

## ADIA Policy Statement –

<b>Policy</b>	<b>R3 – Medical Device Regulation (Product Standards)</b>
<b>Statement</b>	Regulations and procurement guidelines should reference international standards for the design, testing, performance and maintenance of dental products where appropriate and where such standards are available.
<b>Principle/s</b>	If there are internationally acceptable products for dental standards, then Australian regulators and clients should not impose any additional Australian requirements, unless it can be demonstrated that there is a good reason to do so.
<b>Background</b>	<ul style="list-style-type: none"> <li>▪ 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.</li> <li>▪ Where technical regulations are required and relevant international standards exist or their completion is imminent, the <i>World Trade Organization Treaty on Technical Barriers to Trade (WTO/TBT)</i> requires that WTO member nations shall use them, or the relevant parts of them, as a basis for their technical regulations except where such international standards or relevant parts would be an ineffective or inappropriate.</li> <li>▪ The WTO/TBT includes <i>Annex 3 - The Code of Good Practice for the Preparation, Adoption and Application of Standards</i>. All signatories to the Code, including Standards Australia, are required to use International Standards as a basis for their national standards wherever this is effective and appropriate.</li> <li>▪ The ISO (International Organization for Standardization) is an independent, non-governmental membership organisation and the world's largest developer of voluntary International Standards with a membership of 166 member countries who are the national standards bodies around the world, including Standards Australia.</li> <li>▪ The ISO-TC106 – Dentistry committee is tasked with standardisation in oral health care including: terms and definitions; performance, safety, and specification requirements of dental products; and clinically relevant laboratory test methods, all of which contribute to improved global health.</li> </ul>
<b>Framework Documents</b>	<ul style="list-style-type: none"> <li>▪ ADIA Advocacy Agenda</li> <li>▪ ADIA Stakeholder Engagement Strategy</li> </ul>
<b>Engagement &amp; Advocacy Partner/s</b>	<ul style="list-style-type: none"> <li>▪ <u>Internal:</u> ADIA-DRC Dental Regulation Committee</li> <li>▪ <u>External:</u> ISO &amp; Standards Australia</li> </ul>
<b>Currency</b>	ADIA-DRC Endorsement: 28/1/2015      ADIA Board Approval: 18/2/2015 (Reference 1.9.2)



Australian Dental Industry Association Limited  
ABN 32 003 314 396

National Office: GPO Box 960, Sydney, NSW, 2001  
Government Affairs: GPO Box 1, Canberra, ACT, 2601

e: [national.office@adia.org.au](mailto:national.office@adia.org.au) [www.adia.org.au](http://www.adia.org.au)  
t: 1300 943 094 f: 1300 943 794