



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	338589	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	29/06/2020	
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
SANSURE BIOTECH INC	No 680 Lusong Road Yuelu District Changsha People's Republic of China , China, 410205 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	Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing) is used for qualitative detection of the ORF1ab and N genes of novel coronavirus (2019-nCoV) in nasopharyngeal swab, oropharyngeal swab, alveolar lavage fluid, sputum, serum, whole blood and feces from suspected pneumonia cases with novel coronavirus infection, patients with suspected clusters of novel coronavirus infection, and other patients requiring diagnosis or differential diagnosis of novel coronavirus infection.		

Specific Conditions

- The person (the sponsor) in relation to whom the Device is included in the ARTG may only supply the Device to
 - laboratories that are accredited pathology laboratories and/or
 - medical practitioners who are registered under a law of a State or Territory and/or
 - health care professionals in residential and aged care facilities and/or
 - Commonwealth, State or Territory department of health and/or
 - an agency of the Commonwealth, State or Territory acting on behalf of Commonwealth, State or Territory department of health.

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