

Information for NSW Health staff

TGA Medical Device Reforms

Software-based medical devices (including software as a medical device)

In Australia, software-based medical devices are those that either contain software, are entirely software, or depend on specific hardware to function correctly. Software, such as mobile applications (apps), qualify as a medical device if they meet the criteria outlined in section 41BD of the *Therapeutic Goods Act 1989*, unless explicitly exempted.

Software is classified as a medical device when the manufacturer intends for its products to be used for diagnosis, prevention, monitoring, treatment or alleviation of a disease, injury or disability. These encompass a wide range of products: from health monitoring apps, artificial intelligence (AI), cloud, complex diagnostic algorithms, through to software that runs a medical device.

With the rise of software-based medical devices including AI, the Australian Government's Therapeutic Goods Administration (TGA) has implemented medical device reforms to address the unique challenges and opportunities presented by these innovations.

Changes to the regulation of software as a medical device (SaMD) take effect from 1 November 2024.

What is the “intended purpose” of the software?

This means what the software's:

- core function is (what it does; for example, monitors cardiac rhythm)
- desired purpose or outcome is (what it intends to achieve; for example, to diagnose, alert and/or treat a cardiac dysrhythmia).

Depending on the intended purpose, a particular software could be:

- SaMD – regulated by the TGA.
- excluded or exempt software-based medical devices or consumer health software – these are not officially regulated by the TGA.

Refer to the TGA's [flowchart](#) if you are unsure if your software is regulated.

What is regulated software?

- Digital software. That is, any software running on computing platforms such as computers, tablets, smartphones, and browsers.
- SaMD. If software is an integral component of a medical device, it is regulated as part of that device. For example, software that runs the ventilation component of a ventilator – this controller software is pre-loaded on the ventilator.

- Apps controlling a medical device. Apps that control a medical device are regulated either as an accessory or as a device itself.
- Apps relying on medical device hardware. That is, apps that depend on medical device hardware, in addition to a general computing platform (for example, sensors).

SaMD follows a four-tier classification system based on the level of harm it may pose to users or patients, in the same way all medical devices are classified.

Class	Examples
I (low risk)	• Software that consists of a deep learning neural network that monitors patient recovery from shingles (herpes zoster) using uploaded images of shingles rashes.
IIa (medium)	• Diabetes diagnosis software. • Software that records an image directly from an MRI scanner. • Risk-prediction software that analyses blood pressure information for a health practitioner to assist them in diagnosing hypertension.
IIb (medium-high risk)	• Cardiac MRI analyser. • Software intended to perform analysis of a coronary angiogram and based on the results of the analysis, provides a recommendation to a cardiac surgeon to perform coronary artery bypass grafting surgery. • A wearable device that analyses the wearer's cardiac rhythm for the purpose of screening for a serious heart condition.
III (high risk)	• Software intended to perform an analysis of a consumer's coronary angiogram and based on the results of the analysis, specifies coronary artery bypass grafting surgery as the appropriate treatment. • A consumer smartphone app that takes an image of a mole or lesion to screen for and detect malignant melanoma. • Software for programming an implanted pacemaker.

Software excluded from the TGA regulation:

If the software has any of the following functions, it is excluded and not regulated by the TGA.

- Consumer health products – prevention, management and follow up devices that do not provide specific treatment or treatment suggestions; for example, a “sun smart” app.
- Enabling technology intended to support telehealth, remote diagnosis, healthcare, or dispensing.
- Digitisation of paper-based or other published clinical rules or data. including simple dose calculators and Electronic Patient Records (eMR).
- Population-based analytics that do not drive outcomes for individuals.
- Laboratory Information Management Systems that automate workflows, integrate instruments, manage orders and samples, and associated information.
- Some aspects of clinical decision support software; for example, if they are not intended to replace health professional judgement in making a diagnosis or treatment decision.

For further information, and assistance in defining if your software is regulated, please refer to [Regulation of software based medical devices | Therapeutic Goods Administration \(TGA\)](#).

The **Clinical Excellence Commission** is supporting NSW Health staff through the reforms. Visit its dedicated page at www.cec.health.nsw.gov.au/keep-patients-safe/medical-device-governance-program. Email enquiries to cec-medicaldevicegovernance@health.nsw.gov.au



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SHPN (CEC) 240486, 4 July 2024