



Therapeutic Goods (Medical Device Standard— Therapeutic Vaping Devices) Amendment Order 2024

I, Anthony Lawler, as delegate of the Minister for Health and Aged Care, make the following order.

Dated 27 September 2024

Professor Anthony Lawler
Deputy Secretary
Health Products Regulation Group
Department of Health and Aged Care

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1 Name

This instrument is the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Amendment Order 2024*.

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	1 October 2024.	1 October 2024

Note: This table relates only to the provisions of this instrument as originally made.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 41CB of the *Therapeutic Goods Act 1989*.

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023

1 Section 4

Insert:

accredited certification body means a body that is accredited to undertake certification for compliance with IEC 60086-1, IEC 62133-1 or IEC 62133-2, by an International Electrotechnical Commission accepted national certification body.

AS/NZS 3820 means Australian/New Zealand Standard AS/NZS 3820, *Essential safety requirements for electronic equipment*, published jointly by, or on behalf of, Standards Australia and Standards New Zealand, as in force or existing from time to time.

Note: AS/NZS 3820 is published at www.standards.org.au.

AS/NZS 4417.1 means Australian/New Zealand Standard AS/NZS 4417.1, *Marking of electronic products to indicate compliance with regulations*, published by, or on behalf of, Standards Australia and Standards New Zealand, as in force or existing from time to time.

Note: AS/NZS 4417.1 is published at www.standards.org.au.

2 Section 4 (definition of *EU Directive 2014/40/EU*)

Repeal the definition.

3 Section 4 (definition of *IAF accredited organisation*)

Omit “ISO 9001 or”.

4 Section 4

Insert:

IEC 60086-1 means IEC 60086-1, *Primary Batteries – Part 1: General*, published by the International Electrotechnical Commission, as in force or existing from time to time.

Note: IEC 60086 is published at www.webstore.iec.ch.

IEC 62133-1 means IEC 62133-1, *Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications – Part 1: Nickel systems*, published by the International Electrotechnical Commission, as in force or existing from time to time.

Note: IEC 62133-1 is published at www.webstore.iec.ch.

IEC 62133-2 means IEC 62133-2, *Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable*

applications – Part 2: Lithium systems, published by the International Electrotechnical Commission, as in force or existing from time to time.

Note: IEC 62133-2 is published at www.webstore.iec.ch.

instructions for use has the same meaning as in the MD Regulations.

ISO 14971 means International Standard ISO 14971, *Medical devices – Application of risk management principles to medical devices*, issued by the International Organization for Standardization, as in force or existing from time to time.

Note: ISO 14971 is published at www.iso.org.

ISO 17025 means International Standard ISO 17025, *Testing and calibration laboratories*, issued by the International Organization for Standardization, as in force or existing from time to time.

Note: ISO 17025 is published at www.iso.org.

ISO 17025 accredited laboratory means a laboratory that is accredited, by a member body of the International Laboratory Accreditation Cooperation, to operate in accordance with ISO 17025 to undertake certification for compliance with UN/DOT 38.3.

5 Section 4 (definition of ISO 9001)

Repeal the definition (including the note).

6 Section 4 (definition of Regulations)

Before “***Regulations***” (first occurring), insert “***MD***”.

7 Section 4

Insert:

TG Regulations means the *Therapeutic Goods Regulations 1990*.

text size means the height of the following:

- (a) capital letters or lower case letters, including an ascender or descender;
- (b) numbers or numerals;
- (c) symbols.

8 Section 4 (definition of therapeutic vaping device)

Before “Regulations”, insert “MD”.

9 Section 4 (definition of therapeutic vaping device accessory)

Before “Regulations”, insert “MD”.

10 Section 4

Insert:

therapeutic vaping substance has the same meaning as in the TG Regulations.

UN/DOT 38.3 means section 38.3 of the United Nations document *Recommendations on the Transport of Dangerous Goods: Manual of Tests and*

Criteria, established by the United Nations, as in force or existing from time to time.

