Therapeutic Goods (Restricted Representations—Diabetes Devices) Permission 2026

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

Dated 28 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—Diabetes Devices) 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.	29 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Note: This table relates only to the provisions of this instrument as originally made.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) accessory;
(b) advertise;
(c) device number;
(d) included in the Register;
(e) medical device;
(f) Register;
(g) Therapeutic Goods Advertising Code.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

active implantable medical device has the same meaning as in the MD Regulations.

Class I medical device has the same meaning as in the MD Regulations.

Class IIa medical device has the same meaning as in the MD Regulations.

Class IIb medical device has the same meaning as in the MD Regulations.

Class III medical device has the same meaning as in the MD Regulations.

Class 3 IVD medical device has the same meaning as in the MD Regulations.

device for measurement of blood glucose levels means an IVD medical device for self-testing that:

(a) is included in the Register; and

(b) is classified as a Class 3 IVD medical device, other than an implantable medical device or an active implantable medical device; 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 the use of the device by a lay person in relation to diabetes mellitus.

device for measurement of blood glucose levels that incorporates ketone test strips means an IVD medical device for self-testing that:

(a) is included in the Register; and

(b) has the same ARTG number as a device for measurement of blood glucose levels; and

(c) is classified as a Class 3 IVD medical device when in combination with a device for measurement of blood glucose levels, other than an implantable medical device or an active implantable medical device; and

(d) 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 the use of the device by a lay person in relation to diabetes mellitus.

device for measurement of interstitial-fluid glucose levels means a medical device for self-testing, that:

(a) is included in the Register; and

(b) is classified as a Class IIb medical device, other than an implantable medical device or an active implantable medical device; 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 the use of the device by a lay person in relation to diabetes mellitus.

diabetes includes diabetes mellitus.

implantable medical device has the same meaning as in the MD Regulations.

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

IVD medical device for self-testing 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.

relevant companion software application means a software application that is:

(a) included in the Register; and

(b) classified as a Class I, Class IIa, Class IIb or Class III medical device.

relevant insulin pump means an insulin pump that:

(a) is included in the Register; and

(b) is classified as a Class IIb or Class III medical device, other than an implantable medical device or an active implantable medical device; 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 the use of the device by a lay person in relation to diabetes mellitus.

relevant medical device means a medical device that:

(a) is included in the Register as any one of the following:

(i) pen needle;

(ii) insulin syringe;

(iii) electronic insulin pen;

(iv) lancets or lancing device;

(v) test strips designed to measure blood glucose in blood when used in combination with a dedicated blood glucose meter; and

(b) 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 the use of the device by a lay person in relation to diabetes mellitus.

relevant subsidised medical device means a medical device that:

(a) is included in the Register; and

(b) is included as a subsidised product on the National Diabetes Services Scheme; 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 the use of the device by a lay person in relation to diabetes mellitus.

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

5 Permission

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

6 Repeals

Each instrument that is specified in Schedule 2 to this instrument is repealed as set out in the applicable items in that Schedule.

Schedule 1—Permission

Note: See section 5.

Permitted use of restricted representations			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Restricted representation**	**Therapeutic good**	**Conditions**
1	one or more of the following: (a) a representation to the effect that the therapeutic good can assist in: (i) the monitoring, or self-monitoring, of interstitial-fluid glucose levels for persons diagnosed with diabetes; or (ii) the management of diabetes; (b) a representation that refers to diabetes in the context of the name of: (i) the therapeutic good; or (ii) the entity supplying the therapeutic good; (c) a representation relating to the therapeutic good that is necessary to describe the function of the good and that refers, expressly or by implication, to diabetes; (d) a representation to the effect that the therapeutic good	a device for measurement of interstitial-fluid glucose levels	all of the following: (a) the advertisement must not be inconsistent with the intended purpose of the therapeutic good or with any conditions relating to the inclusion of the good in the Register; (b) the advertisement must contain statements, prominently displayed or communicated, to the effect of the following: (i) if glucose values do not match expectations, use a blood glucose meter to make diabetes treatment decisions; (ii) where the therapeutic good is intended for use in or by persons of a particular age range—the age range; (iii) where the therapeutic good is intended for use in or by persons with insulin-requiring diabetes—this product is indicated for measuring interstitial-fluid glucose levels in people with insulin-requiring diabetes; (c) where the advertisement includes a representation to the effect that the therapeutic good can assist in the management of diabetes without finger pricks or be used in substitution of, or to

