



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	333149	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	1/04/2020	
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	24/01/2023 1:11:01 PM
GMDN	CT772 Severe acute respiratory syndrome-associated coronavirus IVDs		
Intended Purpose	The device is a test kit intended for screening and aiding in the diagnosis of patients who are suspected to be infected with the SARS-CoV-2 virus.		

Specific Conditions

The following conditions apply to COVID-19 POCT serology tests

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

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