Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	347730	Cartex Hoya Pty Ltd - Severe acute respiratory syndrome-associated coronavirus IVDs
ARTG entry for	Medical Device Included - IVD Class 3	
Sponsor	Cartex Hoya Pty Ltd	
Postal Address	Brookfield Place Level 11 125 St Georges Terrace, Perth, WA, 6000 Australia	
ARTG Start Date	9/11/2020	
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
Xiamen Biotime Biotechnology Co Ltd	3F/4F No 188 Pingcheng South Road Haicang Street Haicang District Xiamen, Fujian, 361026 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 Biotime SARS CoV-2 IgG/IgM Rapid Qualitative Test is intended to be used to qualify the presence of SARS CoV-2 IgG and IgM antibodies in human plasma, serum or whole blood by colloidal gold immunochromatography assay. The test can be used as an aid for detection of the SARS CoV-2 infection and is a useful screening tool to assist with challenges in identifying COVID-19 cases. This test is for In Vitro Diagnostic use only and for use by professionals only.		

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.

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