Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	408459 Touch Biotechnology Pty Ltd - Multiple-viruses IVDs
ARTG entry for	Medical Device Included - IVD Class 3
Sponsor	Touch Biotechnology Pty Ltd
Postal Address	119 Willoughby Road, Crows Nest, NSW, 2065 Australia
ARTG Start Date	4/05/2023
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
Vitrosens Biyoteknoloji LTD STI	Serifali Mah Sht Sk No 17/1 Umraniye, Istanbul, Turkey

Products

1 . Multiple-viruses IVDs

Product Type	IVD	**Effective Date**	4/05/2023
GMDN	CT702 Multiple-viruses IVDs		
Intended Purpose	Intended to detect Respiratory syncytial virus, Influenza A/B and the novel coronavirus SARS-CoV-2 from symptomatic individuals for self-testing by lay persons (nasal swab).		

Specific Conditions

The following non-standard conditions apply to the self-testing device:

Customer support service
1. The sponsor must provide a telephone helpline or on-line interactive support service that
a. provides immediate customer support on an individualised basis in relation to the correct use of the device, and the interpretation of the test result, and any safety related information, and
b. operates between 9 am and 7 pm (AEST), or 9 am and 8 pm (AEDT), 7 days per week.

2. The sponsor must ensure that telephone helpline and on-line operators providing customer support services mentioned in condition 1
a. have received training in the correct use and performance of the device, and the interpretation of the test result, and
b. provide advice to users on how to contact relevant local state and territory health department support services, including phone lines and websites.

3. The sponsor must provide simple, clear and effective instructions, in video, pictorial or graphical form, in the correct use and performance of the device, and the interpretation of the test result, and any safety related information on the sponsor's website.

4. The sponsor must maintain records, and provide the records to the Secretary on request, that demonstrate that the device has been supplied in compliance with conditions 1 and 3 and has complied with condition 2.

Instructions for use
5. The sponsor must publish on the sponsor's website, and also provide to the Therapeutic Goods Administration (TGA) for publication on the TGA website any new version of the IFU released by the manufacturer, within 3 business days of the release.

Complaints
6. The sponsor must submit all complaints related to the use and performance of the device including, but not limited to, adverse events and reports of false positive and false negative results to the TGA
a. for the period beginning on the day this condition is imposed, and ending at the conclusion of the next five (5) financial years and
b. through the Medical Device Incident Reporting Scheme https://www.tga.gov.au/medical-device-incident-reporting-investigation-scheme-iris (IRIS) and
c. in accordance with the timeframes specified for providing information about adverse events etc, as specified in Regulation 5.7 of the Therapeutic Goods (Medical Devices) Regulations, 2002

Post market surveillance report
7. The sponsor must provide a post market surveillance report, which includes the following information:
a. the numbers of tests supplied in Australia and overseas
b. any adverse events, reported problems, issues or complaints associated with the use or interpretation of the device, including numbers of any reported false positive or false negative results for tests supplied in Australia and overseas
c. for each type of problem, issue or complaint, provide the manufacturer's analysis of the issue and its risks, as well as any emerging trends. Provide a list of decisions and actions taken, or that are in progress in relation to investigations and risk minimisation of the issue to users and the general public, including well-reasoned rationale if no action is being taken.

8. The report is to be sent to the TGA (at the email address postmarketdevices@health.gov.au) for:
a. the period beginning on the day when this condition is imposed and ending on the day at the end of that month for Australian data
b. each subsequent month up until 30 June 2023
c. on or before the last day of the following month
d. Overseas data is only required 6 monthly from the period beginning on the day when this condition is imposed.

9. The sponsor must provide a post market surveillance report, which includes the following information:
a. any adverse events, reported problems, issues or complaints associated with the use or interpretation of the device, including numbers of any reported false positive or false negative results, both in Australia and overseas
b. for each type of problem, issue or complaint reported in Australia, provide the manufacturer's analysis of the issue and its risks, as well as any emerging trends. Provide a list of decisions and actions taken, or that are in progress in relation to investigations and risk minimisation of the issue to users and the general public, including well-reasoned rationale if no action is being taken.

10. The report is to be sent to the TGA (at the email address postmarketdevices@health.gov.au) for:
a. the period beginning on the day when this condition is imposed, and ending on the next 30 June
b. each of the next three financial years.
c. before 1 October after that reporting period