Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	334542 ALLSAFE MEDICAL PTY LTD - Severe acute respiratory syndrome-associated coronavirus IVDs
ARTG entry for	Medical Device Included - IVD Class 3
Sponsor	ALLSAFE MEDICAL PTY LTD
Postal Address	1/106 Oxford Street, Paddington, NSW, 2021 Australia
ARTG Start Date	18/04/2020
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
Guangzhou Wondfo Biotech Co Ltd	No 8 Lizhishan Road Science City Luogang District, Guangzhou, 510663 China

Products

1 . Severe acute respiratory syndrome-associated coronavirus IVDs

Product Type	IVD	**Effective Date**	20/03/2023 2:32:02 PM
GMDN	CT772 Severe acute respiratory syndrome-associated coronavirus IVDs		
Intended Purpose	Wondfo SARS-CoV-2 Antibody Test (Lateral Flow Method) is an immunochromatographic assay for rapid, qualitative detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) IgG/IgM antibody in human whole blood, serum or plasma sample. The test is to be used as an aid in the diagnosis of coronavirus infection disease (COVID-19), which is caused by SARS-CoV-2. The test provides preliminary test results. Negative results don't preclude SARS-CoV- 2 infection and they cannot be used as the sole basis for treatment or other management decision. For in vitro diagnostic use only. For professional use only.		

Specific Conditions

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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