Australian Government

Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

MD Solutions Australasia Pty Ltd

for approval to supply

Severe acute respiratory syndrome-associated coronavirus IVDs

ARTG Identifier	332961
ARTG Start Date	31/03/2020
Product Category	Medical Device Included - IVD Class 3
GMDN	CT772
GMDN Term	Severe acute respiratory syndrome-associated coronavirus IVDs
Intended Purpose	The OnSite/Aria COVID-19 IgG/IgM Rapid Test is a lateral flow immunoassay for the detection of anti-SARS-CoV-2 IgG and IgM antibodies in human serum, plasma or whole blood. It is intended to be used by healthcare professionals as an aid in the diagnosis of infection with SARS-CoV-2 coronavirus, which causes COVID-19 disease. Any interpretation or use of this preliminary test result must also rely on other clinical findings as well as on the professional judgment of healthcare providers. Alternative test method(s) should be considered to confirm the test result obtained by this device.

Manufacturer Details	Address	Certificate number(s)
CTK Biotech Inc	13855 Stowe Drive Poway , California , 92064 United States Of America	DV-2020-MC-03953-1

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. Severe acute respiratory syndrome-associated coronavirus IVDs

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

IVD Information

Name	Category Description
OnSite COVID-19 Ag Rapid Test	Point of care testing
Aria COVID-19 IgG/IgM Rapid Test	Point of care testing
Aria COVID-19	Point of care testing

Name	Category Description
Ag Rapid Test	
OnSite COVID-19 IgG/IgM Rapid Test	Point of care testing

Product Specific Conditions

No specific conditions have been recorded against this entry.

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