Australian Government

Department of Health
Therapeutic Goods Administration

# Australian Register of Therapeutic Goods Certificate

for approval to supply

## Severe acute respiratory syndrome-associated coronavirus IVDs

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|---|---|
| **ARTG Identifier** | 382031 |
| **ARTG Start Date** | 6/01/2022 |
| **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 for self testing by lay persons (nasal swab). |

| Manufacturer Details | Address | Certificate number(s) |
|---|---|---|
| Acon Biotech (Hangzhou) Co Ltd | No 210 Zhenzhong Road<br>West Lake<br>District , Hangzhou ,<br>310030<br>China | DV-2021-MC-18357-1 |

### 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 |
|---|---|
| Flowflex SARS-CoV-2 Antigen Rapid Test (Self Testing) Remove this entry Self Testing | Self Testing |

### Product Specific Conditions

· 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
(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 access laboratory PCR testing to confirm a positive test result and
(c)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.
- 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)as soon as the complaints are received by the sponsor.
- Post market surveillance report
(7)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 8
(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.
- (8)For the purposes of condition 7, 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.
- (9)The report mentioned in condition 7, must be given
(a)for a reporting period mentioned in paragraph (a) or (b) of condition 8 on or before the last day of the following month
(b)for a reporting period mentioned in paragraph (c) of condition 8 before 1 October after that reporting period.

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