Public Summary

Summary for ARTG Entry:	345191 Suretest - Severe acute respiratory syndrome-associated coronavirus IVDs
ARTG entry for	Medical Device Included - IVD Class 3
Sponsor	Suretest
Postal Address	1291 Malvern Road, Malvern, Melbourne, VIC, 3144 Australia
ARTG Start Date	30/09/2020
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
Beijing Wantai Biologicalpharmacy Enterprise Co Ltd	31 Kexueyuan Road Changping District, Beijing, 102206 China

Products

1 . Severe acute respiratory syndrome-associated coronavirus IVDs

Product Type	IVD	**Effective Date**	29/11/2022 4:54:17 PM
GMDN	CT772 Severe acute respiratory syndrome-associated coronavirus IVDs		
Intended Purpose	IVDs for the detection of severe acute respiratory syndrome associated coronavirus (for example Covid-19) for use in laboratories and at the point of care.		

Specific Conditions

The following non-standard conditions apply to the point of care device:

The following conditions are imposed on the supply of COVID-19 rapid antigen tests included in the Register

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), (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.

Post market surveillance report
5. The sponsor must provide a post market surveillance report, which includes the following information:
a. the numbers of tests supplied in Australia and overseas
b. any adverse events, reported problems, issues or complaints associated with the use or interpretation of the device, including numbers of any reported false positive or false negative results for tests supplied in Australia and overseas
c. for each type of problem, issue or complaint, provide the manufacturer's analysis of the issue and its risks, as well as any emerging trends.

6. The report is to be sent to the TGA (at the email address postmarketdevices@health.gov.au) for:
a. the period beginning on the day when this condition is imposed, and ending on the next 30 June
b. each of the next three financial years
c. before 1 October after that reporting period.

The following non-standard conditions apply to the serology device:

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
b. medical practitioners who are registered under a law of a State or Territory
c. health care professionals in residential and aged care facilities;
d. Commonwealth, State or Territory department of health
e. An agency of the Commonwealth, State or Territory acting on behalf of Commonwealth, State or Territory department of health.