Permitted use of restricted representations			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Restricted representation**	**Therapeutic good**	**Conditions**
	is intended for any of the following: (i) persons diagnosed with diabetes; (ii) persons living with diabetes; (iii) persons living with type 1 diabetes; (iv) persons living with type 2 diabetes; (v) diabetes management; (e) a representation to the effect that the therapeutic good can: (i) assist in the management of diabetes without finger pricks; or (ii) be used in substitution of, or to replace, fingerstick blood glucose readings		replace, fingerstick blood glucose readings—the advertisement must contain the following advisory statement, prominently displayed or communicated: (i) if your glucose alerts and readings from the device do not match symptoms or expectations, use a blood glucose meter to make diabetes treatment decisions
2	one or more of the following: (a) a representation to the effect that the therapeutic good can assist in: (i) the monitoring, or self-monitoring, of blood glucose levels for persons diagnosed with diabetes; or	a device for measurement of blood glucose levels	all of the following: (a) the advertisement must not be inconsistent with the intended purpose of the therapeutic good or with any conditions relating to the inclusion of the good in the Register; (b) the advertisement must contain statements, prominently displayed or communicated, to the effect of the following:

Permitted use of restricted representations			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Restricted representation**	**Therapeutic good**	**Conditions**
	(ii) the management of diabetes; (b) a representation that refers to diabetes in the context of the name of: (i) the therapeutic good; or (ii) the entity supplying the therapeutic good; (c) a representation relating to the therapeutic good that is necessary to describe the function of the good that refers, expressly or by implication, to diabetes; (d) a representation to the effect that the therapeutic good is intended for any of the following: (i) persons diagnosed with diabetes; (ii) persons living with diabetes; (iii) persons living with type 1 diabetes; (iv) persons living with type 2 diabetes; (v) diabetes management		(i) where the therapeutic good is intended for use in or by persons of a particular age range—the age range; (ii) where the therapeutic good is intended for use in or by persons with insulin-requiring diabetes—this product is indicated for measuring blood glucose levels in people with insulin-requiring diabetes
3	one or more of the following:	a relevant insulin pump	the advertisement must not be inconsistent with the intended

Permitted use of restricted representations			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Restricted representation**	**Therapeutic good**	**Conditions**
	(a) a representation to the effect that the therapeutic good can assist in the management of diabetes; (b) a representation that refers to diabetes in the context of the name of: (i) the therapeutic good; or (ii) the entity supplying the therapeutic good; (c) a representation relating to the therapeutic good that is necessary to describe the function of the good that refers, expressly or by implication, to diabetes, including by reference to insulin; (d) a representation to the effect that the therapeutic good is intended for any of the following: (i) persons diagnosed with diabetes; (ii) persons living with diabetes; (iii) persons living with type 1 diabetes; (iv) diabetes		purpose of the therapeutic good or with any conditions relating to the inclusion of the good in the Register

Permitted use of restricted representations			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Restricted representation**	**Therapeutic good**	**Conditions**
	management		
4	one or more of the following: (a) a representation to the effect that the therapeutic good is intended for any of the following: (i) persons diagnosed with diabetes; (ii) persons living with diabetes; (iii) persons living with type 1 diabetes; (iv) persons living with type 2 diabetes; (v) diabetes management; (b) where the therapeutic good collects data relating to the measurement of interstitial-fluid glucose—a representation to the effect of any of the following: (i) the therapeutic good displays diabetes data, including forecasting or prediction data; (ii) the therapeutic good enables the user to view their diabetes data; (c) a representation to the effect that the	a relevant companion software application: (a) that is intended by the manufacturer of the therapeutic good specified in column 3 of item 1 (the ***specified good***) to be used by a lay person as an accessory to the specified good; and (b) when used as an accessory to a specified good	all of the following: (a) the advertisement must not be inconsistent with the intended purpose of the therapeutic good or with any conditions relating to the inclusion of the good in the Register; (b) where the therapeutic good uses artificial intelligence to support its intended purpose—the advertisement must contain all of the following advisory statements, prominently displayed or communicated together: (i) this product uses artificial intelligence (AI) technology to support its intended purpose; (ii) there can be limitations with information generated using artificial intelligence (AI); (iii) if glucose values do not meet expectations, use a blood glucose meter to make diabetes treatment decisions

