Australian Government
Department of Health
Therapeutic Goods Administration

TRIM Reference: E20-50964
(D20-524636)

Notice under sections 41FI, 41FJ and 41FO of the *Therapeutic Goods Act 1989* of decision to include the kind of device in the ARTG and impose conditions

Device Application / Submission ID:	DV-2020-IVA-05403-1/ DA-2020-02455-1
GMDN[1]:	Severe acute respiratory syndrome-associated coronavirus IVDs [CT772]
Sponsor's Reference:	Covid-19 Rapid Testing Kit - Hangzhou Realy Tech Co Ltd
Device Name:	2019-nCOV/COVID-19 IgG/IgM Rapid Test Device
ARTG Entry:	To be confirmed, see next steps below

As a delegate of the Secretary of the Department of Health (the Secretary) for the purposes of section 41FI of the *Therapeutic Goods Act 1989* (the Act), I have made a decision to include the kind of medical device 2019-nCOV/COVID-19 IgG/IgM Rapid Test Device (GMDN: Severe acute respiratory syndrome-associated coronavirus IVDs [CT772]) Class 3 (the Device) in the Australian Register of Therapeutic Goods (ARTG)[2].

Further, as a delegate of the Secretary for the purposes of section 41FO of the Act, I have decided to impose conditions on the inclusion of the Device in the ARTG.

The *conditions* imposed on the Device are that:

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

[1] Information as stated in the application
[2] An automatic email should have been already sent to you informing you of the decision to include the Device in the ARTG

e. an agency of the Commonwealth, State or Territory acting on behalf of Commonwealth, State or Territory department of health.

Within 12 months of approval for inclusion in the ARTG the sponsor must provide to the Therapeutic Goods Administration (TGA) updated documentation and information to demonstrate ongoing evidence of the compliance of the Device(s) with the requirements of Parts 1 and 2 of Schedule 1 - Essential Principles of the Therapeutic Goods (Medical Devices) Regulations 2002, including:

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.
6. Evidence of how the user may verify, at the time of use that the device will perform as intended by the manufacturer through the use of controls.

This post-market information must be sent to the TGA at the following email address: postmarketdevices@health.gov.au.

Note: These conditions imposed on the kind of device are in addition to any other conditions imposed on the ARTG entry and conditions applying automatically under the *Therapeutic Goods Act 1989* and *Therapeutic Goods (Medical Devices) Regulations 2002*.

The imposition of the condition takes effect when the Device is included in the ARTG.

Reasons for the decision[3]

COVID-19/SARS-CoV-2 is an emerging viral infectious disease. There is limited information available regarding the disease profile and the ability of available tests to accurately detect SARS-CoV-2 infections. This IVD medical device has been included in the Register based on the initial analytical and clinical performance data available at the time of inclusion of the device. It is expected that the manufacturer will be undertaking further validation studies to support the intended use of the device.

The correct interpretation of test results in conjunction with the clinical presentation of a patient is critical to informing patient management and minimisation of further transmission of the virus. Accurate identification of a COVID-19 infection based on serology results, particularly those obtained from rapid tests used at the point of care, requires an understanding of the antibody response profile. There is a window period between virus infection and the production of IgM and IgG antibodies, and the sensitivity and specificity of IgM/IgG antibody tests early in SARS-CoV-2 infection, is as yet, not well characterised. The misinterpretation of serology results in the point-of-care setting if testing is not performed by suitably qualified persons with appropriate skills and knowledge presents grave risk to public health, which could result in serious illness and death of the patient and other persons that the patient comes into contact with.

[3] The statement of reasons will only relate to my decision to impose condition on the inclusion of the Device in the ARTG under section 41FO of the Act

Transmission-based precautions must also be used when collecting specimens from patients with a communicable disease. Blood specimens collected for point-of-care testing should be regarded as potentially infectious not just for SARS-CoV-2, but also for other blood-borne infectious diseases. Staff must be trained in appropriate specimen collection and infection control procedure.

The conditions also allow for supply of the Device to the Government for the purpose of the national stockpile. The Government maintains control of the stockpile and is responsible for ensuring that devices to test for COVID-19 that are included in the stockpile are provided to suitably qualified persons with appropriate skills and knowledge.

Therefore, I am of the view that imposing non-standard conditions on the ARTG entry is necessary to ensure ongoing compliance of the Device with the essential principles.

