Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Product Category	Medical Device Included - IVD Class 3
GMDN	CT702
GMDN Term	Multiple-viruses IVDs
Intended Purpose	Intended for the detection of combination SARS-CoV-2, Influenza A&B, RSV, or ADV antigens in human nasal swab specimens from symptomatic individuals as an aid for diagnosis (Self-testing) or nasopharyngeal specimens from symptomatic individuals as an aid for diagnosis (Point-of-care testing)

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. Multiple-viruses IVDs

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

IVD Information

Name	Category Description
	Class 3 IVD medical device IVD medical device that is intended for self-testing
	IVD medical device that is intended for point of care testing IVD medical device that is intended for self-testing

Name	Category Description
	IVD medical device that is intended for self-testing
	IVD medical device that is intended for self-testing

Product Specific Conditions

- The following conditions are imposed on the supply of COVID-19 rapid antigen tests included in the Register:
- The following non-standard conditions apply to the point of care testing device:
  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; 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.
- The following non-standard conditions apply to the self-testing device:
- Customer support service
  1. The sponsor must provide 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), 5 days per week.
- 2. The sponsor must ensure that 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 any safety related information, 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 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. The new version of the IFU can be sent to the TGA at the email address IVDs@tga.gov.au.

Therapeutic Goods Administration
PO Box 100, Woden ACT 2606 Australia
Phone: 1800 020 653
Email: info@tga.gov.au

ARTG Start Date: 26/04/2023