Australian Government

Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Innovation Scientific Pty Ltd

for approval to supply

Severe acute respiratory syndrome-associated coronavirus IVDs

ARTG Identifier	336146
ARTG Start Date	11/05/2020
Product Category	Medical Device Included - IVD Class 3
GMDN	CT772
GMDN Term	Severe acute respiratory syndrome-associated coronavirus IVDs
Intended Purpose	The COVID-19 IgG/IgM Rapid Tests are intended to be used for the direct and qualitative detection of anti-SARS-CoV-2 IgM and anti-SARS-CoV-2 IgG in human blood, serum or plasma as an aid in the diagnosis of primary and secondary SARS-COV-2 infections. The test if for professional use only.

Manufacturer Details	Address	Certificate number(s)
Innovation Scientific Pty Ltd	5/25 Stoddart Road Prospect , NSW , 2148 Australia	DV-2016-MC-14633-1

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
InnoScreen COVID-19 Antigen Rapid Test Device	Point of care testing
COVID-19 IgG/IgM Rapid Test Device	Point of care testing

Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration
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