The abovementioned condition has been imposed in accordance with paragraphs 41FO(2)(c), (d) and (e) (condition to keep records relating to devices of that kind, including records relating to the tracking and location of devices of that kind after their supply; matters dealt with in, or matters additional to matters dealt with in, the essential principles; and other matters relating to devices of that kind as the Secretary thinks appropriate).

Important

The conditions imposed on the Device under this Notice are in addition to any other conditions imposed on the ARTG inclusion and conditions applying automatically under the Act and Regulations[4]. The inclusion of the Device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry.

Breaching conditions of the inclusion related to the Device may lead to suspension or cancellation of the ARTG entry[5]; may be a criminal offence[6]; and civil penalties may apply[7].

You may download and print the ARTG Certificate by logging into the TGA Business Services website <https://www.tga.gov.au/tga-business-services> when the Certificate becomes available. The TGA will not be sending you a hard-copy of this certificate.

Related evidence

In making this decision I have reviewed the following:

- Information provided in and with the application DV-2020-IVA-05403-1 (received by the TGA 25 March 2020), including:
    - Conformity assessment certificate – ISO 13485:2016 (certificate number Q5 094846 0002 Rev.01, expiry 23 January 2023).
    - Declaration of conformity made in accordance with Clause 1.8 of Schedule 3 of the Regulations by the manufacturer on 28 March 2020 for the 2019-nCOV IgG/IgM Rapid Test Device.
    - Supporting documentation
- Information provided to the TGA on 29 March 2020, 1 April 2020, 2 April 2020, 7 April 2020 and 14 April 2020.

Relevant legislation

An effective application for a kind of medical device[8] must be made prior to the device being included in the ARTG.

Under section 41FD of the Act an applicant for inclusion of a kind of device in the ARTG must certify certain matters, including that:

[4] Section 41FN of the Act (Conditions applying automatically) and Division 5.2 (Conditions) of the Regulations
[5] Part 4-6 *Suspension and cancellation from the Register* of Chapter 4 *Medical devices* of the Act
[6] Section 41MN of the Act
[7] Section 41MNA of the Act
[8] The definition of "a kind of medical device" is set out in section 41BE of the Act. Effective application is the application that is made in accordance with section 41FC of the Act

(d) devices of that kind comply with the essential principles; and
(e) the applicant has sufficient information to substantiate compliance with the essential principles, or has procedures in place, including a written agreement with the manufacturer, to ensure that such information can be obtained within the period specified in the regulations;
(f) an appropriate conformity assessment procedure has been applied to devices of that kind, or requirements, comparable to the conformity assessment procedures, have been applied to devices of that kind; and
(g) the applicant has available sufficient information to substantiate application of those procedures (conformity assessment procedures, or requirements comparable to the conformity assessment procedures), or has procedures in place, including a written agreement with the manufacturer to ensure that such information can be obtained within the period specified in the regulations.

Paragraph 41FH(1)(a) of the Act and Regulation 5.3 of the Regulations stipulate that the applications for ARTG inclusion of some medical devices must be selected for audit. In accordance with sub regulation 5.3(1)(j)(iii) an IVD medical device that is intended for point of care testing must be selected for audit.

Section 41FI of the Act provides that in auditing the application, the Secretary may consider all or some aspects of one or both of the following matters:

- whether an application for inclusion of a medical device in the ARTG is made in accordance with Subdivision A of the Act[9]; and
- whether the matters to which an applicant has certified under section 41FD are correct.

In accordance with subsection 41FI(2) the Secretary must decide to include the kind of device to which the application relates in the ARTG if the Secretary is satisfied as to all aspects considered in the audit.

Under subsection 41FO(1) of the Act if the Secretary includes a kind of medical device in the ARTG in relation to a person, the Secretary may, in writing, impose conditions on that ARTG inclusion.

Subsection 41FO(2) of the Act provides that the conditions may relate to:

a) manufacture of devices of that kind; or
b) custody, intended purpose, supply, disposal or destruction of devices of that kind; or
c) keeping of records relating to devices of that kind, including records relating to the tracking and location of devices of that kind after their supply; or
d) matters dealt with in, or matters additional to matters dealt with in, the essential principles; or
e) such other matters relating to devices of that kind as the Secretary thinks appropriate.

