Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	343116 LJCJ Pty Ltd - Severe acute respiratory syndrome-associated coronavirus IVDs
ARTG entry for	Medical Device Included - IVD Class 3
Sponsor	LJCJ Pty Ltd
Postal Address	5 Borrell Street, Keilor, VIC, 3036 Australia
ARTG Start Date	7/09/2020
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
Zhongshan Chuangyi Biochemical Engineering Co Ltd	8 Kangtai Road National Health Technology Industry Base Torch High-tech Industrial Development Zone Zhongshan, Guangdong, 528437 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	This kit is used for in vitro qualitative detection of novel coronavirus (COVID-19) IgM / IgG antibodies in human serum, plasma, and whole blood samples. It is only used as a supplementary indicator for suspected cases negative for novel corona virus detection or used in conjunction with nucleic acid detection in the diagnosis of suspected cases. The test results can NOT be the only basis for diagnosis or exclusion of the coronavirus caused pneumonia. The detection kit is not applicable to general population screening.		

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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