Therapeutic Goods (Restricted Representations—Wound Dressings) Permission 2025

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

Dated 18 July 2025

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—Wound Dressings) Permission 2025*.

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.	19 July 2025

Note: This table relates only to the provisions of this instrument as originally made.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

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

chronic wound means a wound that has not progressed through normal healing stages in 30 days.

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.

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 classified as a Class IIa or Class IIb 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 as a dressing for wounds.

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.

Column 1	Column 2	Column 3
Item	**Restricted representations**	**Conditions**
1	a representation that refers to a chronic wound, including, but not limited to, a reference to one or more of the following: (a) diabetic ulcers; (b) leg ulcers; (c) skin tears; (d) vasculitic ulcers; (e) venous ulcers	all of the following: (a) the advertisement must not be inconsistent with the intended purpose of the specified goods or with any conditions relating to the inclusion of the goods in the Register; (b) the advertisement must contain statements, which are prominently displayed or communicated, to the effect of the following: (i) the specified goods should only be used under the supervision of a healthcare professional; (ii) if you are concerned about your wound, consult a healthcare professional