For further information on the legislation relevant to these decisions refer:

- *Therapeutic Goods Act 1989* (https://www.legislation.gov.au/Series/C2004A03952);
- *Therapeutic Goods (Medical Devices) Regulations 2002* (https://www.legislation.gov.au/Series/F2002B00237).

The next steps

Although the device is approved for inclusion in the ARTG it will take some additional time for the administrative process to finalise and generate and ARTG entry and number. To ensure this process can be completed as soon as possible please finalise payment of any outstanding invoices.

[9] Subdivision A (Applications) of Division 1, Part 4-5, Chapter 4 of the *Therapeutic Goods Act 1989*

The continued inclusion of the Device on the ARTG is subject to payment of annual charges.

Ongoing monitoring of quality, safety and performance
Medical devices included in the ARTG are subject to ongoing monitoring of their quality, safety and performance. At any time, the ARTG entry for the Device may be selected for a review to verify compliance of the Device with the regulatory requirements.

Sponsors' ongoing regulatory responsibilities
Australian sponsors of medical devices have ongoing regulatory responsibilities for the medical devices they supply to the Australian market. It is important that you read the information provided in the attached document on sponsor obligations and responsibilities to ensure you are able to demonstrate ongoing compliance with the legislation.

For further information refer the Australian Regulatory Guidelines for Medical Devices (ARGMD) that is available on the TGA website:
http://www.tga.gov.au/industry/devicesargmd.htm.

Review of the decision
Should you wish to seek a review of my decision to include the Device in the ARTG and to impose condition on the ARTG entry, your rights of review are outlined in Attachment A to this letter.

Yours sincerely,

Signed and authorised by
Michelle McNiven

Delegate of the Secretary for the purposes of sections 41FI, 41FJ and 41FO of the Act
Medical Devices Branch
16 April 2020

Attachment A

Request for reconsideration of an initial decision
This decision is a reviewable initial decision under section 60 of the Act. Under section 60, a person whose interests are affected by a 'reviewable' initial decision, can seek reconsideration of the initial decision.

As this document constitutes written notice of the making of an initial decision being given by the Secretary, a request for reconsideration of this initial decision must be given to the Minister within 90 days and be accompanied by any information that you wish to have considered. A request for reconsideration given to the Minister outside the statutory 90 day reconsideration period cannot be accepted.

The Minister may either personally undertake a request for reconsideration of an initial decision or delegate to an officer of the Department with the appropriate delegation.

Under section 60(3A) of the Act, the Minister (or the Minister's delegate) is not able to consider any information provided after the notification is made of a request for reconsideration of an initial decision unless the information is provided in response to a request from the Minister (or the Minister's delegate), or it is information that indicates that the quality, safety or efficacy of the relevant therapeutic goods is unacceptable.

Guidelines for requesting reconsideration of an initial decision
A request for reconsideration should be made in writing, signed and dated by the person requesting reconsideration, should be titled **"<insert person/company name> - Request for Reconsideration Under Section 60 of the *Therapeutic Goods Act 1989***" and should include the following:

- a copy of the initial decision notification letter (or other evidence of notification);
- identify, and describe with as much specificity as possible, which component(s) of the initial decision should be reconsidered and set out the reasons why reconsideration is requested;
- any information/documentation in support of the request, clearly labelled to correspond with (any or each of) the reasons why reconsideration is requested; and
- an email address nominated for the purposes of receiving correspondence in relation to the request for reconsideration.

All requests for reconsideration should be given to the Minister by email:
Email: '**minister.hunt.DLO@health.gov.au**' and copied to '**decision.review@health.gov.au**'

Requests for reconsideration that include dossiers (or similar bulk material) that cannot easily be attached to the request given first by email, may then be submitted on a USB drive or CD sent by express post or registered mail to:
Mail: **Minister for Health**
Suite M1 40
c/- Parliament House
CANBERRA ACT 2600

Subject to the *Administrative Appeals Tribunal Act 1975* (AAT Act), if you are dissatisfied with the decision upon reconsideration by the Minister (or the Minister's delegate), you can apply to the Administrative Appeals Tribunal (AAT) for a review of that decision upon reconsideration.

NOTE: This initial decision remains in effect unless and until it is revoked or revoked and substituted by the Minister (or the Minister's delegate) as a result of a request for reconsideration under section 60 of the Act OR is set aside, varied or remitted by the AAT or is otherwise overturned or stayed.