Permitted use of restricted representations			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Restricted representation**	**Therapeutic good**	**Conditions**
	therapeutic good is designed to be used with the therapeutic good specified in column 3 of item 1		
5	a representation to the effect that the therapeutic good is intended for any of the following: (a) persons diagnosed with diabetes; (b) persons living with diabetes; (c) persons living with type 1 diabetes; (d) persons living with type 2 diabetes; (e) diabetes management	a relevant companion software application: (a) that is intended by the manufacturer of the therapeutic good specified in column 3 of item 2 (the ***specified good***) to be used by a lay person as an accessory to the specified good; and (b) when used as an accessory to the specified good	all of the following: (a) the advertisement must not be inconsistent with the intended purpose of the therapeutic good or with any conditions relating to the inclusion of the good in the Register; (b) where the therapeutic good uses artificial intelligence to support its intended purpose—the advertisement must contain all of the following advisory statements, prominently displayed or communicated together: (i) this product uses artificial intelligence (AI) technology to support its intended purpose; (ii) there can be limitations with information generated using artificial intelligence (AI); (iii) if glucose values do not meet expectations, use a blood glucose meter to make diabetes treatment decisions
6	a representation to the effect that the therapeutic good is intended for any of the following: (a) persons diagnosed	a relevant companion software application: (a) that is intended by the manufacturer of the therapeutic good specified in column 3	all of the following: (a) the advertisement must not be inconsistent with the intended purpose of the therapeutic good or with

Permitted use of restricted representations			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Restricted representation**	**Therapeutic good**	**Conditions**
	with diabetes; (b) persons living with diabetes; (c) persons living with type 1 diabetes; (d) diabetes management	of item 3 (the ***specified good***) to be used by a lay person as an accessory to the specified good; and (b) when used as an accessory to the specified good	any conditions relating to the inclusion of the good in the Register; (b) where the therapeutic good uses artificial intelligence to support its intended purpose—the advertisement must contain all of the following advisory statements, prominently displayed or communicated together: (i) this product uses artificial intelligence (AI) technology to support its intended purpose; (ii) there can be limitations with information generated using artificial intelligence (AI); (iii) if glucose values do not meet expectations, use a blood glucose meter to make diabetes treatment decisions
7	one or more of the following: (a) a representation to the effect that the therapeutic good can assist in the testing or monitoring of blood ketone levels for persons diagnosed with diabetes; (b) a representation to the effect that the therapeutic good is intended for monitoring blood glucose and	a medical device for measurement of blood glucose levels that incorporates ketone test strips when used as an accessory to the therapeutic good specified in column 3 of item 2	all of the following: (a) the advertisement must not be inconsistent with the intended purpose of the therapeutic good or with any conditions relating to the inclusion of the good in the Register; (b) the advertisement must contain the following advisory statement, prominently displayed or communicated: (i) diabetics with elevated blood ketone levels should seek medical advice

Permitted use of restricted representations			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Restricted representation**	**Therapeutic good**	**Conditions**
	ketone levels		
8	one or more of the following: (a) a representation relating to the therapeutic good that is necessary to describe the function of the good and that refers, expressly or by implication, to diabetes; (b) a representation to the effect that the therapeutic good is intended for use by persons diagnosed with diabetes	a relevant medical device	the advertisement must not be inconsistent with or extend beyond the intended purpose of the therapeutic good or with any conditions relating to its inclusion in the Register
9	one or more of the following: (a) a representation to the effect that the therapeutic good is subsidised for eligible patients diagnosed with diabetes (b) a representation that refers to the National Diabetes Services Scheme	a relevant subsidised medical device	the advertisement must not be inconsistent with or extend beyond the intended purpose of the therapeutic good or with any conditions relating to its inclusion in the Register

Schedule 2—Repeals

Note: See section 6.

Meters for monitoring blood glucose levels

1 The whole of the instrument

Repeal the instrument.

Powered insulin infusion pumps & insulin pump administration sets

2 The whole of the instrument

Repeal the instrument.