

AUSTRALIA Regulatory

Category Name	Software-based medical devices
Responsible Regulatory Agency	Therapeutic Goods Administration (TGA) TGA Regulation of software-based medical devices . General medical device enquiries: devices@tga.gov.au TGA's Digital Devices team: digital.devices@tga.gov.au
Product Risk Classification	<p>Classification of active medical devices (including software-based medical devices): Class I, Class IIa, Class IIb, Class III</p> <p>Multiple classification rules may apply for any given medical device. The device will be classified at the highest applicable classification. Devices that include a measuring function (Class 1m), or are required to be supplied sterile (Class 1s), require third party certification/conformity assessment.</p> <p>In Australia, certain health and digital health products may be excluded from regulation.</p> <p>How the TGA regulates Software as a Medical Device (SaMD): Provides useful steps on the process for obtaining conformity assessment/third party certification and application to be listed on the Australian Register for Therapeutic goods.</p> <p>Regulated devices that meet the definition of a medical device and are not excluded/exempted are required to be listed on the ARTG (Australian Register of Therapeutic Goods):</p> <p>Step 1 is for the manufacturer of the medical device to obtain certification from the TGA or a comparable overseas regulator. This is not required for manufacturers of class I (non-sterile) medical devices (which provide a self declaration of conformity).</p> <p>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.</p> <p>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.</p>
Presubmission Opportunities	<p>Yes, a formal pre-submission process is available for all TGA applications, but not required.</p> <p>Companies can approach TGA for an informal conversation at any stage of the process. When doing so, manufacturers should provide as much information as possible (marketing documents, technical and instruction manuals, initial data, etc) so the TGA has sufficient information to advise correctly.</p> <p>Contact for conformity assessment applications: dcas@tga.gov.au Contact for ARTG applications: devices@tga.gov.au</p>
Product Recognition	Companies can declare "our product is listed on the ARTG for {describe scope}."
Guidelines To Be Met	<p>Overview of the regulatory pathway for SaMD: All must comply (and hold evidence if > Class I) with Essential Principles listed in Regulations (Schedule 1 or also available as a checklist) of which 1, 2, 3, 4, 5, 6, 9, 12, 13, 14 apply to all SaMD. Any other relevant EPs for the device must be considered.</p> <p>Clinical Trials are not required per se, but relevant clinical evidence must be demonstrated under the Essential Principles: Clinical Evidence Guidelines</p> <p>Depending on classification, appropriate levels of clinical evidence are required, while Class I may be based on literature or common experience, novel products and Class II and Class III likely require an RCT.</p> <p>Before applying for inclusion on the ARTG, the TGA conducts a preliminary assessment to assess if conformity assessment documents are appropriate for the category and class of device. An application that passes preliminary assessment will either proceed to a final decision or be selected for audit. The requirement [link "requirement" to https://www.tga.gov.au/application-requirements-medical-devices-preliminary-assessment] to provide certain documentation with the application applies to all classes of medical device, except Class I (Export Only), Class 1 IVD, and Class 1 IVD (Export Only).</p> <p>Cybersecurity guidance</p> <p>Essential Principles General principles</p> <ul style="list-style-type: none"> • Use of medical devices not to compromise health and safety • Design and construction of medical devices to conform to safety principles • Medical devices to be suitable for intended purpose • Long-term safety • Medical devices not to be adversely affected by transport or storage • Benefits of medical devices to outweigh any side effects

[more >](#)

Guidelines To Be Met (continued)

Principles about design and construction

- Chemical, physical and biological properties
- Infection and microbial contamination
- Construction and environmental properties
- Medical devices with a measuring function
- Protection against radiation
- Medical devices connected to or equipped with an energy source
- Information to be provided with medical devices
- [Clinical evidence](#)
- Principles applying to IVD medical devices only

Standards to consider

IEC 62304 – Medical device software — Software life cycle processes
 ISO 13485 – Medical devices — Quality management systems — Requirement for regulatory purposes
 ISO 14971 – Medical devices — Application of risk management to medical devices

Timing

[Times](#) for the SaMD under new regulations may differ as regulators ensure self classification and evidence provided is appropriate. Selection for audit may be significantly higher for SaMD during this transition phase.

If conformity assessment is obtained in Australia, listing is an administrative request. However with the new SaMD rules, it is anticipated that greater scrutiny is being currently applied to ensure classifications are being applied appropriately, so audits may be more frequent.

Fees

[Fees](#) including annual charges (listed goods), application fee, conformity assessment among others may apply.

Other

[Accessing unapproved products](#): This page details the different ways patients can gain access to products that have not been approved for use in Australia. Includes information on use in clinical trials, authorised prescribers, and personal importation.

[Comparable overseas regulators and recognition of certification](#):

The TGA, unlike many major regulators, accept or recognise certification from a number of major regulators (European member states, US FDA, Health Canada, Japan, and the MDSAP), provided the classification is comparable or higher than that which the product would be classified as in Australia. MDSAP (medical device single audit process) is a third party audit for multiple jurisdictional requirements (Australia, Brazil, USA, Canada, Japan).

[Use of market authorisation evidence from comparable overseas regulators / assessment bodies for medical devices](#): This guidance details the regulatory pathway options available in Australia, including where evidence provided from comparable overseas regulators can be used for applications to supply medical devices in Australia (inclusion on the ARTG).

TGA assessment of applications for ARTG inclusion

The degree of rigour of the TGA's assessment of applications for inclusion of medical devices in the ARTG depends on the intended purpose and risk classification of the device, and the source of the conformity assessment certification.