Note: UN/DOT 38.3 applies to lithium cells and batteries, and contains criteria, test methods and procedures for the safe transportation of dangerous goods. UN/DOT 38.3 is published at www.unece.org.

venting means the emission of the battery or cell electrolyte as a liquid, droplets or vapour from a designed vent or through a seal intended to preclude rupture.

11 Section 5

Repeal the section.

12 Section 6

Repeal the section, substitute:

6 Application

This instrument applies to therapeutic vaping devices or therapeutic vaping device accessories that:

- (a) were excluded under item 16 of the table in Schedule 1 to the *Therapeutic Goods (Excluded Goods) Determination 2018*, as in force immediately before the commencement of the *Therapeutic Goods (Excluded Goods) Amendment (Vaping) Determination 2023*; and
- (b) is intended by the person under whose name the device is or is to be supplied, only to administer, or contain, a therapeutic vaping substance for which the only indication is use for smoking cessation or the management of nicotine dependence.

Note: The *Therapeutic Goods (Excluded Goods) Determination 2018* is a legislative instrument published on the Federal Register of Legislation at www.legislation.gov.au.

13 Subsection 7(2)

Before “Regulations”, insert “MD”.

14 After section 7

Insert:

8 Application, saving and transitional provisions

- (1) In this section:

former order means the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023*, as in force immediately before the commencement of the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Amendment Order 2024*.

- (2) Despite the amendments to the former order made by the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Amendment Order 2024*, the former order continues to apply in relation to therapeutic vaping devices and therapeutic vaping device accessories that are:
 - (a) imported or manufactured before 1 March 2025; and
 - (b) supplied before 1 July 2025.

(3) This section ceases to apply on 1 July 2025.

15 Schedule 1

Repeal the Schedule, substitute:

Schedule 1—Medical device standard for therapeutic vaping devices and therapeutic vaping device accessories

Note: See section 7.

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Column 1	Column 2
Item	Matters
1	<p>all of the following matters:</p> <ul style="list-style-type: none">(a) ISO 13485 certification for the manufacture of the therapeutic vaping device or the therapeutic vaping device accessory, issued by one of the following:<ul style="list-style-type: none">(i) an IAF accredited organisation;(ii) a notified body;(iii) an auditing organisation recognised by Health Canada;(iv) an Australian conformity assessment body determined under the MD Regulations;(b) compliance to ISO 13485 for the manufacture of the therapeutic vaping device or the therapeutic vaping device accessory
2	<p>all of the following matters:</p> <ul style="list-style-type: none">(a) ISO 14971 compliance for the application of risk management to the therapeutic vaping device or the therapeutic vaping device accessory, including but not limited to the management of:<ul style="list-style-type: none">(i) hazards or risks relating to the toxicity of emissions from the therapeutic vaping device or the therapeutic vaping device accessory, for the expected lifetime of the device, as identified in a toxicological risk assessment; and(ii) hazards or risks relating to the toxicity of the materials within the therapeutic vaping device or therapeutic vaping device accessory, and any residues or contaminants, for the expected lifetime of the device; and(iii) hazards or risks relating to batteries (if applicable), including risk of fire or explosion; and(iv) electrical hazards or risks; and(v) hazards or risks relating to the usability of the therapeutic vaping device or the therapeutic vaping device accessory; and(vi) hazards or risks relating to the reasonably foreseeable misuse of the therapeutic vaping device or the therapeutic vaping device accessory; and(vii) hazards or risks relating to the containment of a therapeutic vaping substance in, and the administration of a therapeutic vaping substance by, the therapeutic vaping device or the therapeutic vaping device accessory; and(viii) hazards or risks relating to heating of the therapeutic vaping device or therapeutic vaping device accessory;(b) the manufacturer must establish and maintain a risk management file, which documents the risk assessment process for managing all hazards or risks associated

