**Effective Date**	2/12/2022 3:01:34 PM
GMDN	CT772 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 (nasopharyngeal swab and saliva) and for self-testing by lay persons (saliva and nasal swab).		

Specific Conditions

The following non-standard conditions apply to the point of care device:

The following conditions are imposed on the supply of COVID-19 rapid antigen tests included in the Register

1. The person in whose name the device is included in the Register (the sponsor) may only supply the device to one or more of the following:
a. a laboratory that is an accredited pathology laboratory within the meaning of the Health Insurance Act 1973;
b. a person who is registered under a law of a state or territory to practice pharmacy (a pharmacist), where:
i. the pharmacist is responsible for performing or supervising the performance of the test; and
ii. the person mentioned in subparagraph (i) and any other person acting under their supervision to perform the test have received training in the correct use of the device and the interpretation of the test result;
c. a health practitioner within the meaning of the Therapeutic Goods Act 1989 (other than a pharmacist) or a person registered under a law of a state or territory to practice paramedicine (a paramedic), where:
i. the health practitioner or the paramedic is responsible for performing or supervising the performance of the test; and
ii. the person mentioned in subparagraph (i) and any other person acting under their supervision to perform the test have received training in the correct use of the device and the interpretation of the test result; and
iii. the device is only used to test employees or contractors of, or a patient under the direct care of, the health practitioner or the paramedic;
d. a residential care or aged care facility, or a home care service provider, that employs or engages a health practitioner within the meaning of the Therapeutic Goods Act 1989 or a paramedic, where:
i. the health practitioner or the paramedic is responsible for performing or supervising the performance of the test; and
ii. the person mentioned in subparagraph (i) and any other person acting under their supervision to perform the test have received training in the correct use of the device and the interpretation of the test result; and
iii. the device is only used to test residents, employees or contractors of, or visitors to, the residential care or aged care facility, or clients, employees, or contractors of the home care service provider;
e. an organisation, business or institution that employs or engages a health practitioner within the meaning of the Therapeutic Goods Act 1989 or a paramedic, where:
i. the health practitioner or the paramedic is responsible for performing or supervising the performance of the test; and
ii. the person mentioned in subparagraph (i) and any other person acting under their supervision to perform the test have received training in the correct use of the device and the interpretation of the test result; and
iii. the device is only used to test employees, contractors or students of the organisation, business or institution.
f. a department of the Commonwealth, state or territory, with responsibility for health, or a department or other agency of the Commonwealth, state or territory acting on its behalf.

2. The device must not be supplied for the purpose of self-testing.

3. The sponsor of the device must provide training to a person mentioned in subparagraphs (1)(b)(ii), (1)(c)(ii), (1)(d)(ii) or (1)(e)(ii) in the correct use of the

device and the interpretation of the test result, prior to that person performing or supervising the performance of the test.

4. The sponsor must maintain records that demonstrate the device has been supplied in compliance with these conditions, including any kits supplied by distributors and on-sellers.

Post market surveillance report
5. The sponsor must provide a post market surveillance report, which includes the following information:
a. the numbers of tests supplied in Australia and overseas
b. any adverse events, reported problems, issues or complaints associated with the use or interpretation of the device, including numbers of any reported false positive or false negative results for tests supplied in Australia and overseas
c. for each type of problem, issue or complaint, provide the manufacturer's analysis of the issue and its risks, as well as any emerging trends.

6. The report is to be sent to the TGA (at the email address postmarketdevices@health.gov.au) for:
a. the period beginning on the day when this condition is imposed, and ending on the next 30 June
b. each of the next three financial years
c. before 1 October after that reporting period.

The following non-standard conditions apply to the self-testing device:

Customer support service
1. The sponsor must provide a telephone helpline or on-line interactive support service that
a. provides immediate customer support on an individualised basis in relation to the correct use of the device, and the interpretation of the test result, and any safety related information, and
b. operates between 9 am and 7 pm (AEST), or 9 am and 8 pm (AEDT), 7 days per week.

2. The sponsor must ensure that telephone helpline and on-line operators providing customer support services mentioned in condition 1
a. have received training in the correct use and performance of the device, and the interpretation of the test result, and
b. provide advice to users on how to contact relevant local state and territory health department support services, including phone lines and websites.

3. The sponsor must provide simple, clear and effective instructions, in video, pictorial or graphical form, in the correct use and performance of the device, and the interpretation of the test result, and any safety related information on the sponsor's website.

4. The sponsor must maintain records, and provide the records to the Secretary on request, that demonstrate that the device has been supplied in compliance with conditions 1 and 3 and has complied with condition 2.

Instructions for use
5. The sponsor must publish on the sponsor's website, and also provide to the Therapeutic Goods Administration (TGA) for publication on the TGA website any new version of the IFU released by the manufacturer, within 3 business days of the release.

Complaints
6. The sponsor must submit all complaints related to the use and performance of the device including, but not limited to, adverse events and reports of false positive and false negative results to the TGA
a. for the period beginning on the day this condition is imposed, and ending at the conclusion of the next five (5) financial years and
b. through the Medical Device Incident Reporting Scheme https://www.tga.gov.au/medical-device-incident-reporting-investigation-scheme-iris (IRIS) and
c. in accordance with the timeframes specified for providing information about adverse events etc, as specified in Regulation 5.7 of the Therapeutic Goods (Medical Devices) Regulations, 2002

Post market surveillance report
7. The sponsor must provide a post market surveillance report, which includes the following information:
a. the numbers of tests supplied in Australia and overseas
b. any adverse events, reported problems, issues or complaints associated with the use or interpretation of the device, including numbers of any reported false positive or false negative results for tests supplied in Australia and overseas
c. for each type of problem, issue or complaint, provide the manufacturer's analysis of the issue and its risks, as well as any emerging trends. Provide a list of decisions and actions taken, or that are in progress in relation to investigations and risk minimisation of the issue to users and the general public, including well-reasoned rationale if no action is being taken.

8. The report is to be sent to the TGA (at the email address postmarketdevices@health.gov.au) for:
a. the period beginning on the day when this condition is imposed and ending on the day at the end of that month for Australian data
b. each subsequent month up until 30 June 2023
c. on or before the last day of the following month
d. Overseas data is only required 6 monthly from the period beginning on the day when this condition is imposed.

9. The sponsor must provide a post market surveillance report, which includes the following information:
a. any adverse events, reported problems, issues or complaints associated with the use or interpretation of the device, including numbers of any reported false positive or false negative results, both in Australia and overseas
b. for each type of problem, issue or complaint reported in Australia, provide the manufacturer's analysis of the issue and its risks, as well as any emerging trends. Provide a list of decisions and actions taken, or that are in progress in relation to investigations and risk minimisation of the issue to users and the general public, including well-reasoned rationale if no action is being taken.

10. The report is to be sent to the TGA (at the email address postmarketdevices@health.gov.au) for:
a. the period beginning on the day when this condition is imposed, and ending on the next 30 June
b. each of the next three financial years
c. before 1 October after that reporting period.