Therapeutic Goods (Restricted Representations—Medical Devices with Irregular Heartbeat Notifications) Permission 2021

I, Nicole McLay, as delegate of the Secretary of the Department of Health, make the following permission.

Dated 19 May 2021

Nicole McLay
Assistant Secretary
Regulatory Compliance Branch
Health Products Regulation Group
Department of Health

Contents

1 Name

This instrument is the *Therapeutic Goods (Restricted Representations—Medical Devices with Irregular Heartbeat Notifications) Permission 2021*.

2 Commencement

(1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information

Column 1	Column 2	Column 3
Provisions	**Commencement**	**Date/Details**
1. The whole of this instrument	The day after this instrument is made.	20 May 2021

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

(2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under section 42DK of the *Therapeutic Goods Act 1989*.

4 Definitions

Note: A number of expressions used in this instrument are defined in subsection 3(1) of the Act, including the following:
(a) advertise;
(b) included in the Register;
(c) label;
(d) medical device;
(e) therapeutic goods;
(f) Therapeutic Goods Advertising Code.

In this instrument:

Act means *Therapeutic Goods Act 1989*.

intended purpose has the same meaning as in the MD Regulations.

MD Regulations means the *Therapeutic Goods (Medical Devices) Regulations 2002*.

prominently displayed or communicated has the same meaning as in the Therapeutic Goods Advertising Code.

restricted representation means a representation referred to in section 42DD of the Act.

specified device means a medical device that is:

(a) intended by the manufacturer to be used to detect, and notify the user of the device of, atrial fibrillation or an irregular heartbeat indicative of atrial fibrillation; and

(b) included in the Register; and

(c) classified under the MD Regulations as Class IIa or higher;

including a device that is a software-only mobile medical application, or a combination of software and non-invasive hardware.

5 Permission

For subsection 42DK(1) of the Act, in relation to each item mentioned in the table in Schedule 1, the restricted representations specified in column 2 are permitted to be used in the advertisements specified in column 3, about the therapeutic goods specified in column 4, subject to the conditions (if any) specified in column 5.

Schedule 1—Permission: restricted representation

Note: See section 5.

Permitted use of restricted representation

Column 1 Item	Column 2 Restricted representation	Column 3 Advertisement	Column 4 Therapeutic goods	Column 5 Conditions
1	a representation to the effect of one or both of the following: (a) the therapeutic goods may detect atrial fibrillation or an irregular heartbeat that is indicative of atrial fibrillation; (b) the therapeutic goods may detect atrial fibrillation or an irregular heartbeat that is indicative of atrial fibrillation to enable the user to consult a doctor for potential diagnosis and treatment, the consequence of which may prevent stroke or may detect or prevent heart failure	an advertisement about the therapeutic goods including, but not limited to, an advertisement that is: (a) on the label of the therapeutic goods; (b) on the package in which the therapeutic goods are contained; (c) on any material included with the package in which the therapeutic goods are contained	a specified device	all of the following: (a) the advertisement must not be inconsistent with the intended purpose of the specified device, including restrictions relating to the use of the device in certain population groups, such as those with contraindicated pre-existing conditions; and (b) the representation must be accompanied by advisory statements, which are prominently displayed or communicated and to the effect of the following: (i) the device is not intended to replace traditional methods of diagnosis; and (ii) if an irregular heartbeat or atrial fibrillation is detected, consult a doctor; and (iii) if the user has symptoms of a heart attack, stroke, or other cardiovascular conditions, do not rely on the notification of the device and consult a doctor; and (c) the advertisement must not contain any statement or

				implication that the use of the device, or detection of atrial fibrillation, will prevent stroke or heart failure
2	a representation to the effect of one or both of the following: (a) atrial fibrillation is an arrhythmia that can be asymptomatic and intermittent, and can lead to stroke and heart failure; (b) early detection and diagnosis of atrial fibrillation enables a doctor to recommend appropriate treatment, the consequence of which may prevent stroke or heart failure	an advertisement about the therapeutic goods including, but not limited to, an advertisement that is: (a) on the label of the therapeutic goods; (b) on the package in which the therapeutic goods are contained; (c) on any material included with the package in which the therapeutic goods are contained	a specified device	all of the following: (a) the advertisement must not be inconsistent with the intended purpose of the specified device, including restrictions relating to the use of the device in certain population groups, such as those with contraindicated pre-existing conditions; and (b) the representation must be accompanied by advisory statements, which are prominently displayed or communicated and to the effect of the following: (i) the device is not intended to replace traditional methods of diagnosis; and (ii) if an irregular heartbeat or atrial fibrillation is detected, consult a doctor; and (iii) if the user has symptoms of a heart attack, stroke or other cardiovascular conditions, do not rely on the notification of the device and consult a doctor; and (c) the advertisement must not contain any statement or implication that the use of the device, or early detection of

				atrial fibrillation, will prevent stroke or heart failure
3	a representation that comprises one or both of the following: (a) accurate and balanced information about age-related prevalence of atrial fibrillation; (b) accurate and balanced information about the prevalence of stroke and heart failure cases due to atrial fibrillation	an advertisement about the therapeutic goods including, but not limited to, an advertisement that is: (a) on the label of the therapeutic goods; (b) on the package in which the therapeutic goods are contained; (c) on any material included with the package in which the therapeutic goods are contained	a specified device	all of the following: (a) the advertisement must not be inconsistent with the intended purpose of the specified device, including restrictions relating to the use of the device in certain population groups, such as those with contraindicated pre-existing conditions; and (b) the representation must be accompanied by advisory statements, which are prominently displayed or communicated and to the effect of the following: (i) the device is not intended to replace traditional methods of diagnosis; and (ii) if an irregular heartbeat or atrial fibrillation is detected, consult a doctor; and (iii) if the user has symptoms of a heart attack, stroke or other cardiovascular conditions, do not rely on the notification of the device and consult a doctor; and (c) the advertisement must not contain any statement or implication that the use of the device, or detection of atrial fibrillation, will prevent stroke or heart failure; and

		(d) the representation must not be: (i) given prominence, such that it becomes a dominant claim in the advertisement; and (ii) used in a way that would create fear or distress for consumers