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	with a therapeutic vaping device or a therapeutic vaping device accessory, including the hazards or risks mentioned in paragraph (a)
3	<p>all of the following matters, as applicable to the therapeutic vaping device or the therapeutic vaping device accessory:</p> <ul style="list-style-type: none">(a) for a primary battery (other than a button battery)—IEC 60086-1 certification (as applicable) issued by an accredited certification body;(b) for a secondary battery (other than a button battery) that is a lithium battery—both of the following:<ul style="list-style-type: none">(i) UN/DOT 38.3 certification, or declaration of conformity with UN/DOT 38.3, supported by independent test reports from an ISO 17025 accredited laboratory;(ii) IEC 62133-2 certification issued by an accredited certification body;(c) for a secondary battery (other than a button battery) that is a nickel system battery—IEC 62133-1 certification issued by an accredited certification body;(d) for a button battery—compliance with all of the following:<ul style="list-style-type: none">(i) the <i>Consumer Goods (Button/Coin Batteries) Information Standard 2020</i>;(ii) the <i>Consumer Goods (Button/Coin Batteries) Safety Standard 2020</i>;(iii) the <i>Consumer Goods (Products Containing Button/Coin Batteries) Safety Standard 2020</i>;(iv) the <i>Consumer Goods (Products Containing Button/Coin Batteries) Information Standard 2020</i> <p>Note: These legislative instruments are published on the Federal Register of Legislation at www.legislation.gov.au</p>
4	<p>all of the following matters, as applicable to the therapeutic vaping device or the therapeutic vaping device accessory:</p> <ul style="list-style-type: none">(a) AS/NZS 3820 compliance with essential safety requirements for low voltage electrical equipment;(b) AS/NZS 4417.1 compliance with marking of electrical products to indicate compliance with regulations
5	<p>a therapeutic vaping device, and a therapeutic vaping device accessory as applicable, must be designed and constructed in a way that:</p> <ul style="list-style-type: none">(a) when operated in accordance with the instructions for use, the device provides the emitted mass or dose as specified and verified by the manufacturer; and(b) incorporates a reliable venting mechanism that channels the pressure wave in the direction where the harm is minimised; and(c) minimises the risk of inadvertent actuation; and(d) ensures that any external parts or accessible surfaces, other than the mouthpiece, of the device that may be held or grasped during use does not exceed 48°C during use; and(e) ensures that the external surface of the mouthpiece does not exceed 55°C during use; and(f) ensures that the device will withstand regular use, and foreseeable misuse or abuse, without breaking, leaking or failing in an unsafe manner; and(g) incorporates child-resistant features to prevent:<ul style="list-style-type: none">(i) the operation of the device by children; and

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- (ii) the accidental ingestion of components of, or substances contained in, the device; and
 - (h) for a therapeutic vaping device or a therapeutic vaping device accessory that is, or contains, a battery—accords with relevant electrical safety standards to protect against overheating, short-circuiting, and the risk of explosion during use and recharging; and
 - (i) prevents leaks of the therapeutic vaping substance being vaporised; and
 - (j) ensures that all materials used in the inhalation pathway of the device, including any by-products or degradants, are biocompatible and the amount of harmful chemicals (such as heavy metals, volatile organic compounds, and other toxic substances) that the patient receives is less than the tolerable exposure limit below which there would be no appreciable risk to human health
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6 the name (including brand name) of a therapeutic vaping device or a therapeutic vaping device accessory must not:

- (a) be in any way attractive to children or adolescents; and
 - (b) whether expressly or by implication—
 - (i) suggest that the device is a food, beverage or cosmetic product; or
 - (ii) suggest that the device has health benefits other than its intended purpose, including healing, vitalising, natural, organic or rejuvenating properties; or
 - (iii) suggest that the device is safe, without harm or without side effects; or
 - (iv) promote the use or supply of the device; or
 - (v) exaggerate, or be likely to exaggerate, the efficacy or performance of the device; or
 - (vi) encourage, or be likely to encourage, inappropriate or excessive use of the device
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7 all of the following matters:

