



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	346951	Emergence Technology Pty Ltd - Severe acute respiratory syndrome-associated coronavirus IVDs
ARTG entry for	Medical Device Included - IVD Class 3	
Sponsor	Emergence Technology Pty Ltd	
Postal Address	PO Box 420, Brunswick, VIC, 3056 Australia	
ARTG Start Date	2/11/2020	
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
Ustar Biotechnologies (Hangzhou) Ltd	Room 801-808 3766 Nanhuan Road Fl 8 Binjiang Dist Hangzhou, Zhejiang, 310053 China

Products

1 . Severe acute respiratory syndrome-associated coronavirus IVDs

Product Type	IVD	Effective Date	18/01/2023 5:10:23 PM
GMDN	CT772 Severe acute respiratory syndrome-associated coronavirus IVDs		
Intended Purpose	This product is a diagnostic kit for Novel-Coronavirus (2019-nCoV) RNA (Isothermal Amplification-Real Time Fluorescence Assay). This product is intended to be used in testing to provide information about infection with Severe acute respiratory syndrome-associated coronavirus (SARSCoV).		

Specific Conditions

No Specific Conditions included on Record

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