Australian Government

Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	335082 MD Solutions Australasia Pty Ltd - Severe acute respiratory syndrome-associated coronavirus IVDs
ARTG entry for	Medical Device Included - IVD Class 3
Sponsor	MD Solutions Australasia Pty Ltd
Postal Address	Unit 1/16-18 Tennyson Street, WILLIAMSTOWN NORTH, VIC, 3016 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
CTK Biotech Inc	13855 Stowe Drive Poway, California, 92064 United States Of America

Products

1 . Severe acute respiratory syndrome-associated coronavirus IVDs

Product Type	IVD	**Effective Date**	24/04/2020
GMDN	CT772 Severe acute respiratory syndrome-associated coronavirus IVDs		
Intended Purpose	A COVID-19 Real-Time PCR Test is designed for specific and qualitative detection of the novel coronavirus SARS-CoV-2, responsible for COVID-19, in oropharyngeal swabs, nasopharyngeal swabs or sputum specimens as an aid in the diagnosis of COVID-19 infections, alongside all available clinical and epidemiological data, patient history, and other laboratory test outcomes.		

Specific Conditions

Within 12 months of an approval the following information will be required to be provided to the TGA: 1. A report of any adverse events, corrective and preventative actions, and customer complaints provided in the context of the number of devices supplied since the introduction of the Device(s) to market in Australia and Worldwide. 2. Information regarding any refusals by Regulatory Authorities for the supply of the Device(s) in any other regulatory jurisdictions. 3. Further analytical and clinical evidence to support a. Analytical and clinical performance of the device b. Device stability (e.g, shelf-life stability, transport stability) 4. Instructions for use that provide updated information on the analytical and clinical performance characteristics of the device.