- (a) a therapeutic vaping device or a therapeutic vaping device accessory must be supplied with instructions for use of the device that are:
 - (i) in English (noting the instructions may also be provided in any other language); and
 - (ii) clearly legible; and
 - (iii) supplied in paper or electronic format that is readily accessible to patients;
 - (b) where the instructions for use are supplied in electronic format—a paper copy must be provided, without charge, to a patient upon request;
 - (c) the instructions for use must contain the following information, in a text size of at least 3 mm:
 - (i) the manufacturer's name, or trading name, and address;
 - (ii) the intended purpose of the device, the intended user of the device, and the kind of patient on whom the device is intended to be used;
 - (iii) the device name, brand name and model;
 - (iv) the batch code, lot number or serial number that identifies the kind of medical device;
 - (v) any particular handling or storage requirements applying to the device, including recommended storage conditions;
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- (vi) any warnings, restrictions or precautions that may apply in relation to the use of the device, including a statement that informs the patient or user to seek advice from a healthcare professional if the device is not functioning correctly;
 - (vii) if applicable, information about the risks associated with button or coin batteries;
 - (viii) any actions that need to be performed prior to using the device, including any preparatory actions for first-time use;
 - (ix) information about how to use the device, including instructions for assembly;
 - (x) any cleaning requirements for the device;
 - (xi) information about the replacement of the consumable components of the device during its expected lifetime, including the size and type of battery;
 - (xii) either the expiry date for the device or the expected lifetime of the device, indicated as duration of use after the first use or the number of actuations before being discarded;
 - (xiii) any precautions a patient or user should take if there are risks associated with the disposal of the device, including instructions on how to dispose of the device or its parts, or how to recycle used batteries
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- 8 all of the following matters:
- (a) a therapeutic vaping device must be labelled with information that is:
 - (i) in English; and
 - (ii) clearly legible; and
 - (iii) printed in a manner that is durable; and
 - (iv) in a text colour that is matte grey or matte black, unless required by an applicable standard to be another colour; and
 - (v) in a text colour that contrasts with the colour of the therapeutic vaping device;
 - (b) the label on the therapeutic vaping device must be matte white or matte grey, unless required by an applicable standard to be another colour;
 - (c) the label must contain the following information on the device itself:
 - (i) the sponsor's name;
 - (ii) the device name, brand name and model;
 - (iii) the batch code, lot number or serial number that identifies the kind of medical device;
 - (iv) the warning statement "Risk of fire or explosion. Replace only with the same size and type of battery";
 - (d) the label must contain the following information on the device itself, or on the packaging of the device if it is impracticable or inappropriate to be on the device itself:
 - (i) the address of the sponsor;
 - (ii) the name and address of the manufacturer;
 - (e) the information required by paragraphs (c) and (d) must be displayed in a text size of at least 3 mm
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- 9 all of the following matters:
- (a) a therapeutic vaping device accessory must be labelled with information that is:
 - (i) in English; and
 - (ii) clearly legible; and
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	<ul style="list-style-type: none">(iii) printed in a manner that is durable; and(iv) in a text colour that is matte grey or matte black, unless required by an applicable standard to be another colour; and(v) in a text colour that contrasts with the colour of the therapeutic vaping device; <p>(b) the label on the therapeutic vaping device accessory must be matte white, matte grey or matte black, unless required by an applicable standard to be another colour;</p> <p>(c) the label must contain the following information on the vaping device accessory itself:</p> <ul style="list-style-type: none">(i) the device name and model;(ii) the batch code, lot number or serial number that identifies the kind of medical device;(iii) if the therapeutic vaping device accessory contains a battery (of any kind)—the warning statement “Risk of fire or explosion. Replace only with the same size and type of battery”; <p>(d) the label must contain the following information on the vaping device accessory itself, or on the packaging or instructions for use of the vaping device accessory if it is impracticable or inappropriate to be on the vaping device accessory itself:</p> <ul style="list-style-type: none">(i) the brand name;(ii) the sponsor’s name;(iii) the address of the sponsor;(iv) the name and address of the manufacturer; <p>(e) the information required by paragraphs (c) and (d) must be displayed in a text size of at least 1 mm</p>
10	<p>all of the following matters:</p> <ul style="list-style-type: none">(a) a therapeutic vaping device must be predominantly either matte white or matte grey, and feature no more than 3 other matte colours or shades, including the colour or shade of any text;(b) a therapeutic vaping device accessory must be predominantly either matte white, matte grey or matte black, and feature no more than 3 other matte colours or shades, including the colour or shade of any text;(c) where the therapeutic vaping device or therapeutic vaping device accessory features a colour or shade other than matte white or matte grey, that colour must not be visible when the device is fully assembled for use;(d) a therapeutic vaping device or a therapeutic vaping device accessory may have a clear panel, which must be the smallest size that enables visibility of the amount of therapeutic vaping substance in the device;(e) any information on a therapeutic vaping device or therapeutic vaping device accessory must be:<ul style="list-style-type: none">(i) in English; and(ii) clearly legible; and(iii) printed in a manner that is durable; and(iv) in a text colour that is matte grey or matte black, unless required by an applicable standard to be another colour; and(v) in a text colour that contrasts with the colour of the therapeutic vaping device or therapeutic vaping device accessory;

