

ADIA Policy Statement –

Policy	R2 – Medical Device Regulation (International Harmonisation)
Statement	Australia's dental product (medical device) regulatory framework should be consistent with international regulatory standards.
Principle/s	If a dental product has been approved under a trusted international standard or risk assessment, then Australian regulators should not impose any additional requirements for approval in Australia, unless it can be demonstrated that there is a good reason to do so.
Background	<ul style="list-style-type: none"> ▪ The Therapeutic Goods Administration (TGA) regulates all medical devices that are imported into, supplied in or exported from Australia under the <i>Therapeutic Goods Act (Cth) 1989</i> and subordinate regulations. ▪ The framework administered by the TGA is broadly consistent with that of the European Union which, in turn, reflects many requirements of the International Medical Device Regulators Forum (IMDRF) ▪ The IMDRF was established in 2011 to provide a forum to discuss future directions in medical device, including dental product, regulatory harmonisation at an international level. The IMDRF builds upon the work of the Global Harmonization Task Force (GHTF). ▪ Although the TGA's framework is broadly consistent with that in the European Union, there are differences in the medical device classification system and approaches to pre-market scrutiny and post-market surveillance which costs and provides little or no additional protection for patients. ▪ The Australian market for dental products is around 2% of the global market and, as a general rule, not of sufficient size to sustain domestic manufacturing operations. For this reason, Australian businesses must export to grow, create jobs and operate sustainably. As such, an Australian regulatory framework that is consistent with international regulatory standards places Australian manufacturers on the same footing as overseas competitors.
Framework Documents	<ul style="list-style-type: none"> ▪ ADIA Advocacy Agenda ▪ ADIA Stakeholder Engagement Strategy
Engagement & Advocacy Partner/s	<ul style="list-style-type: none"> ▪ <u>Internal:</u> ADIA-DRC Dental Regulation Committee ▪ <u>External:</u> TGA & IMDRF
Currency	ADIA-DRC Endorsement: 28/1/2015 ADIA Board Approval: 18/2/2015 (Reference 1.9.2)



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