The TGA may approve the inclusion of a device in the ARTG based on the information provided in the application received, or TGA may select an application for audit assessment. The audit of the application may involve a desktop review of information such as the labelling, instructions for use, technical documentation and advertising materials for the device, clinical evidence, risk management documentation for the device, or reports from the notified bodies.

The scope of any audit will depend largely on the issues identified by the TGA as requiring further scrutiny. Applications for devices, such as Class III, AIMDs, and selected Class IIb medical devices, must be selected for audit (mandatory application audits) where the manufacturer's conformity assessment certification was issued by a comparable overseas regulator.

[Useful Source page for Australian Regulations for Medical Devices](#)

Advertising Standards: Whether regulated or not, SaMDs must be accurately represented in the market and not promoted to deliver benefits beyond what their stated classification confers. Advertising standards are governed by the [ACCC](#) (Australian Competition and Consumer Commission).

Note: [Excluded](#) products do not qualify as medical devices, are not subject to TGA regulatory requirements, and do not need to be included in the Australian Register of Therapeutic Goods (ARTG). [Exempt](#) products are medical devices and are not subject to all regulatory requirements. This currently includes some clinical decision support software (CDSS), but does not currently pertain to digital therapeutic products.

AUSTRALIA Reimbursement

Currently there is no defined pathway for reimbursement for most digital health products and services. Dependent on the therapeutic area, and whether the SaMD is integrated with, or a companion to, a device, prosthetic, therapeutic or service, there may options for reimbursement through select public and private schemes (see below). Government wants evidence a proposed intervention offers a “value for money” alternative compared with current practice (and other ways of spending health care resources).

Legislation and policy governing the area includes:

MSAC – Medical Services Advisory Committee: Is an independent non-statutory committee established by the Australian Government Minister for Health in 1998. MSAC appraises new medical services proposed for public funding and provides advice to Government on whether a new medical service should be publicly funded (and if so, its circumstances) on an assessment of its comparative safety, clinical effectiveness, cost-effectiveness, and total cost, using the best available evidence.

PBAC – Pharmaceutical Benefits Advisory Committee: The PBAC is an independent expert body appointed by the Australian Government. Members include doctors, health professionals, health economists, and consumer representatives.

HTA – Health Technology Assessment: The purpose of HTA is to provide policy-makers, funders, health professionals, and health consumers with the necessary information to understand the benefits and comparative value of health technologies and procedures. This information is then used to inform policy, funding and clinical decisions, and assist with consumer decision-making. The Australian Government cannot financially support every new health technology that comes onto the market, so it aims to direct government funding, in the form of subsidies, to health technologies that are clinically relevant, cost effective, and safe.

PLAC – Prostheses List Advisory Committee: This committee provides recommendations and advice to the Minister for Health and the Department of Health about the listing of products on the Prostheses List and the benefits payable by private health insurers.

Prescription Required?	With no clearly defined pathway, prescription requirements will be unique to each SaMD and whether it is integrated with, or a companion to, a device, prosthetic, therapeutic, or service. For reimbursement, typically a prescription from and/or involvement of a medical practitioner is required or, in the case of NDIS funding, recommendation/endorsement by a disability service provider.
Public Health Insurance	<p>Various schemes may be applicable, dependent on the therapeutic area and whether SaMD is integrated with, or companion to a device, prosthetic, therapeutic, or service (such as remote monitoring).</p> <p>PBS – Pharmaceutical Benefits Scheme: The PBS Schedule lists all of the medicines available to be dispensed to patients at a Government-subsidised price. The Schedule is part of the wider Pharmaceutical Benefits Scheme managed by the Department of Health and administered by Services Australia.</p> <p>MBS – Medical Benefits Schedule (currently under review): The Medicare Benefits Schedule (MBS) is a list of health professional services that the Australian Government subsidises. MBS items provide patient benefits for a wide range of health services including consultations, diagnostic tests, and operations.</p> <p>NDSS – National Diabetes Services Scheme: An initiative of the Australian Government that provides support services for practical help and guidance, diabetes health information, and resources subsidised diabetes products.</p> <p>NDIS – National Disability Insurance Scheme: The NDIS is a federally government program that provides support to eligible people with intellectual, physical, sensory, cognitive, and psychosocial disability.</p> <p>There is some ad hoc uptake of mental health apps by Veterans Affairs (VA). Future potential funding for VA may be through their Rehabilitation Appliances Program, though there is no known indication yet, of consideration for SaMD.</p>
Private Health Insurance	<p>There is no clear pathway, but on occasion where the SaMD increases engagement/membership, directly reduces cost of care, or creates an efficiency gain for the health insurer, private insurers have engaged. Generally speaking, health insurers commonly fund some or all of the gap between a publicly funded ‘device’ or service and the full price to consumer (such as those on the Prostheses List).</p> <p>PL – Prostheses List: Under the <i>Private Health Insurance Act 2007</i>, private health insurers are required to pay benefits for a range of prostheses that are provided as part of an episode of hospital treatment or hospital substitute treatment for which a patient has cover and for which a Medicare benefit is payable for the associated professional service.</p>
Employer Sponsored	There are some indications that private Income Protection Insurance providers are becoming active in funding digital health. Government departments/public service are also engaging on an ad hoc basis (as employers) with digital health. Similarly, there is an increasing ad hoc enterprise uptake of digital health to support mental health and wellness.
Direct to Consumer	Consumer pay models are difficult in Australia due to the public expectation that the government should fund healthcare costs. Co-pays (gap payments) are common. It is possible to see consumer sentiment change post-covid (as has occurred in other jurisdictions).

Note: This document represents pathways that continue to evolve. It does not provide legal advice.