Australian Government
Department of Health
Therapeutic Goods Administration

Regulatory changes for software based medical devices

Version 1.2, August 2021

TGA Health Safety Regulation

The purpose of this guidance is to help manufacturers and sponsors understand how the TGA interprets requirements, and thus indicate how manufacturers and sponsors can comply.

This is a guide only, and manufacturers and sponsors are encouraged to familiarise themselves with the legislative and regulatory requirements in Australia, and if necessary, to seek professional advice. It is the responsibility of each manufacturer or sponsor to understand and comply with these requirements.

Contents

About this guidance

This guidance provides a summary of changes to the regulation of software based medical devices (including software as a medical device - SaMD) which commenced on **25 February 2021**. It outlines transition arrangements available for devices that may need to be reclassified or that qualify for an exemption or exclusion from the *Therapeutic Goods (Medical Devices) Regulations 2002*.

For further information on the regulation of software based medical devices, see:

- Is my software regulated?
- Scope of regulated software based medical devices – examples
- How the TGA regulates software based medical devices

Changes to the regulation of software based medical devices

The Therapeutic Goods Administration (TGA) regulates software-based medical devices; including software that functions as a medical device in its own right, and software that controls or interacts with a medical device either from within the device or externally. If a product is a medical device, it must be included in the Australian Register of Therapeutic Goods (ARTG), unless exempt, before it can be legally supplied in Australia.

Rapid innovation in technology has driven significant changes to software function and adoption, giving rise to a larger number of devices able to inform, drive or replace clinical decisions, or directly provide therapy to an individual. Access to software has become much easier, with personal devices including smartphones, wearables and tablets becoming ubiquitous, and improvements to network technology providing increased connectivity via technologies such as Bluetooth and Wi-Fi.

These rapid advances in computing technology and software production have led to a large increase in the number of software-based medical devices available on the market.

Following consultation with stakeholders including with global medical device regulators in 2019 and 2020, the *Therapeutic Goods (Medical Devices) Regulations 2002* were amended by the Government to clarify some existing requirements and to introduce new requirements for software-based medical devices.

The changes, which commenced on **25 February 2021,** include**:**

- clarifying the boundary of regulated software products (including 'carve outs')
- introducing new classification rules
- providing updates to the essential principles to more clearly express the requirements for software-based medical devices.

Excluded or exempt software-based medical devices

The clarification of the boundary for software-based products regulated as medical devices in Australia is important to ensure sponsors and manufacturers of software-based products are not subject to unnecessary regulatory oversight.

From 25 February 2021, certain software-based medical devices were carved-out (through either an exemption or exclusion) from the scope of the TGA regulation, based on the following principles:

- Align with international regulatory frameworks where appropriate.
- Reduce or remove unnecessary regulatory burden:
  - by not regulating products where there is no significant risk to safety
  - by not regulating where suitable frameworks for product or system oversight are already in place.

As a result, a number of exclusions and exemptions for specific types of software products have been introduced.

Certain clinical decision support systems have been exempted. Exempt software is a medical device but is not subject to all regulatory requirements. Further detail on the exemption, including which products are covered, and which requirements still apply can be found in the guidance for Clinical Decision Support Software.

Other products have been excluded and are not subject to any TGA regulatory requirements. See the Therapeutic Goods (Excluded Goods) Determination 2018 for more detail; the types of excluded products include:

- **Consumer health products** – prevention, management and follow up devices that do not provide specific treatment or treatment suggestions:
  - Software intended for self-management of an existing disease or condition that is not serious (without providing specific treatment or treatment suggestions)
  - Consumer health and wellness products (may be software or a combination of non-invasive hardware and software), excludes serious conditions
  - Behavioural change or coaching software intended to be used to improve general health or wellness factors (such as weight, exercise, sun exposure or dietary intake) that does not provide information to the consumer that would generally be accepted to require the interpretation of a health professional
  - PROMs (patient recorded outcome measures) and patient surveys (including those that form part of an electronic health record)
  - Digital mental health tools (including a cognitive behaviour therapy tool) based on established clinical practice guidelines that are referenced and displayed in the software

- **Enabling technology** – for telehealth, healthcare or dispensing:
  - Communication software that enables telehealth consultations, including the transmission of patient information, for the purposes of supporting the delivery of health services
  - Software intended to administer or manage health processes or facilities, rather than patient clinical use cases
  - Systems that are intended only to store or transmit patient images
  - Software intended to provide alerts or additional information to health professionals in relation to patient care. The health professional can exercise their own judgement in determining whether to action the alert or information
  - Software embedded in delivery of health services (clinical workflow management software)
  - Middleware that does not control IVD instruments or medical devices and does not recommend a diagnosis or make treatment decisions.
- **Digitisation** - of paper based or other published clinical rules or data including simple dose calculators and Electronic Patient Records
  - Simple calculators that use relevant published clinical standards or authoritative sources to make calculations or display calculations and outputs so they may be validated by the user, but do not control the administration of a calculated dosage.
  - Electronic Patient Records (EMRs) and Electronic Health Records (EHRs) that use relevant published clinical standards or authoritative sources to make calculations or display calculations and outputs so they may be validated by the user, but do not control the administration of a calculated dosage.
- **Population based analytics** – Data analytics that are for the collection and analysis of class, group or population data that are not intended to be used for clinical use cases for individuals
- **Laboratory Information Management Systems** – these systems include pathology and radiology use cases and typically allow laboratories to automate workflows, integrate instruments, manage orders and samples and associated information.

More detailed information including examples of products that are excluded or exempt (carved-out) from *Therapeutic Goods (Medical Devices) Regulations 2002* can be found:

- Is my software regulated?
- Examples of regulated and unregulated software-based products
- Clinical Decision Support Software

New classification rules

Note

These new classification rules **do not apply** to *in vitro* diagnostic (IVD) medical devices.

On **25 February 2021** changes to the Regulations commenced to introduce new classification rules for programmed and programmable medical devices, and medical devices that are software. This includes all software-based medical devices.

The following guidance provides information about the new classification rules for software based medical devices that:

- Provide a diagnosis or screens for a disease or condition
- Monitor the state or progression of a disease or condition, or the parameters of a person with a disease or condition
- Specify or recommend a treatment or intervention
- Provides therapy through the provision of information

Note

All new applications will need to meet the new classification rules from **25 February 2021**, with a transition period ending **1 November 2024.**

If the regulatory changes result in the r**e-classification** of a software-based medical device that is currently included in the ARTG, you are able to access **transition arrangements** that will allow you to **continue supplying the device** while you apply to **include it in the ARTG under the new, higher classification**. More information about these arrangements can be found under what you need to do.

