Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	427686 Australia Health Products Central Pty Ltd - Multiple-viruses IVDs
ARTG entry for	Medical Device Included - IVD Class 3
Sponsor	Australia Health Products Central Pty Ltd
Postal Address	PO Box 1090, Burwood North, NSW, 2134 Australia
ARTG Start Date	10/11/2023
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
Hangzhou Fanttest Biotech Co Ltd	Room 201 Building 1 No 37-3 Futang Road Tangqi Town Linping District Hangzhou City, Zhejiang Province, China

Products

1 . Multiple-viruses IVDs

Product Type	IVD	**Effective Date**	25/11/2024 4:08:26 PM
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

For Self Tests

1. The sponsor must provide 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), 5 days per week.

2.The sponsor must ensure that 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, and any safety related information on the sponsor's website.

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.

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. To be submitted to ivds@health.gov.au