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- (f) a therapeutic vaping device or a therapeutic vaping device accessory must not display:
 - (i) any words, symbols, trade marks, images, figures, logos or emblems, that are in contravention of another provision of this standard; or
 - (ii) any promotional statement, pictorial representation or design;
- (g) a therapeutic vaping device or a therapeutic vaping device accessory must not include any features designed to change the appearance of the device, including the following:
 - (i) heat activated inks;
 - (ii) inks or embellishments designed to appear gradually over time;
 - (iii) inks that appear fluorescent in certain light;
 - (iv) panels designed to be scratched or rubbed to reveal an image or text

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- 11 all of the following matters:
- (a) a therapeutic vaping device or a therapeutic vaping device accessory must be supplied in a primary pack, where the label of the primary pack and the primary pack are white;
 - (b) any information on the label of the primary pack and the primary pack must be:
 - (i) in English; and
 - (ii) clearly legible; and
 - (iii) printed in a manner that is durable; and
 - (iv) in a text colour that is matte grey or matte black, unless required by an applicable standard to be another colour;
 - (c) the label of the primary pack and the primary pack must not contain the following:
 - (i) any feature that suggests, whether expressly or by implication, that the device has health benefits other than its intended purpose, including healing, vitalising, natural, organic, or rejuvenating properties;
 - (ii) any words, symbols, trade marks, images, figures, logos or emblems that are in contravention of another provision of this standard;
 - (iii) any promotional statement, pictorial representation or design;
 - (d) the label and packaging must not include any features designed to change the appearance of the primary pack, including the following:
 - (i) heat activated inks;
 - (ii) inks or embellishments designed to appear gradually over time;
 - (iii) inks that appear fluorescent in certain light;
 - (iv) panels designed to be scratched or rubbed to reveal an image or text;
 - (v) removable tabs;
 - (vi) fold out panels;
 - (e) the label of the primary pack must include the warning statements:
 - (i) “KEEP OUT OF REACH OF CHILDREN”; and
 - (ii) “WARNING CONTAINS BUTTON OR COIN BATTERY. HAZARDOUS IF SWALLOWED – SEE INSTRUCTIONS” (if applicable); and
 - (iii) “RISK OF FIRE OR EXPLOSION. REPLACE ONLY WITH THE SAME SIZE AND TYPE OF BATTERY” (if applicable);
 - (f) the warning statements required by paragraph (e) must be in bold-face, sans serif, capital letters of uniform thickness and size
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12	<p>a therapeutic vaping device or a therapeutic vaping device accessory must be subject to a toxicological risk assessment of the emissions from the device, for the expected lifetime of the device, including but not limited to an assessment of all of the following, having regard to the generally acknowledged state of the art:</p> <ul style="list-style-type: none">(a) the atomiser (or the part of the device that heats and vaporises the therapeutic vaping substance);(b) all materials within the device that the therapeutic vaping substance and its vapour come in contact with;(c) any leachable substances, contaminants and thermal degradation products from the device
