Australian Government

Department of Health

Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Roche Diagnostics Australia Pty Limited

for approval to supply

Severe acute respiratory syndrome-associated coronavirus IVDs

ARTG Identifier	352250
ARTG Start Date	24/12/2020
Product Category	Medical Device Included - IVD Class 3
GMDN	CT772
GMDN Term	Severe acute respiratory syndrome-associated coronavirus IVDs
Intended Purpose	IVDs that are intended to be used in testing to provide information about infection with or exposure to Severe acute respiratory syndrome-associated coronavirus (SARS-CoV)

Manufacturer Details	Address	Certificate number(s)
SD Biosensor Inc	C-4th & 5th 16 Deogyeong-daero 1556beon-gil Yeongtong-gu Suwon-si , Gyeonggi-do , 16690 Korea - Republic of	DV-2020-MC-28479-1

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: does not contain System(s)/Procedure Pack(s)

IVD Information

Name	Category Description
SARS-CoV-2 Antigen Control	Point of care testing
SARS-COV-2 Rapid Antigen Test	Point of care testing

Product Specific Conditions

- 1. The person (the sponsor) in relation to whom the Device is included in the ARTG may only supply the Device to
  a. laboratories that are accredited pathology laboratories and/or
  b. medical practitioners who are registered under a law of a State or Territory and/or
  c. health care professionals in residential and aged care facilities and/or
  d. Commonwealth, State or Territory department of health and/or
  e. an agency of the Commonwealth, State or Territory acting on behalf of Commonwealth, State or

Territory department of health.

- 2. 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.
- 3. Information regarding any refusals by Regulatory Authorities for the supply of the Device(s) in any other regulatory jurisdictions.
- 4. 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)
- 5. Instructions for use that provide updated information on the analytical and clinical performance characteristics of the device.
- And within 12 months of an approval the following information will be required to be provided to the TGA.

Therapeutic Goods Administration
PO Box 100, Woden ACT 2606 Australia
Phone: 1800 020 653
Email: info@tga.gov.au

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