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	CT772
GMDN Term	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 as an aid to diagnosis. For self-testing by lay persons (nasal swabs)

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

IVD Information

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

Product Specific Conditions

- 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.

- 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.
- 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.
- Instructions for Use (IFU)
  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.

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