ADIA Policy Statement –

Policy	**R1 – Medical Device Regulation (Regulatory Approach)**
Statement	The regulatory framework for dental products (medical devices) should be based on a risk management approach designed to ensure public health and safety, while at the same time freeing industry from any unnecessary regulatory burden.
Principle/s	Dental products are required in the provision of dental and oral health care and to be effective they must modify the way the body works and / or interact directly with a patient. This means there are risks, as well as benefits, associated with their use. Because of these risks, these products must be regulated in order to protect public health; however this regulation should not constrain legitimate operations of business.
Background	▪ The Therapeutic Goods Administration (TGA) regulates all medical devices that are imported into, supplied in or exported from Australia under the *Therapeutic Goods Act (Cth) 1989* and subordinate regulations. ▪ Therapeutic goods must be entered in the Australian Register of Therapeutic Goods (ARTG) before they can be lawfully supplied in or exported from Australia, unless exempt from being entered in the ARTG, or otherwise authorised by the TGA. ▪ A sponsor (*i.e.* the individual or company intending to supply the goods) is responsible for meeting the regulatory requirements of the therapeutic goods legislation. ▪ ADIA believes that businesses in the dental industry often have to undertake a regulatory approvals process to use or sell products in Australia that duplicates a process that has already occurred in other developed countries. This adds to costs and provides little or no additional protection.
Framework Documents	▪ ADIA Advocacy Agenda ▪ ADIA Stakeholder Engagement Strategy
Engagement & Advocacy Partner/s	▪ Internal: ADIA-DRC Dental Regulation Committee ▪ External: TGA
Currency	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 www.adia.org.au
t: 1300 943 094 f: 1300 943 794