



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	333909	Stonestar Wholesale Pty Ltd - Severe acute respiratory syndrome-associated coronavirus IVDs
ARTG entry for	Medical Device Included - IVD Class 3	
Sponsor	Stonestar Wholesale Pty Ltd	
Postal Address	305 Boundary Road, Mordialloc, VIC, 3195 Australia	
ARTG Start Date	10/04/2020	
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
VivaChek Biotech (Hangzhou) Co Ltd	Level 2 Block 2 146 East Chaofeng Road Yuhang Economy Development Zone Hangzhou, Zhejiang, 311100 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 intended use of this lateral-flow immunoassay is for the Qualitative detection of anti COVID-19 IgG&IgM in blood. The intended users are healthcare professionals including professionals at point of care sites.		

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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