

# Orthopedic Device Registration in Australia

OSMA Meeting January 2025


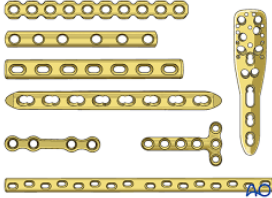

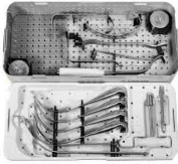

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# Regulatory Framework

- Requirements are generally aligned with EU MDR
- Key components:
  - Legal Manufacturer
  - GMDN
  - Class
  - Sponsor
- Prior to supply, the medical device must be included on the Australian Register of Therapeutic Goods (ARTG)

# Classification Examples

	DEVICE TYPE	TGA Risk Classification
Joint Implants		III
Plates and Screws		IIb
External Fixators		IIb
Instruments		I, Is, Im, IIa, IIb
Digital		IIa, IIb

# Comparable Overseas Evidence

<https://www.tga.gov.au/resources/guidance/use-market-authorisation-evidence-comparable-overseas-regulators-and-assessment-bodies-medical-devices-including-ivds>



Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

## Use of market authorisation evidence from comparable overseas regulators / assessment bodies for medical devices (including IVDs)

For abridgement of TGA conformity  
assessments and as information required for  
applications for ARTG inclusion

Version 1.10, November 2023

# Leveraging Overseas Approvals

## **Key Considerations**

1. Device must still meet the TGA Essential Principles
2. Clinical evidence is required per TGA guidance
3. TGA may conduct an application audit