Australian Government
Department of Health
Therapeutic Goods Administration

TRIM Reference: E20-44564
(D20-384227)

Email: [redacted]

Attention: [redacted]

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-03963-1/DA-2020-01712-1
GMDN[1]:	Severe acute respiratory syndrome-associated coronavirus IVDs [CT772]
Sponsor's reference:	VivaChek3
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 VivaChek3 (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:
The sponsor must provide to the Therapeutic Goods Administration (TGA) updated documentation and information to demonstrate 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* (the Regulations). This evidence must be provided to the TGA no later than 12 months after the date of inclusion in the Register and must include the following:

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:

[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