Australia

Latest Updates

- Updated best ethical practices for AU

Software	
Embedded Software	Embedded software is not registered separately, but as part of the system.
Software as Medical Device (SaMD)	Registration and Classification according to Section 41BD of the Therapeutic Goods Act 1989 https://www.tga.gov.au/how-we-regulate/supply-therapeutic-good/supply-medical-device/medical-devices-reforms/medical-devices-reforms-medical-device-software-regulation
Clinical Decision Support Software (CDS)	17 August 2022: Updated guidance on Exemption for Certain Clinical Decision Support Software https://www.tga.gov.au/resources/resource/guidance/exemption-certain-clinical-decision-support-software 11 October 2021: Clinical decision support software guidance, scope and examples https://www.tga.gov.au/resources/resource/guidance/clinical-decision-support-software
Change Management Requirements for Software/SaMD	Changes affecting TGA-issued conformity assessment certificates https://www.tga.gov.au/sites/default/files/changes-affecting-tga-issued-conformity-assessment-certificate.pdf
Quality management System (QMS)	No specific guidance for SaMD QMS, but expects compliance to ISO:13485
Post-Market Management	Devices are subject to conditions of inclusion such as: Ensuring continued compliance with the EPs and CAPs, reporting adverse events, providing information and samples, reporting annually for higher classes of devices. Devices can be subjected to post-market review or investigations at any time.

Real World Data/Evidence
https://www.tga.gov.au/real-world-evidence-and-patient-reported-outcomes-medical-devices

Artificial Intelligence (SiMD & SaMD)	
Machine Learning	No updates at present.
Deep Learning	No updates at present.
Best Ethical Practices	The State of AI Governance in Australia. See Australia's discussion paper on safe and responsible AI and its AI Roadmap. "https://www.industry.gov.au/publications/australias-artificial-intelligence-ethics-framework/australias-ai-ethics-principles
Generative AI	Guidance on Artificial Intelligence Chat, Text, and Language https://www.tga.gov.au/how-we-regulate/manufacturing/medical-devices/manufacturer-guidance-specific-types-medical-devices/regulation-software-based-medical-devices#software-as-a-mediacal-

Cybersecurity
https://www.tga.gov.au/sites/default/files/medical-device-cyber-security-guidance-industry.pdf

Data Privacy
The Privacy Act 1988 (Privacy Act)

Labelling	
UDI	https://www.tga.gov.au/resources/event/webinars/unique-device-identification-udi-webinar-19-australian-udi-project-update-and-discussing-considerations-and-real-world-benefits-adopting-udi-healthcare https://www.tga.gov.au/sites/default/files/2024-01/bulk-udi-upload-template.xlsx https://www.tga.gov.au/sites/default/files/2024-01/ausudid-data-dictionary-v0.6-draft.xlsx
Specific Market Requirements	"Essential principle 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. https://www.tga.gov.au/sites/default/files/essential-principles-checklist-medical-devices.pdf"