Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	335074	Abbott Australasia Pty Ltd Molecular Division - Severe acute respiratory syndrome-associated coronavirus IVDs

ARTG entry for	Medical Device Included - IVD Class 3
Sponsor	Abbott Australasia Pty Ltd Molecular Division
Postal Address	Locked Bag 2005, North Ryde, NSW, 1670 Australia
ARTG Start Date	24/04/2020
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
Abbott Molecular Inc	1300 East Touhy Avenue Des Plaines, Illinois, 60018 United States Of America

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	The Abbott SARS-CoV-2 assay is a real-time (rt) reverse transcriptase (RT) polymerase chain reaction (PCR) test intended for the qualitative detection of nucleic acid from the SARS-CoV-2 in nasopharyngeal (NP) and oropharyngeal (OP) swabs collected by a healthcare provider, from patients who are suspected of COVID-19 infection.		

Specific Conditions

No Specific Conditions included on Record

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The onus is on the reader to verify the current accuracy of the information on the document subsequent to the date shown.

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