



AUSTRALIA MEDICAL DEVICE REGULATORY MAP

A practical orientation for global RA teams entering the Australian market.

START HERE: WHAT IS THE PRODUCT IN AUSTRALIA? ▶

1 Confirm the Australian regulatory identity

Define the device's intended purpose, users, technology, and claims.

Determine whether the device is non-invasive, invasive, active, software, sterile, measuring, implantable, or an AIMD.



Non-invasive / Invasive



Active / Software



Measuring / Sterile



Implantable / AIMD

2 Choose the regulatory route

CLASS I



Lowest risk

Many non-sterile, non-measuring, non-invasive devices.

CLASS Is / Im



Low risk

Sterile or measuring Class I devices with stronger scrutiny.

CLASS IIa / IIb



Moderate risk

Increasing conformity assessment depth and evidence requirements.

CLASS III / AIMD



Highest risk

Highest risk devices and AIMDs with strongest evidence and review expectations.

3 Build the Australian market-access infrastructure



TGA framework

Medical Devices Regulations 2002 and associated guidance govern the pathway.



Australian Sponsor

Appoint an Australian Sponsor to act as your local representative with the TGA.



ARTG inclusion

Inclusion in the Australian Register of Therapeutic Goods (ARTG) is required before supply.



Conformity assessment / manufacturer evidence

Use an appropriate conformity assessment pathway and compile technical documentation and evidence to support the TGA review.

4 Build the evidence stack



Administrative

Device description, intended use, indications, market claims, and regulatory history.



Quality / QMS

QMS aligned with ISO 13485 and TGA expectations; stability and shelf-life evidence.



Safety & performance

Bench, electrical, biocompatibility, EMC, cybersecurity, and performance data.



Clinical / usability

Clinical evaluation, usability engineering, and performance follow-up where applicable.



Labeling / Essential Principles

IFU and labeling compliant with Essential Principles of Safety & Performance.



RA TRAP TO AVOID

Overseas approvals do not eliminate Australian requirements. You still need TGA compliance, an Australian Sponsor, correct classification, ARTG inclusion, and a complete evidence package.



STRATEGIC INSIGHT

Classify early, align with your Australian Sponsor, plan the ARTG strategy, and assemble a robust evidence package to shorten the path to market.



AUSTRALIA MEDICAL DEVICE: HOW THE WORK ACTUALLY FLOWS

From classification to commercialization — with the decision points a newer RA professional should watch.

A Program flow

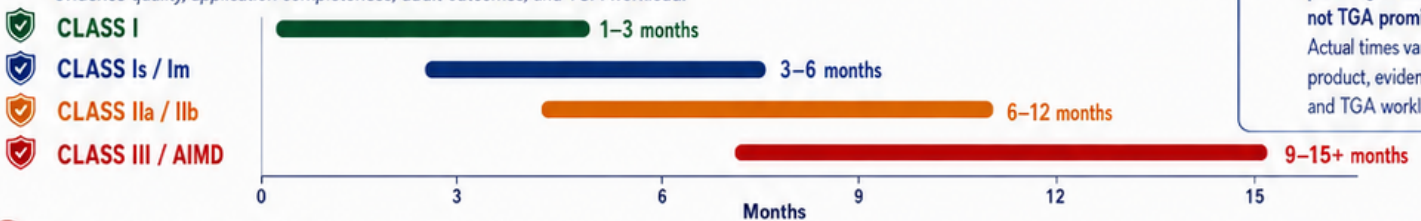


B What gets heavier as the class rises?

Signal	CLASS I	CLASS Is / Im	CLASS IIa / IIb	CLASS III / AIMD
Pathway intensity	Low ● ● ● ● ●	Moderate ● ● ● ● ●	High ● ● ● ● ●	Very high ● ● ● ● ●
Evidence intensity	Basic ● ● ● ● ●	Moderate ● ● ● ● ●	High ● ● ● ● ●	Very high ● ● ● ● ●
Clinical / usability support	Not usually required ● ● ● ● ●	Limited ● ● ● ● ●	Moderate ● ● ● ● ●	Extensive ● ● ● ● ●
QMS readiness	Basic ● ● ● ● ●	Moderate ● ● ● ● ●	High ● ● ● ● ●	Very high ● ● ● ● ●
Post-market control	Lower ● ● ● ● ●	Moderate ● ● ● ● ●	Higher ● ● ● ● ●	Highest ● ● ● ● ●

C Indicative route-based planning ranges

Hopstone planning estimates based on typical experience. Actual timing depends on product complexity, evidence quality, application completeness, audit outcomes, and TGA workload.



i These are Hopstone planning estimates, not TGA promises. Actual times vary by product, evidence, and TGA workload.

D Labeling & language essentials

English labeling
All labeling and IFU must be in English. Translations must be accurate and validated.

Sponsor details
Australian Sponsor details must be clearly stated on labeling and in submissions.

IFU readiness
Provide complete IFU for safe use, including intended use, limitations, and step-by-step instructions.

Claims control
Claims must be supported by evidence and consistent with intended use.

Vigilance / PMS
Plan and maintain vigilance and PMS activities per TGA requirements.

E High-impact Australian decision points

Software / connected devices
Confirm classification impacts from software function, connectivity, and cybersecurity.

Sterile or measuring status
Confirm sterile or measuring function implications for classification.

Implantable / AIMD implications
Higher scrutiny for implantable and AIMD devices (Class III / AIMD).

Conformity assessment evidence
Ensure evidence meets Essential Principles and classification pathway requirements.

PRIMARY RESOURCES USED FOR THIS TRAINING AID

- TGA Medical devices — Overview** <https://www.tga.gov.au/medical-devices>
- ARTG inclusion guidance** <https://www.tga.gov.au/artg-inclusion-and-medical-devices-australian-register-therapeutic-goods-artg>
- Essential Principles** <https://www.tga.gov.au/essential-principles>
- Australian Sponsor guidance** <https://www.tga.gov.au/australian-sponsor-guidance>

IMPORTANT

Current Australian requirements and product-specific obligations govern.

Confirm classification, evidence, labeling, and submission obligations before execution.