Public Summary

Summary for ARTG Entry:	335351 Southwind International Pty Ltd - Severe acute respiratory syndrome-associated coronavirus IVDs
ARTG entry for	Medical Device Included - IVD Class 3
Sponsor	Southwind International Pty Ltd
Postal Address	50 Coorie Crescent, Rosanna, VIC, 3084 Australia
ARTG Start Date	29/04/2020
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
Healgen Scientific Limited Liability Company	3818 Fuqua Street Houston, TX, 77047 United States Of America

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	COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is a solid phase immunochromatographic assay for the rapid, qualitative and differential detection of IgG and IgM antibodies to 2019 Novel Coronavirus in human whole blood, serum or plasma. This test provides only a preliminary test result. Therefore, any reactive specimen with the COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) must be confirmed with alternative testing method(s) and clinical findings.For professional In Vitro diagnostic use only. Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.		

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 ages 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.