



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

**Summary for ARTG Entry:** 421430 Compliance Management Solutions - Cardiac electrophysiology application software

**ARTG entry for** Medical Device Included Class IIa  
**Sponsor** Compliance Management Solutions  
**Postal Address** 3/85 Curzon Street, North Melbourne, VIC, 3051  
Australia  
**ARTG Start Date** 7/09/2023  
**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
Biofourmis Singapore Pte Ltd	2 Venture Drive Vision Exchange , Singapore, #23-01 Singapore

### Products

#### 1 . Cardiac electrophysiology application software

Product Type	Single Device Product	Effective Date	7/09/2023
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**GMDN** 47699 Cardiac electrophysiology application software

**Intended Purpose** RhythmAnalytics (RA) is a software application for the assessment of cardiac arrhythmias using single-lead ECG data in subjects over 18 years of age. It is intended for use by a healthcare solution integrator to build web or mobile applications to let qualified healthcare professionals review and confirm the analytic result. It can also be electronically interfaced, and perform analysis with data transferred from other computer based ECG systems. RA provides ECG signal processing and analysis, QRS and VEB detection, QRS feature extraction, interval measurement, heart rate measurement, and rhythm analysis. RA is not for use in life supporting or sustaining systems or ECG monitor and Alarm devices. Its interpretation results are not intended to be the sole means of diagnosis. RA is offered to physicians and clinicians on an advisory basis only in conjunction with the physician's knowledge of ECG patterns, patient background, clinical history, symptoms, and other diagnostic information.

### Specific Conditions

No Specific Conditions included on Record

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