Public Summary

Summary for ARTG Entry:	406813 HA TECH PTY LTD - Multiple-viruses IVDs
ARTG entry for	Medical Device Included - IVD Class 3
Sponsor	HA TECH PTY LTD
Postal Address	2/3 Packard Avenue, Castle Hill, NSW, 2154 Australia
ARTG Start Date	24/03/2023
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
HA TECH PTY LTD	2/3 Packard Avenue Castle Hill, NSW, 2154 Australia

Products

1 . Multiple-viruses IVDs

Product Type	IVD	**Effective Date**	4/03/2024 3:57:48 PM
GMDN	CT702 Multiple-viruses IVDs		
Intended Purpose	Intended to detect Influenza A/B, RSV 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 any safety related information, 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, 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 that it has complied with condition 2, and provide the records to the Secretary on request.

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. The new version of the IFU is to be sent to the TGA at the email address COVIDtests@tga.gov.au.

Post market surveillance report
6. The sponsor must provide a post market surveillance report, which includes the following information:
a. The number 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, both in Australia and overseas.
c. 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.

7. The report is to be sent to the TGA (at the email address medicaldevicesurveillance@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

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