Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Product Category	Medical Device Included - IVD Class 3
GMDN	CT702
GMDN Term	Multiple-viruses IVDs
Intended Purpose	This kit is intended for in vitro qualitative detection of SARS-CoV-2, influenza A and influenza B nucleic acid of the oropharyngeal swab samples which of the people who were suspected infection of SARS-CoV-2, influenza A and influenza B. It also can be used in suspected pneumonia and suspected cluster cases and for qualitative detection and identify of SARS-CoV-2, influenza A and influenza B nucleic acid in oropharyngeal swab samples of novel Coronavirus infection in other circumstances.

ARTG Standard Conditions

The above Medical Device Included - IVD Class 3 has been entered on the Register subject to the following 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.

Products Covered by This Entry

1. Multiple-viruses IVDs

This entry: contains System(s)/Procedure Pack(s)

Product Specific Conditions

No specific conditions have been recorded against this entry.

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ARTG Start Date: 20/09/2023