Diagnosis or screening

For software-based medical devices that provide a diagnosis or screen for a disease or condition, the classification depends on whether the device provides the diagnosis/screening directly, or whether a relevant health professional makes the diagnosis using information provided by the device.

This rule covers both software-based medical devices intended to be used for:

- the **screening** of apparently healthy, asymptomatic individuals to detect disease, abnormalities or risk factors
- the **diagnosis** of unwell individuals to determine a cause for symptoms.

The second part of this rule differentiates when it is intended the information is provided to a **relevant** health professional for the purposes of diagnosis.

The term 'relevant' describes the health professional with the appropriate expertise that uses the provided information to assist them in making a diagnosis; the information provided by a medical device under this classification rule is not to be solely relied upon for the diagnosis.

For example, a relevant health professional for diagnosis and treatment recommendations for certain forms of cancer would be an oncologist, whereas a general practitioner would not be considered to be a relevant health professional in that case. However, a general practitioner could be a relevant health professional for diagnosing other sorts of diseases and conditions.

This rule also considers how *serious* the disease or condition that is being screened or diagnosed. *Serious* has the meaning defined in the Therapeutic Goods (medical Devices) Regulations:

serious, for a condition, ailment or defect, means a condition, ailment or defect that is:

a. generally accepted as not being appropriate to be diagnosed or treated without consulting a medical practitioner, dentist or other kind of health care worker registered under a law of a State or Territory; or

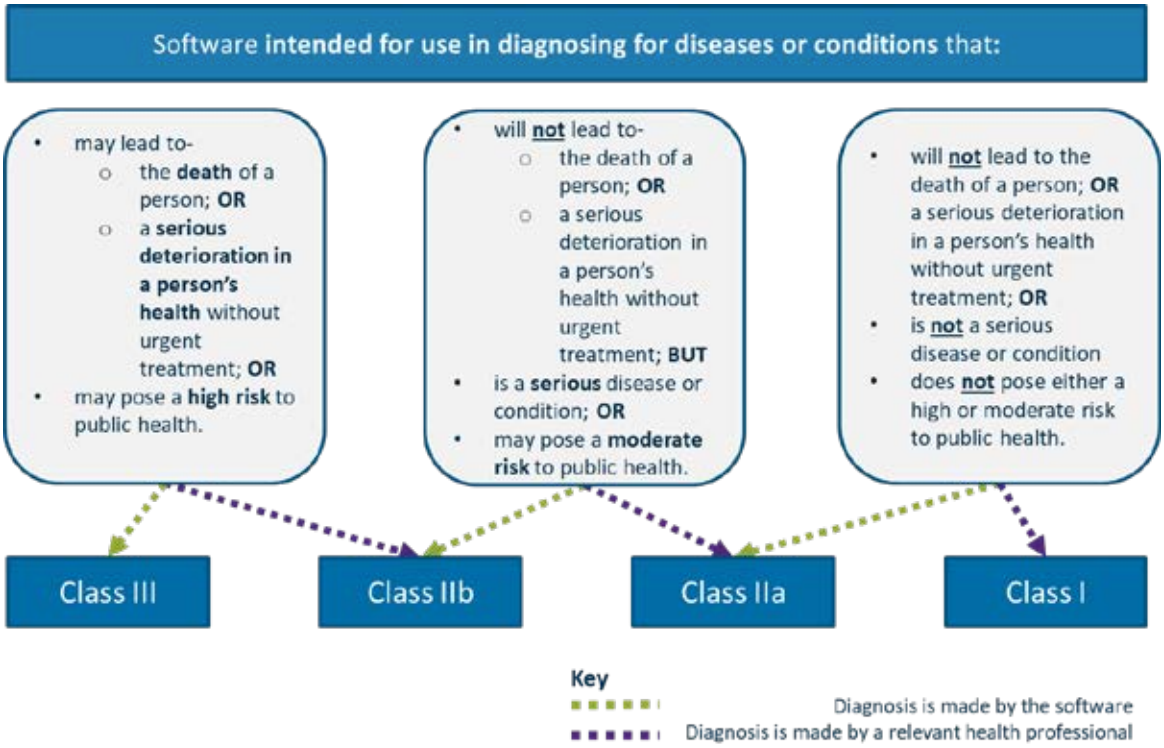
b. generally accepted to be beyond the ability of the average person to evaluate accurately, or treat safely, without supervision by a medical practitioner, dentist or other kind of health care worker registered under a law of a State or Territory.

serious disease means a disease that:

a. may result in death or long-term disability; and

b. may be incurable or require major therapeutic interventions; and

c. must be diagnosed accurately, to mitigate the public health impact of the disease.



Software intended for use in diagnosing for diseases or conditions that may lead to various consequences

Examples

A software developer has produced software that performs an analysis of a photo of a patient's skin, providing information intended to be used to make a diagnosis of malignant melanoma.

Scenario 1

The software is intended to provide the diagnosis to a **relevant health professional** only. The instructions for use reflect the intended purpose and the software package is only sold to specialist healthcare facilities.

In this instance the software-based medical device is a **Class IIb medical device** as the device provides information to **a relevant health professional** so that they can diagnose **a serious disease that may lead to the death, or a severe deterioration in the state of a person's health, without urgent treatment**.

Scenario 2

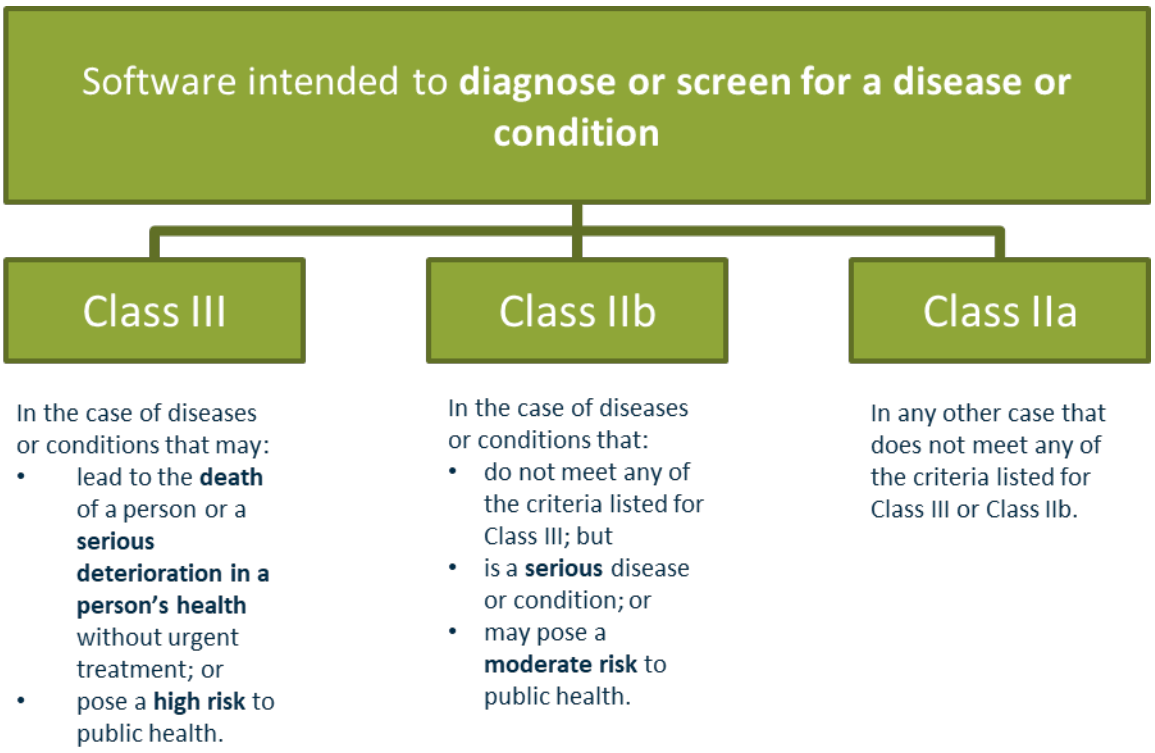
There are no restrictions on the sale of the software, which can be used by anyone who has access to the results of a cardiac MRI to provide an analysis of the results and diagnosis.

In this instance the software would be a **Class III medical device** as it is intended by the manufacturer (the software developer) to provide a diagnosis for a serious disease to someone other than a relevant health professional, such as any member of the general public.

Software performs diagnosis or screening

A software-based medical device that is a medical device intended to provide a diagnosis or screen for a disease or condition will be classified as:

2. **Class III if the disease or condition may:**
    a. lead to the death of a person without urgent treatment
    b. lead to a severe deterioration in the state of a person's health without urgent treatment
    c. pose a high risk to public health.
3. **Class IIb if 1. does not apply, but the disease or condition:**
    a. is a serious disease or serious condition
    b. may pose a moderate risk to public health.
4. **Class IIa if 1. and 2. do not apply.**



Classification of software intended to diagnose or screen for a disease or condition

Example

A software developer has produced an app that performs an analysis of images of a patient's rash, providing information to the user for the purposes of screening for measles.

In this instance the software-based medical device is a **Class IIb medical device** as the software **screens for a disease** that:

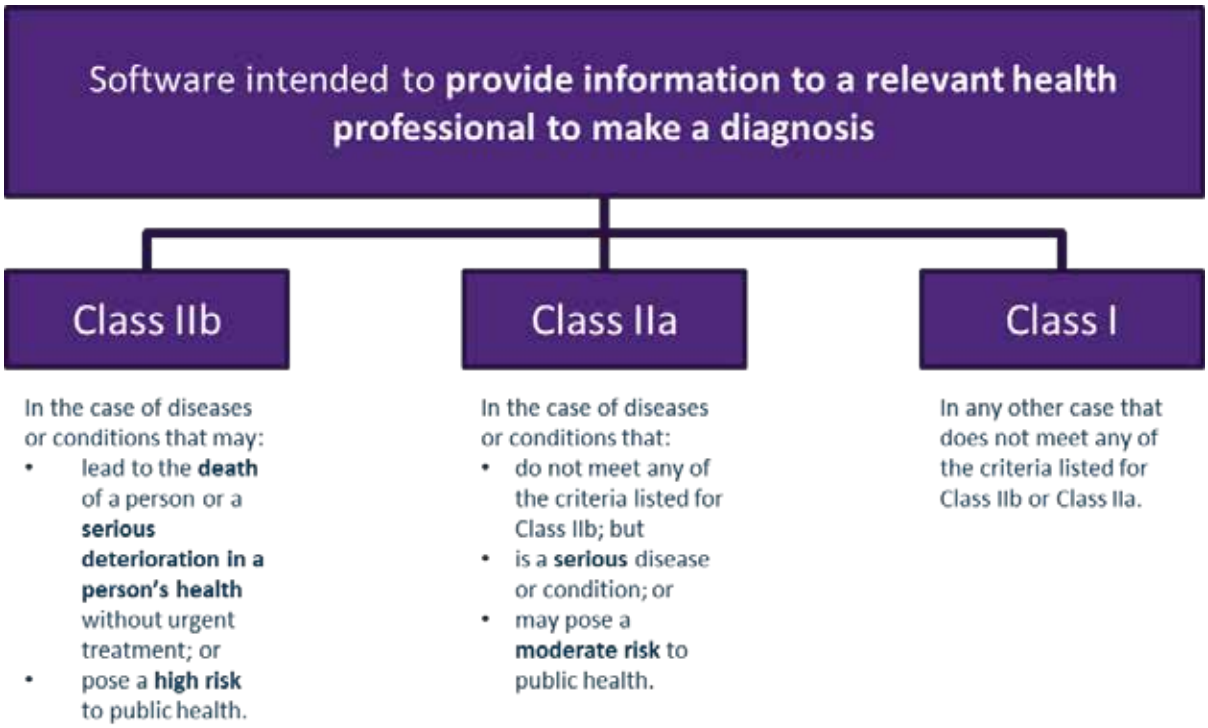
- is a serious disease or serious condition
- may pose a moderate risk to public health.

A relevant health professional performs the diagnosis

A software-based medical device that is intended to provide information to a relevant health professional so they can diagnose a disease or condition will be classified as:

1. **Class IIb if the disease or condition may:**
    a. lead to the death of a person without urgent treatment
    b. lead to a severe deterioration in the state of a person's health without urgent treatment
    c. pose a high risk to public health.

2. **Class IIa if 1. does not apply, but the disease or condition:**
    a. is a serious disease or serious condition
    b. may pose a moderate risk to public health.
3. **Class I if 1. and 2. do not apply.**



Classification of software intended to provide information to a relevant health professional for diagnosis

Example

A software developer has produced software that performs an analysis of a patient's angiogram, providing information to a **relevant health professional** (e.g. a vascular surgeon) so they can make a diagnosis of acute arterial occlusion.

In this instance the software-based medical device is a **Class IIb medical device** as the device **provides information to a health professional** so they can **diagnose a disease** that **may lead to the death or a severe deterioration in health of an individual without urgent treatment.**

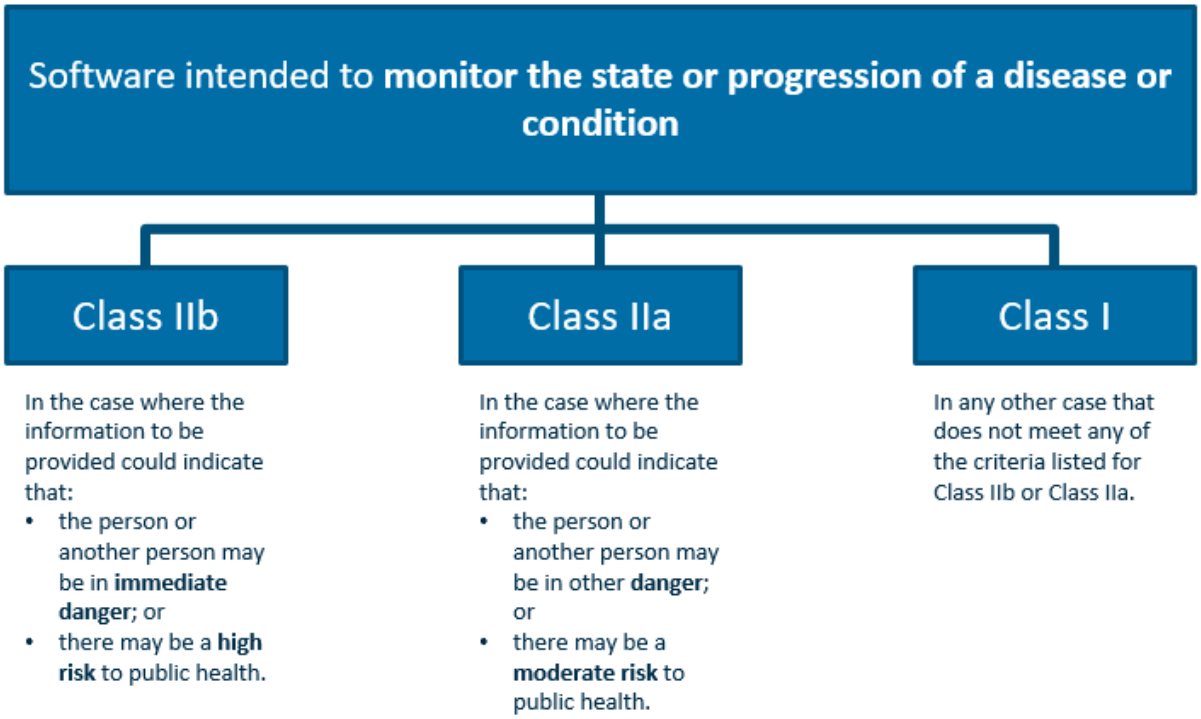
Monitoring

For software-based medical devices intended to provide information to monitor the state or progression of a disease or condition, the classification depends on both the potential risk to public health and whether the information could indicate if a person is in 'danger'. The Macquarie dictionary defines danger as "liability or exposure to harm or injury; risk; peril". This rule considers both:

- immediate danger (danger occurring without delay)
- other danger (i.e. danger that is not immediate)

A software-based medical device that is intended to provide information to monitor the state or progression of a disease or condition, or the parameters in relation to the person will be classified as:

1. **Class IIb where the information could indicate:**
    a. the person who has the disease or condition is in immediate danger
    b. another person may be in immediate danger
    c. there may be a high risk to public health.
2. **Class IIa where the information could indicate:**
    a. the person with the disease or condition is in danger, but not immediate
    b. another person, may be in danger that is not immediate
    c. there may be a moderate risk to public health.
3. **Class I if 1. and 2. do not apply.**



Software intended to monitor the state or progression of a disease or condition

Example

A software developer has produced a cloud-based, deep learning neural network that monitors patient recovery from shingles (herpes zoster) using uploaded images of shingles rashes.

The product can be accessed by health professionals or consumers – allowing real-time monitoring of recovery with or without oversight from a health professional.

In this instance the software-based medical device is a **Class I medical device** as:

- it is intended to monitor the state or progression of a disease
- the information provided does not indicate if an individual may be in danger
- there is a low public health risk.

Specification or recommendation of a treatment or intervention

For software-based medical devices intended to specify or recommend a treatment or intervention, the classification depends on whether the device specifies or recommends the treatment or intervention, or whether the device recommends the treatment or intervention to a relevant health professional so that they may decide whether or not to action the recommendation using information provided by the device.

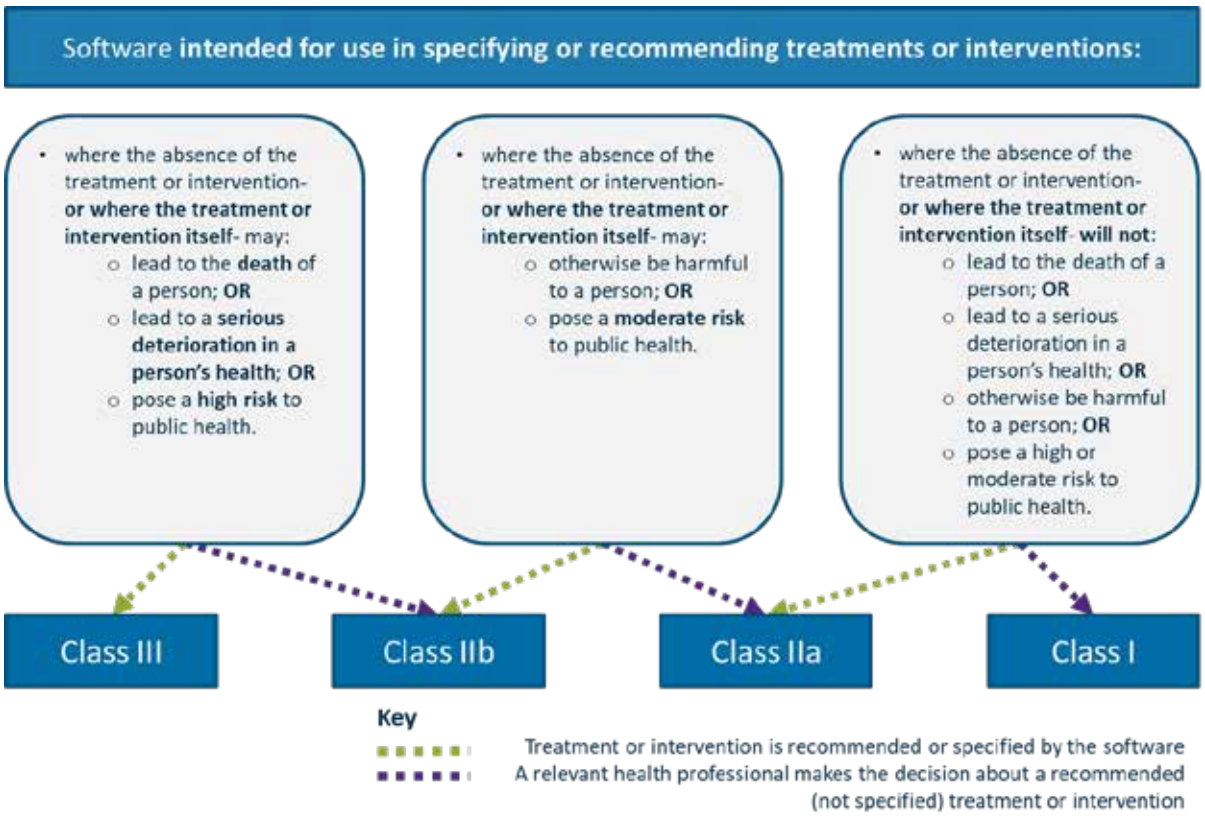
This rule covers both software-based medical devices intended to:

- directly *specify* a treatment or intervention (the software makes the decision)
- *recommend* a treatment or intervention (the user makes the decision)

The second part of this rule differentiates when it is intended to recommend (but does not *specify*) a treatment or intervention to a relevant health professional for the purposes that health professional deciding whether or not to action the recommendation.

The term 'relevant' describes the health professional with the appropriate expertise that uses the provided information to assist them in making a decision about the treatment; the information provided by a medical device under this classification rule is not to be solely relied upon for the proposed treatment. For example, a relevant health professional for performing a hip replacement would be an orthopaedic surgeon, whereas a general practitioner would not be considered to be a relevant health professional in that case. However, a general practitioner could be a relevant health professional for treating other sorts of diseases and conditions.

This rule also references an intervention that may be 'harmful' to a person, other than causing the death of a person or a severe deterioration in the state of a person's health. The Macquarie dictionary defines 'harm' as: "injury; damage; hurt: *to do someone bodily harm*". Under this rule, software will be class I if the treatment or intervention (or its absence) cannot cause harm.

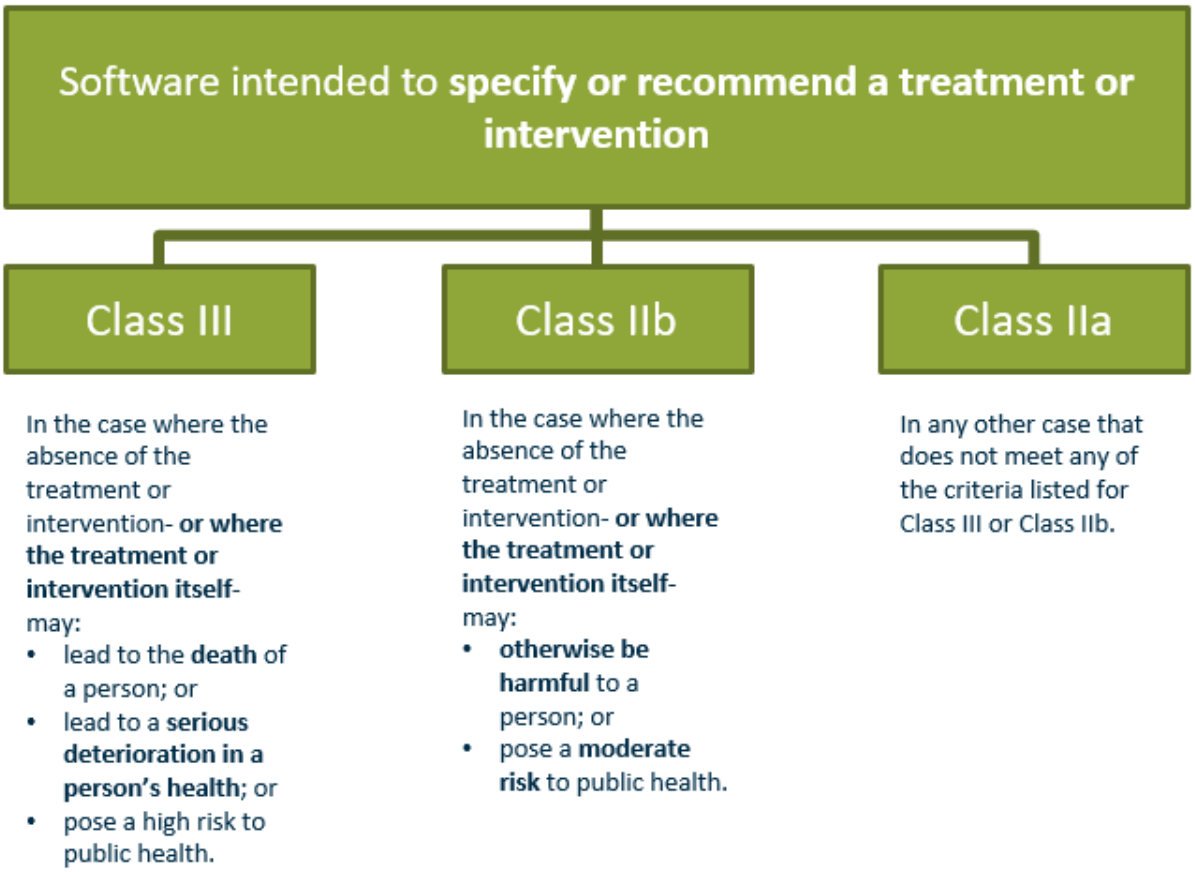


Software intended for use in specifying or recommending treatments or interventions

Software specifies or recommends a treatment or intervention

A software-based medical device that is intended to specify or recommend treatment or intervention will be classified as:

1. **Class III where the treatment or intervention, or the absence of the treatment or intervention may:**
    a. lead to the death of a person
    b. lead to a severe deterioration in the state of a person's health
    c. pose a high risk to public health.
2. **Class IIb where the treatment or intervention, or the absence of the treatment or intervention:**
    a. may be otherwise harmful to a person
    b. may pose a moderate risk to public health.
3. **Class IIa if 1. and 2. do not apply.**



Software intended to specify or recommend a treatment or intervention

Example

A software developer produces software intended to perform an analysis of a patient's coronary angiogram then, based on the results of the analysis, specifies coronary artery bypass grafting surgery as the appropriate treatment.

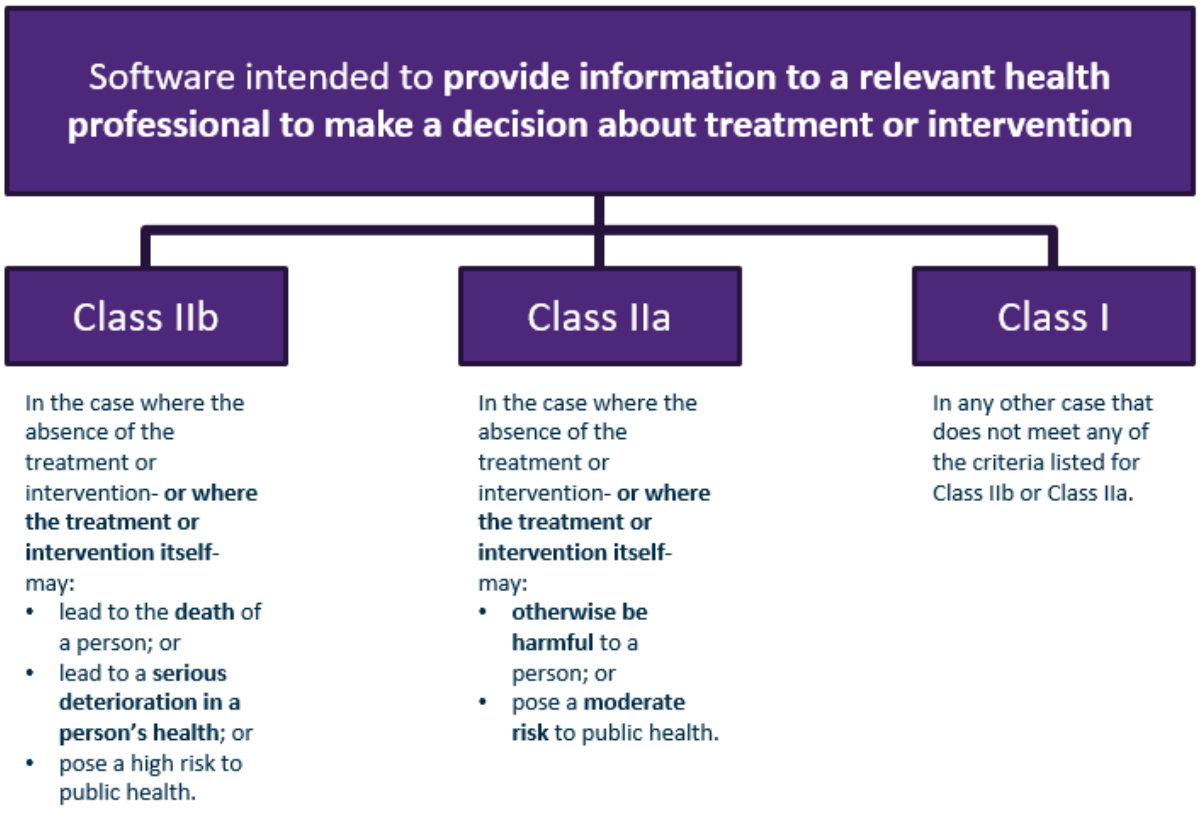
This software is a **Class III medical device** as:

- it is intended to specify a treatment or intervention
- the absence of this treatment, or the treatment itself, may lead to the death or a severe deterioration in health of an individual.

Software recommends a treatment or intervention to a relevant health professional

A software-based medical device that is intended to recommend a treatment or intervention to a health professional so the health professional can make a decision about a treatment or intervention will be classified as:

1. **Class IIb where the treatment or intervention, or the absence of the treatment or intervention may:**
    a. lead to the death of a person
    b. lead to a severe deterioration in the state of a person's health
    c. pose a high risk to public health.
2. **Class IIa where the treatment or intervention, or the absence of the treatment or intervention:**
    a. may be harmful to a person
    b. may pose a moderate risk to public health.
3. **Class I if 1. and 2. do not apply.**



Software intended to provide information to a relevant health professional to make a decision about treatment or intervention

Example

A software developer produces software intended to perform an analysis of a patient's coronary angiogram and, based on the results of the analysis, provides a recommendation to a cardiac surgeon to perform coronary artery bypass grafting surgery.

This software is intended only to be used by a relevant health professional (e.g. a cardiac surgeon).

This software is a **Class IIb medical device** as it:

- is intended to recommend a treatment or intervention to a relevant health professional for the purposes of that health professional making a decision about the treatment or intervention; and
- is a case where the absence of this treatment, or the treatment itself, may lead to the death or a severe deterioration in health of an individual.

Information as therapy

For software-based medical devices intended to provide therapy through the provision if information, the classification depends on the potential to cause harm to the person using the information. For this rule, four levels of harm are referred to:

- harm that may result in the death of a person or a severe deterioration in the state of a person's health
- serious harm
- harm that is not serious and will not harm that may result in the death of a person or a severe deterioration in the state of a person's health
- no harm

The Macquarie dictionary defines 'harm' as: "injury; damage; hurt: *to do someone bodily harm*".

'Serious' has the same meaning as defined in the Therapeutic Goods (medical Devices) Regulations.

A software-based medical device intended to provide therapy to a person through the provision of information will be classified as:

1. **Class III if the therapy may result in:**
    a. the death of the person
    b. a severe deterioration in the state of their health.
2. **Class IIb if both:**
    a. 1. does not apply

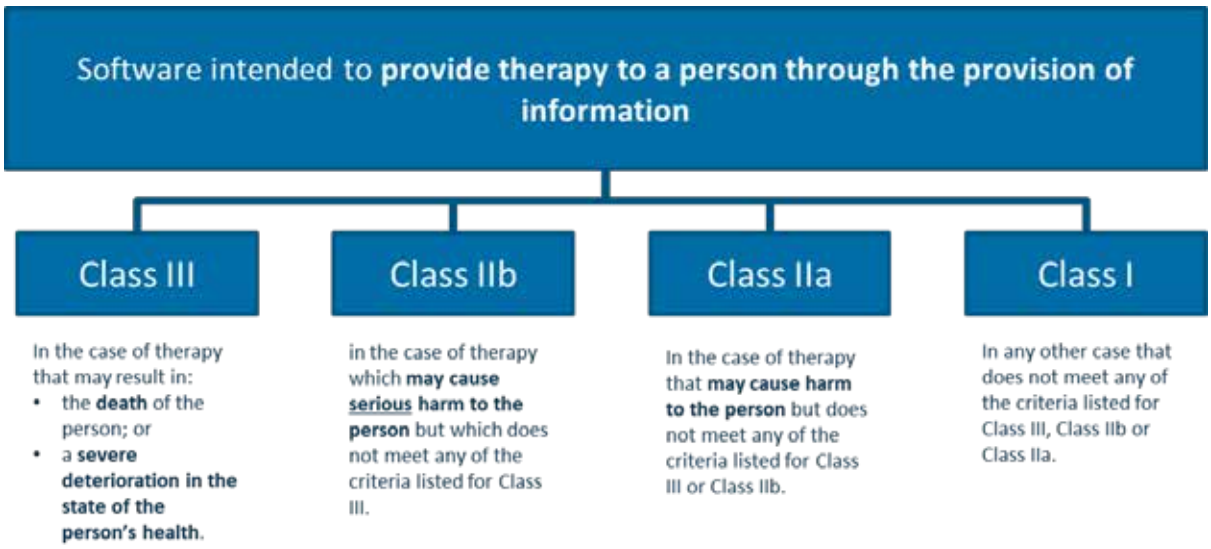
b. the therapy may result in serious harm to the person.

3. **Class IIa if both:**

   a. 1. and 2. do not apply

   b. the therapy may cause harm to the person.

4. **Class I if 1. 2. and 3. do not apply.**



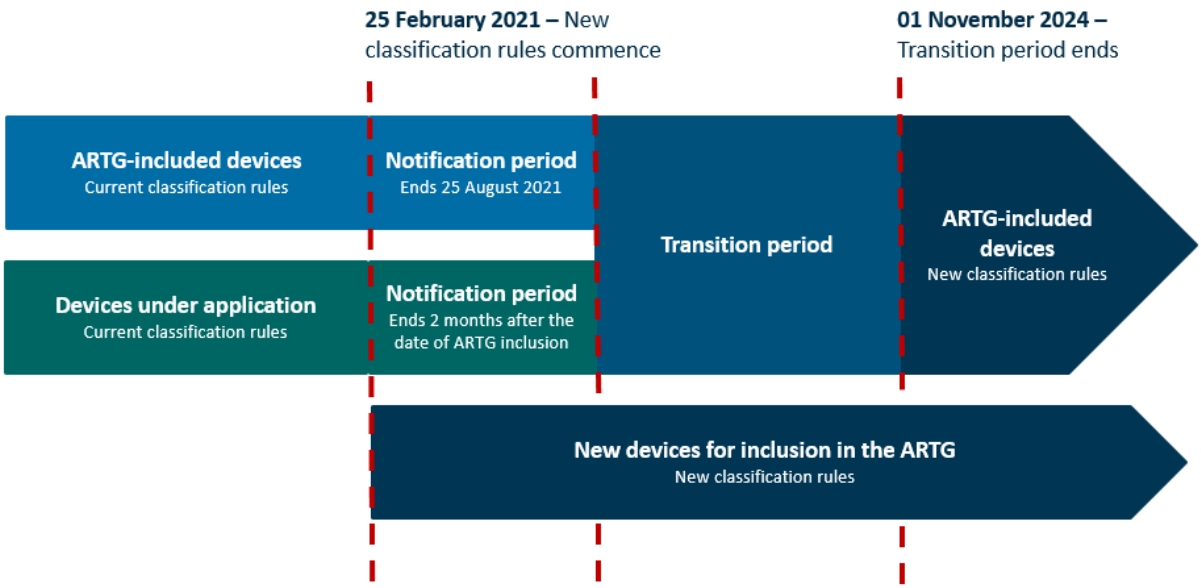
Software intended to provide therapy to a person through the provision of information

What you need to do

The changes to the classification rules for software-based medical devices commenced on **25 February 2021.** All applications for inclusion of software-based medical devices in the ARTG made after this date must meet these classification rules.

For sponsors and manufacturers of devices included in the ARTG that will need to be included at a higher classification as a result of the amendments to the *Therapeutic Goods (Medical Devices) Regulations 2002*, transition arrangements apply.

The transition period (ending **1 November 2024**) applies to sponsors of eligible medical devices already included in the ARTG or included in the ARTG because of an **application lodged before 25 February 2021**.



Timeframe for changes to the new classification rules for software-based medical devices

To be eligible to continue to supply your eligible medical devices under the transition arrangements, you must:

- Notify the TGA via that you have an eligible inclusion by whichever is the later date:
  - Before 25 August 2021
  - Within 2 months of the start date of your ARTG entry

  AND
- Obtain the appropriate evidence of conformity assessment, (see How the TGA regulates software for further information)
- Submit an application for your medical device to be included in the ARTG under the new classification rules **before 1 November 2024**.

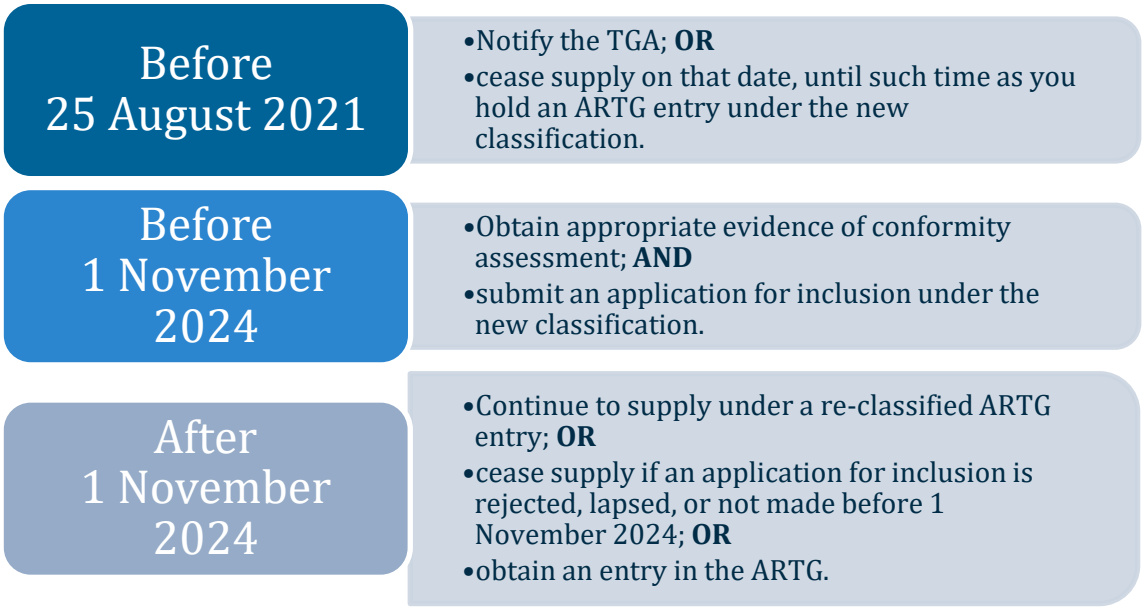
Note

If you do not notify the TGA of your medical devices **before 25 August 2021**, you must **cease supplying the medical device from 25 August 2021**.

If you notify the TGA you have a device that must transition to a higher classification **before 25 August 2021,** you must **submit an application** for inclusion **before 1 November 2024.**

If you **do not submit your application by 1 November 2024**, you must **cease supply** on or before this date and cancel your inclusion.

If your application for inclusion is rejected you are no longer eligible for the transition arrangements and must cease supplying your device immediately and consider cancelling your inclusion.



Notifying the TGA

If you have identified that you need to notify the TGA you have an ARTG inclusion for a software-based medical device to be reclassified, you must notify the TGA using the online form available here.

The following information is required for the notification:

- the ARTG inclusion number for the medical device
- for Class III medical devices, the unique product identifier for each medical device.

You must notify the TGA by the 25 August 2021 or 2 months after the start day of the ARTG entry, whichever is the later date.

Changes to the Essential Principles

To supply a medical device in Australia, the sponsor or manufacturer must be able to demonstrate their medical devices meet the relevant Essential Principles.

From the *Therapeutic Goods Act 1989*

41C The Essential Principles set out the requirements relating to the safety and performance characteristics of medical devices.

Schedule 1 of the *Therapeutic Goods (Medical Devices) Regulations 2002* describes the Essential Principles in full.

There are 6 general Essential Principles that apply to all medical devices. There are a further nine Essential Principles about design and construction that apply to medical devices on a case-by-case basis.

From **25 February 2021** the following changes that will impact programmed or programmable medical devices or software that is a medical device will be made to the **essential principles:**

- **Essential Principle 12.1** is amended to clarify the existing requirements for:

  - cyber security
  - the management of data and information
  - requirements relating to development, production, and maintenance.

- **Essential Principle 13.2(3)** is amended to allow information to be provided electronically rather than on a leaflet.
- A new essential principle, **Essential Principle 13B**, will be introduced requiring the current version and build number for the software to be made accessible and identifiable to users of software-based medical devices. This information must be in English, however may also be displayed in other languages.

Note

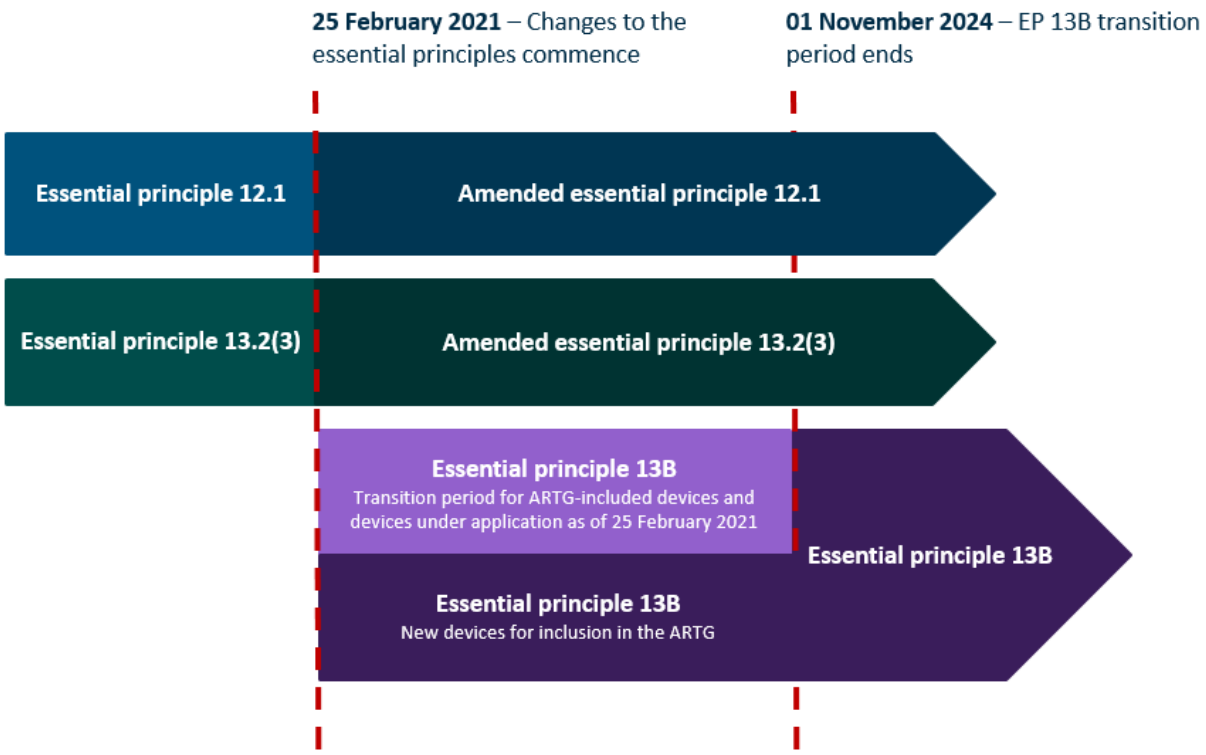
Transition arrangements are available for medical devices already included in the ARTG in order to meet the new requirements imposed by the introduction of **Essential Principle 13B, as** explained in what you need to do.

There are **no transition arrangements available** for medical devices included in the ARTG for **Essential Principles 12.1 and 13.2(3)** as these changes are clarification of **existing requirements** and are **not new requirements.**

What you need to do

Medical devices included in the ARTG as a result of an **application made before 25 February 2021** are **automatically eligible for the transition period** allowing them to continue being supplied without meeting **Essential Principle 13B** until **1 November 2024**.

All new applications for inclusion of a software-based medical device made on or after 25 February 2021 must comply with Essential Principle 13B.



Summary of transition provisions for the new essential principles

Where can I find more information?

Therapeutic Goods Legislation Amendment (2019 Measures No.1) Regulations 2019 provides an overview of the amendments to the Medical Device Regulations.

The Australian Regulatory Guidelines for Medical Devices provides links to a range of medical device related information, including a step-by-step guide to the medical device inclusion process.

What if I have further questions?

You can contact the TGA via digital.devices@health.gov.au.

SME Assist is a dedicated service the TGA provides to assist small to medium enterprises (SMEs), researchers, start-ups and those unfamiliar with regulation to understand their regulatory and legislative obligations.

The Medical Device Information Unit is an information hotline that can provide you with assistance on devices-related inquiries.

Version history

Version	Description of change	Author	Effective date
V1.0	Original draft	Devices Emerging Technology & Diagnostics Section	January 2021
V1.1	Include links for clinical decision support guidance	Devices Emerging Technology & Diagnostics Section	February 2021
V1.2	Update – finalise draft	Devices Emerging Technology & Diagnostics Section	August 2021

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