Therapeutic Goods (Restricted Representations—Hypertension Software) Permission 2026

I, Tracey Lutton, as delegate of the Secretary of the Department of Health, Disability and Ageing, make the following permission.

Dated 8 January 2026

Tracey Lutton
Assistant Secretary
Regulatory Compliance Branch
Health Products Regulation Group
Department of Health, Disability and Ageing

Contents

1 Name

This instrument is the *Therapeutic Goods (Restricted Representations—Hypertension Software) Permission 2026*.

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.	9 January 2026

Note: This table relates only to the provisions of this instrument as originally made.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) medical device;
(d) medical practitioner;
(e) Register;
(f) Therapeutic Goods Advertising Code.

In this instrument:

Act means the *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 goods means a medical device that:

(a) is included in the Register; and

(b) is a software-only mobile medical application, or a non-invasive medical device that incorporates software; and

(c) has an intended purpose, certified under section 41FD of the Act and accepted in relation to the inclusion of the device in the Register, that relates to identifying and notifying users of the device of patterns, from photoplethysmography (PPG) data, that are suggestive of hypertension.

5 Permission

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

Schedule 1—Permission

Note: See section 5.

Permitted use of restricted representations		
Column 1	**Column 2**	**Column 3**
Item	**Representation**	**Conditions**
1	a representation to the effect that the specified goods may identify patterns suggestive of hypertension	all of the following: (a) the advertisement must not: (i) be inconsistent with the intended purpose of the specified goods that is accepted in relation to the inclusion of the goods in the Register; and (ii) be inconsistent with any conditions relating to the inclusion of the specified goods in the Register; (b) the representation must be accompanied by advisory statements, which are prominently displayed or communicated, to the effect of the following: (i) if a pattern suggestive of hypertension is identified by the specified goods, consult a medical practitioner; (ii) the absence of notification does not exclude the presence of hypertension; (c) the advertisement must not include claims that refer to the accuracy, specificity, sensitivity or limit of detection of the specified goods, except where such claims are included solely in instructions for use relating to the goods
2	a representation that refers to hypertension in the name of the specified goods	all of the following: (a) the advertisement must not: (i) be inconsistent with the intended purpose of the specified goods that is accepted in relation to the inclusion of the goods in the Register; and (ii) be inconsistent with any conditions relating to the inclusion of the specified goods in the Register; (b) the representation must be accompanied by advisory statements, which are prominently displayed or communicated, to the effect of the following: (i) the notification feature does not replace advice or assessment from a qualified healthcare professional