



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	370493	Braco Compliance Pty Ltd - Cardiac electrophysiology application software
ARTG entry for	Medical Device Included Class IIa	
Sponsor	Braco Compliance Pty Ltd	
Postal Address	Unit 308, 469-481 High St Northcote, Melbourne, VIC, 3070 Australia	
ARTG Start Date	2/07/2021	
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
Fitbit Inc	199 Fremont Street 14th Floor San Francisco, CA, 94105 United States Of America

Products

1 . Cardiac electrophysiology application software

Product Type	Single Device Product	Effective Date	2/07/2021
GMDN	47699 Cardiac electrophysiology application software		
Intended Purpose	The Fitbit ECG App is a software-only medical device used as a spot check to create, record, display, store and analyze an ECG. The Fitbit ECG App (working name: ECG Spot Check) consists of a Device application ("Device app") integrated on a consumer Fitbit wrist-worn product and a mobile application tile ("mobile app") on Fitbit's consumer mobile application. The Device app uses data from non-medical grade electrical sensors on a consumer Fitbit wrist-worn product to create and record an ECG. The algorithm on the Device app analyzes a 30-second recording of the ECG and provides results to the user. Users are able to view their past results as well as a pdf report of the waveform similar to a Lead I ECG on the mobile app. Intended Purpose: The Fitbit ECG App is intended to allow the user to record a waveform similar to a single lead ECG that is then classified as sinus rhythm or atrial fibrillation (AF) on a classifiable waveform. The ECG and rhythm classification is not recommended for users with other known arrhythmias. The Fitbit ECG App is intended for home use by lay people aged 22 years and over.		

Specific Conditions

No Specific Conditions included on Record

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary