Australian Government
Department of Health
Therapeutic Goods Administration

How the TGA regulates software-based medical devices

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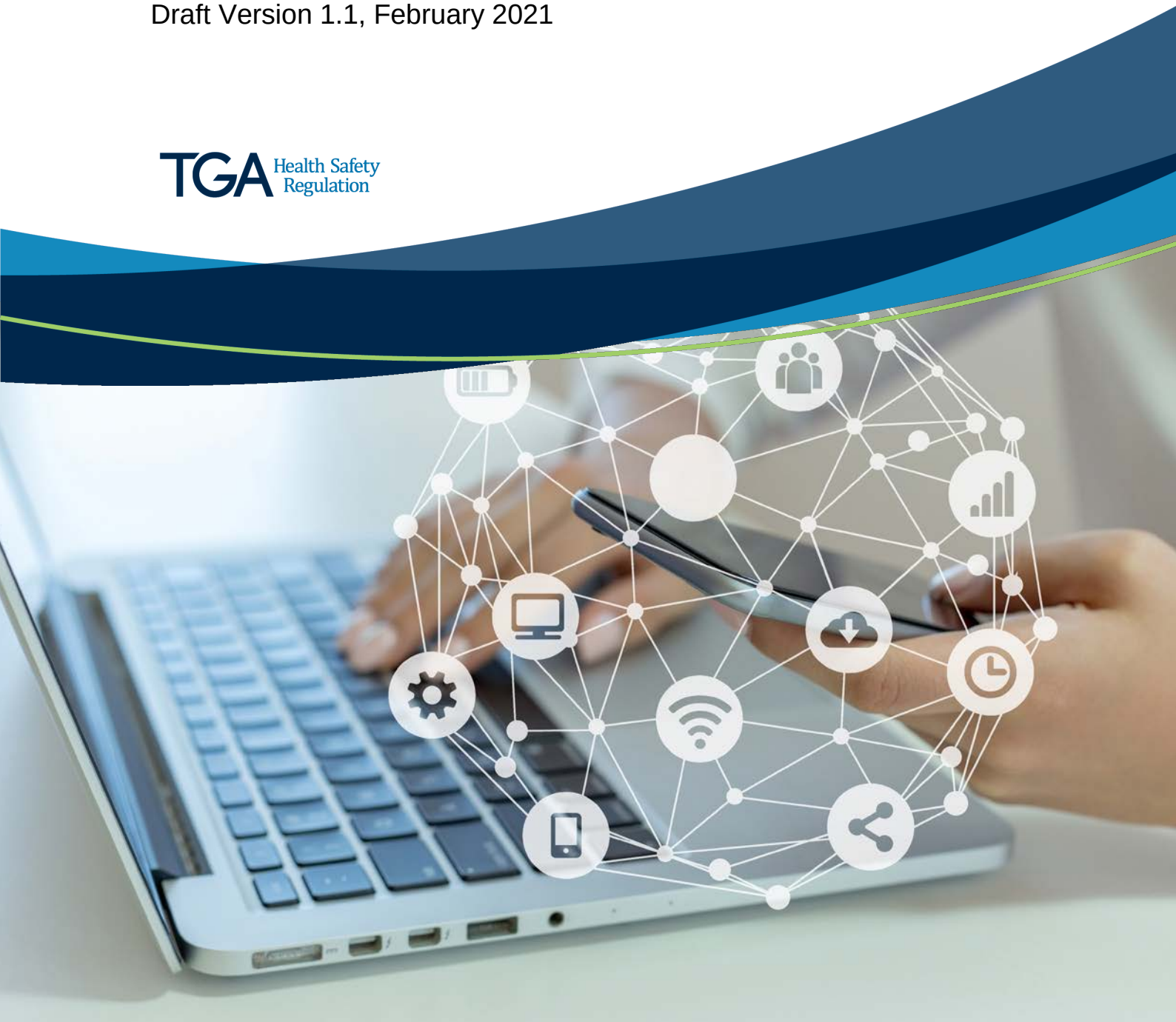
TGA Health Safety Regulation



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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.

This document will evolve over time and updates and clarifications will be included as required. Feedback on the guidance is always welcome, please send any comments to digital.devices@tga.gov.au.

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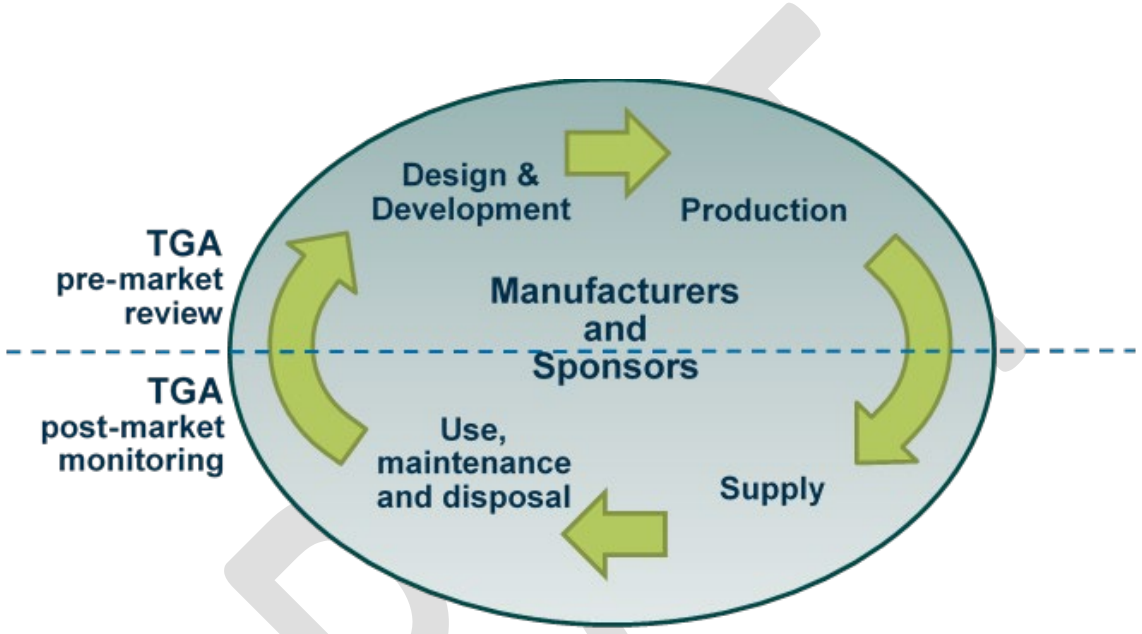
About this guidance

This guidance summarises the regulatory approach of the Therapeutic Goods Administration (TGA) for software based medical devices.

The TGA regulates medical devices in Australia, including software and mobile apps that meet the definition of a medical device. If a software product is a medical device, it must be included in the Australian Register of Therapeutic Goods (ARTG), unless it is exempt, before it can be legally supplied in Australia.

The role of the TGA spans the entire medical device lifecycle, from market authorisation before it is supplied through to post-market monitoring and review of medical devices already on the market to ensure these devices continue to meet regulatory requirements.



Overview of the lifecycle of a medical device

The TGA is a member of the International Medical Device Regulators Forum (IMDRF). The IMDRF is a voluntary group of medical device regulators from around the world who work collaboratively on convergence of regulatory approaches, including working together on emerging regulatory challenges. Australia's approach to the regulation of software-based devices is based on the approach of the IMDRF and is aligned with other international regulators where possible.

TGA regulation of software products

The TGA regulates medical devices in Australia, including software and mobile apps that meet the definition of a medical device, unless otherwise excluded.

A software product is a medical device if it falls within the definition of a medical device under section 41BD of the *Therapeutic Goods Act 1989*. It is the responsibility of the manufacturer to determine if their product is a medical device.

For more information refer to Overview of medical devices and IVD regulation.

These software products are also increasingly known as 'digital' technologies; they may function on either general computing platforms (such as computers, mobile phones or tablets), or require specialised hardware to perform their intended function.

The TGA also regulates in vitro diagnostic (IVD) medical device software. IVD software is regulated differently to other medical device software and is not covered here. See Software as in vitro diagnostic medical devices (IVDs) for more information.

Many software products, including some mobile apps, are simply sources of information or tools to manage a healthy lifestyle. The TGA does not regulate health and lifestyle apps or software that does not meet the definition of a medical device.

Recent reforms have been implemented to clarify the boundary of regulated software products, including a number of exclusions and an exemption for specific types of software products.

See Is my software regulated?, Examples of regulated and unregulated (excluded) software based medical devices and Clinical Decision Support Software for further information on determining if your software is regulated.

Software as a Medical Device

The term Software as a Medical Device (or SaMD) refers to software that can function on, for example, a laptop computer, smartphone or tablet, and has an intended purpose consistent with the definition of a medical device. This could be any kind of software, including but not limited to: computer programs and applications, mobile apps, software as a service (cloud based), websites and browser delivered products.

Software would generally be a medical device if it is intended to be used for:

- diagnosis, prevention, monitoring, prediction, prognosis or treatment of a disease, injury or disability
- compensation for an injury or disability
- investigation of the anatomy or of a physiological process
- to control conception

Note: Monitoring in this instance refers specifically to the active, clinical monitoring of a disease, injury or disability. For example, this definition does not include software for indirect monitoring activities such as regularly reviewing an individual's health records to determine if they meet the criteria to participate in a screening program for a particular disease, or they are due for a particular medical assessment.

Some SaMD may be a accessory to a medical device. Accessories are regulated as separate medical devices.

Examples:

- An example of SaMD is software that takes user input, such as a questionnaire, and uses this information to diagnose a particular condition or disease.
- A mobile phone app that connects via Bluetooth to a blood pressure cuff to obtain readings used to track the blood pressure in the individual wearing the cuff. This is a medical device as it is intended to be used to monitor symptoms related to a disease (such as hypertension).

Software that is part of a device

Software can be part of a device when it is integral to the functioning of that device. This software is sometimes referred to as SiMD (software in a medical device) and is usually supplied with the hardware device. The TGA regulates this software as part of that device.

Example:

The embedded software or firmware in a cardiac pacemaker is regulated as a component of that pacemaker, because it is supplied as part of the device and is necessary for the device to function.

Software that controls a medical device

Some software, including mobile apps, can control or adjust a medical device through a connection, either physical or utilising wireless technology such as Bluetooth or WiFi features.

Where software drives or influences a medical device, the software has the same classification as the medical device.

Software or an accessory to a medical device is a medical device in its own right if it is supplied separately from the related device.

Example:

- Pacemaker programmer and controller software for use on a personal computer or laptop.
- An instance of cochlear implant configuration/optimisation software for use on a personal computer or laptop.

Key regulations

The TGA regulates software under the existing medical device framework. The legislation forming the basis for the regulation of medical devices in Australia is:

- the *Therapeutic Goods Act 1989* (the Act)

- the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Regulations)

Chapter 4 of the Act relates to medical devices and is intended to ensure the safety and satisfactory performance of medical devices.

The **classification rules, essential principles** and **conformity assessment procedures**, are set out in the Regulations.

Parties subject to regulation

There are typically two key parties involved in supplying medical devices in Australia: manufacturers and sponsors.

A **manufacturer** is the person or company taking legal responsibility for the manufacture of a medical device (the name on the label, or the name under which the product is supplied). The manufacturer of a medical device is responsible for the design, production, packaging and labelling of the device, but does not necessarily need to perform these activities themselves.

Example:

A service provider wants to publish some software under their name, but outsource design and development of the software to a third party developer. In this case, the service provider maintains responsibility for these aspects, and publishes the software under their name. This makes the service provider the manufacturer.

The manufacturer is responsible for obtaining conformity assessment certification for the medical devices they manufacture (other than class I medical devices). Manufacturers may choose to obtain this from the TGA or from a comparable overseas regulator.

A person or company is the manufacturer of a medical device if they supply a ready-made product under their name where they, for example, have assigned the device their own intended purpose, or repackaged the device.

A **sponsor** is the person or company legally responsible for supplying devices in Australia, or exporting medical devices out of Australia.

The manufacturer–sponsor relationship is not necessarily always one-to-one. There may be many sponsors supplying the same model of device from one manufacturer, and the sponsor can also supply devices from multiple manufacturers at the same time.

Regulatory pathway

Medical devices must be included in the Australian Register of Therapeutic Goods (ARTG) before being supplied in Australia—unless otherwise the subject of an exemption, approval, or authority under the Act. Information on the inclusion process is available here.

As part of this process, the TGA may accept evidence from comparable overseas regulators, such as certificates issued by notified bodies under European Union medical device regulatory frameworks. The process for including software based medical devices in the ARTG is the same as for other medical devices.

Please note

Evidence of manufacturer's certification is not necessarily required for all Class I devices. However, manufacturers will need to complete a declaration of conformity that their devices comply with the regulatory requirements.

The TGA regulatory pathway to supply medical devices in Australia can be broadly divided into three steps:

Step 1 is for the manufacturer of the medical device to obtain certification from the TGA or a comparable oversees regulator. This is not required for manufacturers of class I (non-sterile) medical devices.

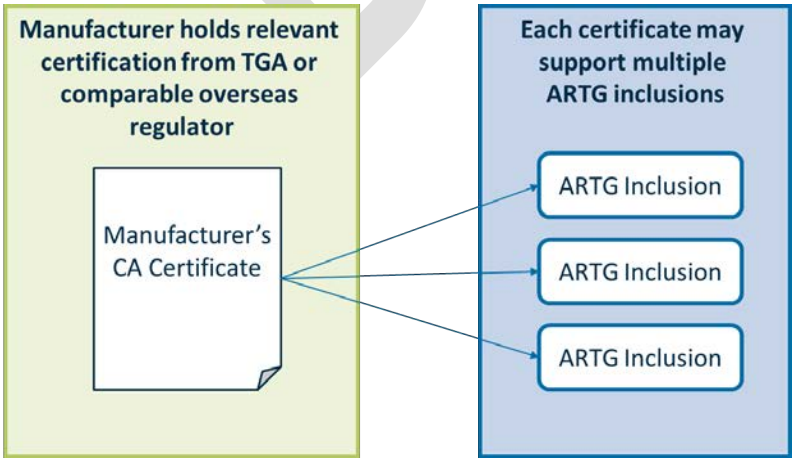
Step 2 is the sponsor of the medical device to submit the manufacturer's certificate to the TGA, in preparation to submit an ARTG application.

Step 3 is for the sponsor to submit the ARTG inclusion application. For applications supported by a TGA certification and for low risk devices, the application is relatively administrative.

Overview of the TGA regulatory pathway for medical devices

The manufacturer may obtain conformity assessment certification (step 1) from a comparable overseas regulator, such as certificates issued by notified bodies under European Union medical device regulatory frameworks.

The manufacturer's evidence of conformity (step 2) can be used to support multiple ARTG inclusions:



Using evidence of conformity to support multiple ARTG inclusions

Conformity assessment requirements are detailed further below.

The importance of intended purpose

The TGA regulates software in different ways depending on the manufacturer's **intended purpose** for the software, and how it is supplied:

- The manufacturer specifies the intended purpose of the medical device. The manufacturer specifies how they *intend* for the device to be used, not all possible ways it could potentially be used. For example, two apps with similar functionality could have different intended purposes:
  - An app intended by the manufacturer only to measure and display a person's heart rate for fitness purposes
  - An app may be intended by the manufacturer to measure and display a person's heart rate to detect bradycardia or tachycardia
- The intended purpose is included in any documentation provided with the device. This documentation can be hard copy or electronic, such as on a website and includes:
  - instructions for use,
  - any advertising material,
  - labelling (if applicable), and
  - technical documentation.
- For regulatory purposes, the intended purpose determines the **classification** of the device and minimum **conformity assessment** procedures.
- The manufacturer must comply with these procedures for inclusion of the device in the ARTG, which is the authorisation to supply the product in Australia.

Classification rules

There is a four-tier classification system for medical devices:

- Class I (lowest classification)
- Class IIa
- Class IIb
- Class III (highest classification)

The higher the classification of the device, the higher the level of regulatory scrutiny.

The classification rules are specified in the *Therapeutic Goods (Medical Devices) Regulations 2002* and the principles for applying them are provided under Part 3, Division 3.1, Regulation 3.3— Principles for applying the classification rules.

The particular principles that need to be considered are the following:

- If a medical device is designed to be used in combination with another medical device, each of the devices is classified separately.
- An accessory to a medical device is classified separately from the medical device.

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- If a medical device is driven, or influenced, by an item of software, the software has the same classification as the medical device.

There are a number of classification rules that may apply to software based medical devices. They can be found in Schedule 2 of the Regulations, in particular Parts 4 and 5. For classification purposes all software is an active medical device.

New rules from 25 February 2021

The Regulations were amended in December 2019 to include new classification rules for software-based medical devices—referred to as "programmed, programmable, and software medical devices", noting these rules do not apply to IVDs. These rules come into effect on **25 February 2021.** Transitional arrangements are in place for sponsors and manufacturers of medical devices that are included in the ARTG prior to **25 February 2021** (see 'Regulatory changes for software based medical devices' for further information).

The rules specifically consider potential harm caused by providing incorrect information to users of these medical devices.

The new rules consider medical devices intended for:

- diagnosing or screening for a disease or condition
- monitoring the state or progression of a disease, condition, etc.
- specifying or recommending a treatment or intervention
- providing therapy (via provision of information)

Please note

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

Specific classification rules apply to IVDs, which can be found in schedule 2A of the Regulations.

The majority of medical devices are supplied in Australia on the basis of EU certification. The Australian classification rules for software based medical devices are broadly aligned with the EU classifications. In most cases, the Australian classification will be the same or lower. If the classification of a device is higher in the EU, the certification can still be used to support an application for a lower risk device in Australia.

The Australian classification rules differ from the EU in that they consider:

- Whether the software is intended to provide information to a *relevant healthcare professional* for diagnosing, screening or recommending a treatment/intervention for a disease or condition. If software is intended for use by a relevant healthcare professional it will be a lower classification than if it was intended to be used by an individual (i.e., non-health professional). In most cases, this will result in such software being a lower classification than what it might be in the EU.

  The term 'relevant' describes a health professional with the appropriate expertise to understand and use the provided information to assist them in making a diagnosis or formulating a treatment plan. For example, a relevant health professional for cancer diagnosis and treatment would be an oncologist. However, a general practitioner could be a relevant health professional for diagnosing other sorts of diseases and conditions.

- Public health risk. In most cases, the classification will be the same as the in the EU except where the risk to public health is higher than that to an individual.
- The risk of harm associated with devices intended to provide therapy through the provision of information. Depending on the intended purpose of the software, these devices may be Class I or higher in Australia.

Summary of the new rules and examples

The new Australian classification rules are summarised in Table 1 below.

For further information on the classification rules for software and how they apply, see Regulatory changes for software based medical devices.

Summary of the new classification rules for software based medical devices

Summary of the new classification rules for software based medical devices			
		Diagnosing and/or recommending treatment or intervention for a disease or condition	
		Provides information to an individual	**Provides information to a health professional**
Risk to individual or public health	**Death/severe deterioration/high public health risk**	Class III	Class IIb
	Serious disease or condition/otherwise harmful/moderate public health risk	Class IIb	Class IIa
	Any other case	Class IIa	Class I
		screening and/or specifying a treatment or intervention for a disease or condition	
	Death/severe deterioration/high public health risk	Class III	
	Serious disease or condition/otherwise harmful/moderate public health risk	Class IIb	
	Any other case	Class IIa	

Summary of the new classification rules for software based medical devices		
		Monitoring the state/progression of a disease or condition
	Immediate danger to a person/high public health risk	Class IIb
	Other danger to a person or another/moderate public health risk	Class IIa
	Any other case	Class I
		For providing therapy through provision of information
	May result in death/ severe deterioration	Class III
	May cause serious harm	Class IIb
	May cause harm	Class IIa
	Any other case	Class I

For the rules in more detail, please refer to Classification Rules. The following are some examples of these classification rules applied.

Example 1 – real-time recovery monitoring of shingles recovery

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** (according to rule 4.6(c)) as:

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

Example 2 – diagnosis of aortic valve stenosis

A software developer has produced software that performs an analysis of a patient's cardiac MRI, providing information intended to be used to make a diagnosis of aortic valve stenosis.

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 IIa medical device** (according to rule 4.5(2)(a)(i)) as the device provides information to a **relevant health professional** so that they can diagnose a **serious disease**.

Example 3 – diagnosis of acute arterial occlusion

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** (according to rule 4.5(2)(a)(i)) as the device **provides information to a relevant health professional** so they can **diagnose a disease** that **may lead to the death** or a **severe deterioration** in the health of an individual without urgent treatment.

Example 4 – Specify surgical treatment

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 (according to rule 4.7(1)(a)(i)) 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 the health of an individual.

Example 5 – screening for measles

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** (according to rule 4.5(1)(d)) as the **software screens for a disease** that **may pose a moderate risk to public health.**

Conformity Assessment Procedures

The conformity assessment procedures set out the regulatory requirements placed on the manufacturer of a medical device, and include:

- controls around manufacture (design and construction) of medical devices
- keeping and maintaining records
- managing complaints and recalls.

The classification of the medical device determines the minimum conformity assessment procedures that must be applied (followed) by the manufacturer.

The manufacturer follows the procedures in order to demonstrate conformity with safety and performance principles (the Essential Principles). This principles-based approach provides flexibility for manufacturers in demonstrating compliance and supports different technologies and technological advances over time.

The degree of regulatory authority oversight of a manufacturers' compliance varies according to the classification of the medical device and the manufacturer's intended purpose for the medical device. The higher the classification of the medical device the higher the level of regulatory scrutiny. Manufacturers of all medical devices, including software-based medical devices, supplied in Australia must:

- meet the minimum conformity assessment certification requirements appropriate to the level of classification of devices being manufactured
- have evidence that demonstrates compliance of their medical devices with the relevant essential principles.

There are different conformity assessment procedures that correspond to the different levels of oversight required for each medical device classification. Conformity assessment procedures provides a summary of the requirements for each of the conformity assessment procedures.

For more information on conformity assessment, see the Australian regulatory guidelines for medical devices (ARGMD).

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.

Changes from February 2021

The *Therapeutic Goods (Medical Devices) Regulations 2002* were amended in December 2019 to improve the clarity of requirements. The changes come into effect on **25 February 2021**:

- **Essential Principle 12.1** was amended to clarify the requirements in more detail around applicable devices, including as relates to cyber security; the management of data and information; and requirements relating to development, production, and maintenance.
- **Essential Principle 13.2(3)** was amended to allow information, where applicable, to be provided electronically rather than on a leaflet for software-based medical devices.
- **Essential Principle 13B** was introduced as a new requirement requiring the identification of current version and build number to be made accessible by and identifiable to, users of medical devices that are, or that incorporate, software. This information must appear in English, and can be displayed in any other language as well.

See Essential Principles for the complete text of the amended and new essential principles.

Transition arrangements are available for medical devices already included in the ARTG in order to meet the new requirements of Essential Principle 13B.

For more information refer to Regulatory changes for software based medical devices.

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

What to consider

Software developers

Software developers may not consider themselves to be manufacturers in the traditional sense. Developers of software will be a manufacturer for regulatory purposes, when their products fall within the definition of a therapeutic good or medical device, and they meet the definition of manufacturer under the *Therapeutic Goods Act 1989.*

Manufacturers of software-based medical devices, including SaMD, are required to apply the relevant conformity assessment procedures, according to the classification of their medical devices, including implementing a quality management system (if applicable). This means that conformity assessment evidence from a recognised third party (such as the TGA or a comparable overseas regulator) will be required for all medical devices, except Class I medical devices. The manufacturer will be required to apply for third-party certification and, once received, maintain

its currency through complying with post-market requirements such as annual inspections by the issuing agency.

Australian manufacturers of software-based medical devices will also be required to include their medical devices in the ARTG and to comply with the requirements for maintaining the inclusion.

The majority of manufacturers of Class I medical devices are self-certified and applications for inclusion in the ARTG are processed with no confirmatory assessment undertaken by the TGA. Manufacturers of Class IIa, Class IIb or Class III medical devices must obtain conformity assessment certification from an independent body (for example, from an EU notified body or the TGA) prior to an application for inclusion in the ARTG. Manufacturers of Class III medical devices are also required to have the design of their devices examined by the conformity assessment certification body.

Supplier or reseller

If you supply software-based medical devices, you must determine whether you would be either the sponsor or manufacturer of the medical device for the purposes of regulation – see Who is subject to regulation?

Sponsors

Sponsors of software-based medical devices will be required to include these medical devices in the ARTG, and to comply with the requirements for maintaining the inclusion.

Sponsors of software-based medical devices already included in the ARTG

Sponsors of software-based medical devices already included in the ARTG need to reassess the classification of their device(s) according to the proposed new classification rules. This may result in some devices being reclassified at a higher level.

In this case, sponsors must ensure the manufacturers of the devices they represent hold conformity assessment evidence from a recognised third party (such as the TGA or a notified body) and, to lodge this evidence with the TGA. They must also submit new applications for inclusion in the ARTG according to the new classification of the device(s).

Please also refer to the information on transition arrangements in Regulatory changes for software based medical devices regarding the notification of existing ARTG inclusions.

Manufacturers

Developers of software will be a manufacturer for regulatory purposes, when their products fall within the definition of a therapeutic good or medical device, and they meet the definition of manufacture under the *Therapeutic Goods Act 1989*.

Manufacturers of software-based medical devices, including SaMD, must apply the relevant conformity assessment procedures, according to the classification of their medical devices, including implementing a quality management system (if applicable). This means conformity assessment evidence from a recognised third party (such as the TGA or a comparable overseas regulator) is required for all devices, except Class I medical devices. The manufacturer must apply for third-party certification and, once received, maintain its currency through complying with post-market requirements such as annual inspections by the issuing agency.

Australian manufacturers of software-based devices must also include their medical devices in the ARTG, and comply with the requirements for maintaining the inclusion.

The majority of manufacturers of Class I medical devices are self-certified and applications for inclusion in the ARTG are processed automatically with no assessment undertaken by the TGA.

Manufacturers of Class IIa, Class IIb or Class III medical devices must obtain conformity assessment certification from an independent body (for example, from a EU notified body the TGA) prior to an application for inclusion in the ARTG. Manufacturers of Class III medical devices must also have the design of their devices examined by the conformity assessment certification body.

Manufacturers of software-based devices already included in the ARTG

Manufacturers of software-based medical devices already included in the ARTG must reassess the classification of their device(s) according to the new classification rules. This may result in some devices being reclassified at a higher level, requiring the manufacturers to hold conformity assessment evidence from a recognised third party (such as the TGA or a notified body). Australian manufacturers must also lodge any new third party conformity assessment evidence with the TGA and, submit new applications for inclusion in the ARTG according to the new classification of the device(s).

Please also refer to the information on transition arrangements in Regulatory changes for software based medical devices.

For more information about applying for TGA conformity assessment certification see Conformity assessment.

Health professionals

Health professionals using software-based devices may want to consider the following:

Is the device on the ARTG?

It is a regulatory requirement that all medical devices be included in the Australian Register of Therapeutic Goods (ARTG) before being supplied in Australia—unless otherwise the subject of an exemption, approval, or authority under the *Therapeutic Goods Act 1989*.

You can search the ARTG for the device.

How can I find more information on a device?

It is a regulatory requirement that specific information be provided with a medical device (printed information supplied on or with the device or packaging, or electronically), including but not limited to information identifying:

- the device
- the manufacturer's name and address
- the sponsor's name and address
- explaining how to use the device safely
- the intended purpose of the device.

If you require further information about a particular device, you should contact the sponsor or manufacturer in the first instance.

How I can report if something goes wrong?

Sometimes there are unintended and harmful occurrences associated with the use of a medical device. These are referred to as 'adverse events', and include problems or incidents involving medical devices.

Examples of adverse events are any unfavourable and unintended sign, symptom or disease associated with the use of a medical device. An abnormal laboratory finding could be one example of an unfavourable and unintended sign.

In the case of medical devices, an adverse event can also be a problem or incident that has caused, or could cause, harm to patients, caregivers, health professionals or others. These can include 'near misses' – events that might have led to a death or serious injury. It may be that timely intervention from a health professional prevented an adverse event.

If you have experienced an adverse event, you can make a report to the TGA via the website.

For more information refer to Reporting adverse events.

Consumers

Consumers using software-based devices may want to consider the following:

Is the device on the ARTG?

It is a regulatory requirement that all medical devices be included in the Australian Register of Therapeutic Goods (ARTG) before being supplied in Australia—unless otherwise the subject of an exemption, approval, or authority under the *Therapeutic Goods Act 1989*.

You can search the ARTG on the web here.

How can I find more information on a device?

It is a regulatory requirement that specific information be provided with a medical device (printed information supplied on or with the device or packaging, or electronically), including but not limited to information identifying:

- the device
- the manufacturer's name and address
- the sponsor's name and address
- explaining how to use the device safely
- the intended purpose of the device.

If you require further information about a particular device, you should contact the sponsor or manufacturer in the first instance.

How I can report if something goes wrong?

If you have any issues, problems or questions relating to your use of a medical device, you should seek advice from a health professional.

Sometimes there are unintended and harmful occurrences associated with the use of a medical device. These are referred to as 'adverse events', and include problems or incidents involving medical devices.

Examples of adverse events are any unfavourable and unintended sign, symptom or disease associated with the use of a medical device.

In the case of medical devices, an adverse event can also be a problem or incident that has caused, or could cause, harm to patients, caregivers, health professionals or others. These can include 'near misses' – events that might have led to a death or serious injury. It may be that timely intervention from a health professional prevented an adverse event.

If you have experienced an adverse event, you can make a report to the TGA via the website.

For more information refer to Reporting adverse events.

Where to find more information

For more information on the amendments to the Regulations refer to *Therapeutic Goods Legislation Amendment (2019 Measures No.1) Regulations 2019*.

Additional guidance on the amendments, including on the new classification rules, may be found on the TGA website.

Contact us

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

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

Definitions

There are a number of terms with specific meaning in the *Therapeutic Goods Act 1989* for the purposes of regulation used in this document. Some other terms are used in the legislation that are not specifically defined.

Accessory – From section 3 of the *Therapeutic Goods Act 1989:* ***accessory***, in relation to a medical device covered by paragraph 41BD(1)(a), (aa) or (ab), means a thing that the manufacturer of the thing specifically intended to be used together with the device to enable the device to be used as the manufacturer of the device intended.

Australian Register of Therapeutic Goods (ARTG or the Register)

In vitro diagnostic (IVD) medical device – What is an IVD medical device?

Digital – For the purpose of this guidance, this term relates to the use of computer technology. (See also Macquarie Dictionary).

Manufacturer – Manufacturer of a medical device

Medical device – What is a medical device?

Programmed or programmable medical device or software that is a medical device (PPSMD) – This is the specific term used in the Regulations to refer to any medical device that is, or has the ability to be, programmed. It includes software based medical devices and programmable hardware.

SaMD – This is a term in general use globally; it typically means stand-alone software that has a therapeutic purpose. In Australia, a software product is considered a medical device if it fits the definition of a medical device in section 41BD of the *Therapeutic Goods Act 1989.* The term is used by the following international regulators:

The IMDRF define SaMD as "software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device".

This term is used in some jurisdictions to refer to regulated software based medical devices. For example, the US FDA uses SaMD to refer to a subset of software they regulate. Other terms are software that is integral to a medical device (Software in a Medical Device or SiMD), and software used in the manufacture or maintenance of a medical device.

The EU uses the term 'Medical Device Software (MDSW)' which it defines as "Medical device software is software that is intended to be used, alone or in combination, for a purpose as specified in the definition of a "medical device" in the medical devices regulation or in vitro diagnostic medical devices regulation".

Software based devices – This term is used in this guidance to refer to all medical devices that incorporate or are software, including SaMD (Software as a Medical Device) or software that relies on particular hardware to function as intended.

Sponsor – sponsor of therapeutic goods

Classification Rules

The classification rules can be found in full at schedules 2 and 2A of the *Therapeutic Goods (Medical Devices) Regulations 2002.*

4.5 Programmed or programmable medical device or software that is a medical device for use in relation to diagnosing or screening for a disease or condition

1. A programmed or programmable medical device, or software that is a medical device, that is intended by the manufacturer to be used to:
    a. provide a diagnosis of a disease or condition; or
    b. screen for a disease or condition;

is classified as:

    c. in the case of a disease or condition that:
        i. may lead to the death of a person, or a severe deterioration in the state of a person's health, without urgent treatment; or
        ii. may pose a high risk to public health;

Class III; or

    d. in the case of a serious disease or serious condition or a disease or condition that may pose a moderate risk to public health, and where paragraph (c) does not apply—Class IIb; or
    e. in any other case—Class IIa.

2. A programmed or programmable medical device, or software that is a medical device, that is intended by the manufacturer to be used to provide information to a relevant

health professional for the purposes of the health professional making a diagnosis of a disease or condition:

a. in the case of a disease or condition that:

i. may lead to the death of a person, or a severe deterioration in the state of a person's health, without urgent treatment; or

ii. may pose a high risk to public health;

is classified as Class IIb; or

b. in the case of a serious disease or serious condition or a disease or condition that may pose a moderate risk to public health, and where paragraph (a) does not apply—is classified as Class IIa; or

c. in any other case—is classified as Class I.

4.6 Programmed or programmable medical device or software that is a medical device for use for monitoring the state or progression of a disease or condition etc.

A programmed or programmable medical device, or software that is a medical device, that is intended by the manufacturer to be used to provide information that is to be used for monitoring the state or progression of a disease or condition of a person or the parameters in relation to a person:

a. in the case where the information to be provided could indicate that the person or another person may be in immediate danger or that there may be a high risk to public health—is classified as Class IIb; or

b. in the case where the information to be provided could indicate that the person or another person may be in other danger or that there may be a moderate risk to public health—is classified as Class IIa; or

c. in any other case—is classified as Class I.

4.7 Programmed or programmable medical device or software that is a medical device for use in specifying or recommending treatment or intervention

1. Subject to subclause (2), a programmed or programmable medical device, or software that is a medical device, that is intended by the manufacturer to be used to specify or recommend a treatment or intervention:

a. in the case where the absence of the treatment or intervention or where the treatment or intervention itself:

i. may lead to the death of a person or a severe deterioration in the state of a person's health; or

ii. may pose a high risk to public health;

is classified as Class III; or

b. in the case where the absence of the treatment or intervention or where the treatment or intervention itself:

i. may otherwise be harmful to a person; or

ii. may pose a moderate risk to public health;

is classified as Class IIb; or

c. in any other case—is classified as Class IIa.

2. A programmed or programmable medical device, or software that is a medical device, that is intended by the manufacturer to be used to recommend a treatment or intervention (the ***recommended treatment or intervention***) to a relevant health professional for the purposes of the health professional making a decision about the treatment or intervention:

   a. in the case where the absence of the recommended treatment or intervention or where the recommended treatment or intervention itself:

      i. may lead to the death of a person or a severe deterioration in the state of a person's health; or

      ii. may pose a high risk to public health;

      is classified as Class IIb; or

   b. in the case where the absence of the recommended treatment or intervention or where the recommended treatment or intervention itself:

      i. may otherwise be harmful to a person; or

      ii. may pose a moderate risk to public health;

      is classified as Class IIa; or

   c. in any other case—is classified as Class I.

4.8 Programmed or programmable medical device or software that is a medical device that is to provide therapy to a person through the provision of information

A programmed or programmable medical device, or software that is a medical device, that is intended by the manufacturer to provide therapy to a person through the provision of information to the person:

a. in the case of therapy that may result in the death of the person or a severe deterioration in the state of the person's health—is classified as Class III; or

b. in the case of therapy that may cause serious harm to the person and where paragraph (a) does not apply—is classified as Class IIb; or

c. in the case of therapy that may cause harm to the person and where neither paragraph (a) nor (b) applies—is classified as Class IIa; or

d. in any other case—is classified as Class I.

Essential Principles

The essential principles can be found in full at schedule 1 of the *Therapeutic Goods (Medical Devices) Regulations 2002.*

12.1 Programmed or programmable medical device or software that is a medical device

1. A programmed or programmable medical device, or software that is a medical device, that is intended to make use of either or both of data and information must be designed and produced in a way that ensures that:

   a. the safety, performance, reliability, accuracy, precision, useability, security and repeatability of the device are appropriate for the intended purpose of the device; and

b. any consequent risks, or impairment of performance, associated with one or more fault conditions is eliminated or appropriately reduced; and

c. the device is resilient with respect to interactions that could occur during the use of the device and that could result in unsafe performance of the device; and

d. if relevant to the safety of a patient, or the safety and health of the user or any other person, the device provides suitable warnings in a timely manner:

   i. following the disruption to services upon which the device is dependent for the device's operation; and

   ii. following the performance of the device being adversely affected; and

e. if relevant to the safety of a patient, or the safety and health of the user or any other person, the device provides a means by which the user can verify correct operation of the device; and

f. if relevant to the safety of a patient, or the safety and health of the user or any other person, the integrity and quality of the data or information is maintained; and

g. if relevant, the privacy of the data or information is maintained.

2. A programmed or programmable medical device, or software that is a medical device, must be developed, produced and maintained having regard to the generally acknowledged state of the art (including for design, development life cycle, development environment, version control, quality and risk management, security, verification and validation, change and configuration management and problem resolution).

3. A programmed or programmable medical device, or software that is a medical device, that is intended to be used in combination with computing platforms must be designed and developed taking into account the capability, resources and configuration of the platforms and the external factors (including information technology environments) related to the use of the platforms.

4. The manufacturer of a programmed or programmable medical device, or software that is a medical device, must provide instructions or information with the device that sets out requirements (including requirements about hardware, software, information technology environments and security measures) necessary to operate the device as intended.

5. A programmed or programmable medical device, or software that is a medical device, must be designed, produced and maintained with regard to best practice in relation to software, security and engineering to provide cybersecurity of the device, including where appropriate the following:

   a. protection against unauthorised access, unauthorised influence or unauthorised manipulation;

   b. minimisation of risks associated with known cybersecurity vulnerabilities (including either or both of remediation of known vulnerabilities and application of compensating controls);

   c. facilitation of the application of updates, patches, compensating controls and other improvements;

   d. disclosure of known vulnerabilities in the device or its components and associated mitigations;

e. making available sufficient information for a user to make decisions with respect to the safety of applying, or not applying, updates, patches, compensating controls and other improvements.

6. The manufacturer of a programmed or programmable medical device, or software that is a medical device, having regard to the intended purpose of the device, the generally acknowledged state of the art and best practice, must ensure that the data that influences the performance of the device is:

   a. representative; and

   b. of sufficient quality; and

   c. maintained to ensure integrity; and

   d. managed to reduce bias.

There are particular requirements for information to be provided with software based products included in essential principle 13:

13.2 Information to be provided with medical devices—location

3. If it is not practicable to comply with subclause (1) or (2) in relation to the provision of the information required under subregulation 10.2(1) or clause 13.3:

   a. for a medical device that is not software—the information must be provided on a leaflet supplied with the device; or

   b. for a medical device that is software—the information must be provided on a leaflet supplied with the device or the information must be provided electronically.

13B Software—version numbers and build numbers

1. For a medical device that is software, or that incorporates software, the current version number and current build number of the software must be accessible by, and identifiable to, users of the device.

2. The current version number and current build number of the software:

   a. must be in English; and

   b. may also be in any other language

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Conformity Assessment Procedures

The conformity assessment procedures can be found in full at schedule 3 of the *Therapeutic Goods (Medical Devices) Regulations 2002* and are summarised below:

Conformity assessment procedures, requirements and applicable classifications

CA procedure	Requirements	Applicable classifications
Part 1, Full quality assurance procedure Encompasses design, production, packaging, labelling, and final inspection of a medical device	Manufacturer must implement a full quality management system (that is, all clauses of ISO 13485 including clauses 7.3 and 7.5.2) and arrange for the quality management system to be audited by the TGA or EU Notified Body. The TGA or EU Notified Body also assesses the manufacturer's technical documentation for the medical devices, including clinical evidence.	All Please note: for class III, clause 1.6 must also be applied
Part 1, Clause 1.6, Examination of Design Involves an examination of the design dossier for medical devices to which the manufacturer has applied a Part 1 conformity assessment procedure	The technical documentation for the Class III device (also referred to as a design dossier) must be submitted for examination to assess the compliance of the device with the Essential Principles.	Class III
Part 2, Type examination Involves an examination of a representative sample of a medical device	Testing can be conducted by the TGA or EU Notified Body, OR The TGA or EU Notified Body can conduct tests on the device at the manufacturer's site and supervise or review the testing, OR The TGA or EU Notified Body will subcontract the testing to an accredited test laboratory (either in Australia or overseas).	Class IIb, Class III

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CA procedure	Requirements	Applicable classifications
Part 3, Verification Procedures Involves an examination (including testing) of the medical device(s) prior to release for supply	The TGA or EU Notified Body will need to assess production records for each device (either on a statistical basis or a 100% sampling rate) and authorise release of the product or batch of products for supply.	Class I (measuring), Class IIa, Class IIb, Class III, Please note: can not be used for sterile devices
Part 4, Production quality assurance A quality management system encompassing the production and final inspection of a medical device	Manufacturer must implement a quality management system (i.e. all clauses of ISO 13485 excluding clause 7.3 but including clause 7.5.2) and arrange for the quality management system to be audited by the TGA or an EU Notified Body. The TGA or EU Notified Body also reviews a sample of the manufacturer's technical documentation for the devices.	Class I (measuring and/or sterile), Class IIa, Class IIb, Class III,
Part 5, Product quality management system A system encompassing the final inspection and testing of a medical device	Manufacturer must implement a quality management system (that is, ISO 13485 excluding clauses 7.3 and 7.5.2) and arrange for the quality management system to be audited by the TGA or a EU Notified Body. The TGA or EU Notified Body also reviews a sample of the manufacturer's technical documentation for the devices.	Class I (measuring), Class IIa, Class IIb Please note: can not be used for sterile devices
Part 6, Declaration of Conformity (not requiring assessment by Secretary) Preparing technical documentation for a medical device and establish a post-market monitoring system	Manufacturer ensures that the device(s) comply with the Essential Principles and prepares documentation that demonstrates conformity.	Class I, Class I (measuring and/or sterile), Class IIa
Part 7, Conformity Assessment Procedures for devices used for a Special Purpose	Applies to custom-made medical devices, systems and procedure packs	All *Please note: sterile systems and procedure packs also require Part 4 certification*

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CA procedure	Requirements	Applicable classifications
Part 8, Clinical Evaluation procedures	The conformity assessment procedures the manufacturer must follow for obtaining and evaluating clinical data.	All

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Version history

Version	Description of change	Author	Effective date
Draft V1.0	Original draft	Devices Emerging Technology & Diagnostics	January 2021
Draft V1.1	Added link to clinical decision support software guidance	Devices Emerging Technology & Diagnostics	February 2021

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