



Australian Government

Department of Health, Disability and Ageing
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:		524625	Tempo Australia Pty Ltd - Multichannel electrocardiograph, interpretive, home-use
ARTG entry for	Medical Device Included Class IIa		
Sponsor	Tempo Australia Pty Ltd		
Postal Address	Level 15/177 Pacific Hwy, North Sydney, NSW, 2060 Australia		
ARTG Start Date	18/03/2026		
Product Category	Medical Device Class IIa		
Status	Active		
Approval Area	Medical Devices		

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	Location Id
Contec Medical Systems Co Ltd	No 112 Qinhuang West Street Economic & Technical Development Zone Qinhuangdao, Hebei Province, 066004 China	88891

Products

1. Multichannel electrocardiograph, interpretive, home-use

Product Type	Single Device Product	Effective Date	18/03/2026
GMDN	62641 Multichannel electrocardiograph, interpretive, home-use		
Intended Purpose	This device is a portable ECG used to monitor and record the user's ECG waveform and HR. After connected with a computer, users can print their ECG waveform, providing data reference for doctors.		

Specific Conditions

No Specific Conditions included on Record

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