Public Summary

Summary for ARTG Entry:	336146 Innovation Scientific Pty Ltd - Severe acute respiratory syndrome-associated coronavirus IVDs
ARTG entry for	Medical Device Included - IVD Class 3
Sponsor	Innovation Scientific Pty Ltd
Postal Address	11/87 Railway Road North, Mulgrave, NSW, 2756 Australia
ARTG Start Date	11/05/2020
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
Innovation Scientific Pty Ltd	11/87 Railway Road North Mulgrave, NSW, 2756 Australia

Products

1 . Severe acute respiratory syndrome-associated coronavirus IVDs

Product Type	IVD	**Effective Date**	28/10/2021
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 (whole blood, serum, plasma, nasal swabs, nasopharyngeal swabs and nasal wash/aspirate) and for self-testing by lay persons with or without symptoms (nasal swabs).		

Specific Conditions

The following conditions apply to COVID-19 serology point-of-care tests

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.

Within 12 months of approval for inclusion in the ARTG the sponsor must provide to the Therapeutic Goods Administration (TGA) updated documentation and information to demonstrate ongoing evidence of the compliance of the Device(s) with the requirements of Parts 1 and 2 of Schedule 1 - Essential Principles of the Therapeutic Goods (Medical Devices) Regulations 2002, including

2. A report of any adverse events, corrective and preventative actions, and customer complaints provided in the context of the number of devices supplied since the introduction of the Device(s) to market in Australia and Worldwide.

3. Information regarding any refusals by Regulatory Authorities for the supply of the Device(s) in any other regulatory jurisdictions.

4. Further analytical and clinical evidence to support
a. Analytical and clinical performance of the device,
b. Device stability (e.g., shelf-life stability, transport stability)

5. Instructions for use that provide updated information on the analytical and clinical performance characteristics of the device.

The following conditions apply to COVID-19 rapid antigen point-of-care tests

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) or 1(d)(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.

Within 12 months of approval for inclusion in the ARTG the sponsor must provide to the Therapeutic Goods Administration (TGA) updated documentation and information to demonstrate ongoing evidence of the compliance of the Device(s) with the requirements of Parts 1 and 2 of Schedule 1 - Essential Principles of the Therapeutic Goods (Medical Devices) Regulations 2002, including

5. A report of any adverse events, corrective and preventative actions, and customer complaints provided in the context of the number of devices supplied since the introduction of the Device(s) to market in Australia and Worldwide.

7. Further analytical and clinical evidence to support
a. Analytical and clinical performance of the device
b. Device stability (e.g. shelf-life stability, transport stability)

8. Instructions for use that provide updated information on the analytical and clinical performance characteristics of the device.

9. Within 6 months from the date of receiving this notice, the sponsor must provide a supplemental clinical study to the TGA, which shows the outcome of testing at least 30 clinical samples collected from individuals that are SARS-CoV-2 positive by RT-PCR for the delta variant.

The following conditions apply to COVID-19 self-tests

Customer support service
1. The sponsor must provide a telephone helpline or on-line interactive support service that
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
operates between 9 am and 7 pm (AEST), or 9 am and 8 pm (AEDT), 7 days per week.
(b) for a reporting period mentioned in paragraph (c) of condition 9Ðbefore 1 October after that reporting period.

2. The sponsor must ensure that telephone helpline and on-line operators providing customer support services mentioned in condition 1 have received training in the correct use and performance of the device, and the interpretation of the test result and provide advice to users on how to access laboratory PCR testing to confirm a positive test result and
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, on the sponsor's website.

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

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.

Clinical studies
6. Within 6 months of inclusion in the ARTG, the sponsor must provide a supplemental clinical study to the TGA, which shows the outcome of testing at least 30 clinical samples collected from individuals that are SARS-CoV-2 positive by RT-PCR for the delta variant.

Complaints
7. 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
for the period beginning on the day this condition is imposed, and ending at the conclusion of the next five (5) financial years and
through the Medical Device Incident Reporting Scheme httpswww.tga.gov.aumedical-device-incident-reporting-investigation-scheme-iris (IRIS) and
as soon as the complaints are received by the sponsor.

Post market surveillance report
8. The sponsor must provide a post market surveillance report, which includes the following information, to the TGA (at the email address postmarketdevices@health.gov.au) for each reporting period specified in condition 9
a. the numbers of tests sold both in Australia and overseas
b. any adverse events, including numbers of any reported false positive or false negative results, both in Australia and overseas
c. reported problems, issues or complaints associated with the use or interpretation of the device, both in Australia and overseas.

9. For the purposes of condition 8, each of the following is a reporting period
a. the period beginning on the day when this condition is imposed, and ending on the day at the end of that month
b. each subsequent month up until 30 June 2022
c. each of the next three financial years.

(10) The report mentioned in condition 8, must be given
(a) for a reporting period mentioned in paragraph (a) or (b) of condition 9 on or before the last day of the following month
(b) for a reporting period mentioned in paragraph (c) of condition 9 before 1 October after that reporting period.

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