Australian Government
Department of Health
Therapeutic Goods Administration

Emergence Technology Pty Ltd
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BRUNSWICK VIC 3056

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Attention: Andrew Lloyd

**Notice under section 9D of the *Therapeutic Goods Act 1989* of decision to vary ARTG inclusions for medical devices**

| ARTG | GMDN Code and Term | Class |
|---|---|---|
| 372335 | Severe acute respiratory syndrome-associated coronavirus IVDs [CT772] | Class 3 |

As a delegate of the Secretary of the Department of Health (the Secretary) for the purposes of section 9D of the *Therapeutic Goods Act 1989* (the Act), I have decided to vary the Australian Register of Therapeutic Goods (ARTG) under subsection 9D(3D) of the Act following your request. I have made this decision on the basis that the information provided for this variation does not indicate any reduction in the quality, safety or performance of the kind of medical devices for the purposes for which these devices are intended to be used.

Therefore, as requested, I have added the following IVD medical devices to those supplied under ARTG 372335:

- Ecotest COVID-19 Antigen Nasal Test Kit
- Ecotest COVID-19 Antigen Saliva Test kit (COV-S35Pen)

And amended the intended purpose to:
*Intended to detect the novel coronavirus SARS-CoV-2 that causes COVID-19 from symptomatic individuals at the point of care by trained health professionals (nasal swabs and saliva) and for self-testing by lay persons (saliva).*

Yours sincerely

Signed and authorised by

***Rodielyn Brown***
Delegate of the Secretary for the purposes of section41FP and 9D of the Act
Medical Devices Authorisation Branch
22 October 2021