



## — Submission

### Changes to a Number of Definitions and the Scope of the Medical Device Regulatory Framework in Australia

This submission is tendered by the Australian Dental Industry Association (ADIA), the peak business organisation representing manufacturers and suppliers of dental products.

## General Comments —

The Australian Dental Industry Association (ADIA), as the peak business organisation representing dental product manufacturers and suppliers, welcomes the opportunity to submit this response to the Therapeutic Goods Administration (TGA) consultation on changes to several definitions and the scope of the medical device regulatory framework in Australia.

ADIA is a strong supporter for a regulatory framework for dental products, and medical devices more broadly, which is based on a risk management approach designed to ensure public health and safety, whilst at the same time not imposing unnecessary regulatory burden.

ADIA provides in-principle support of the TGA's decision to align the regulatory approach for certain products without an intended medical purpose to that of the EU. However, with regard to products that could be captured in Group 5, there is some concern whether the additional regulatory burden is warranted for those consumer products that are used externally, or in the mouth for cosmetic purposes. Examples include lights used in cosmetic dental procedures such as teeth whitening. It is understood that these products are not regulated as medical devices in the EU or USA.

Conversely, lights that are used for curing purposes in dental restorative procedures are regulated as medical devices as there is a medical intended purpose.

ADIA requests that the impact of any regulatory change is reviewed, with a cost benefit assessment undertaken, as there is an existing framework for consumer product safety under the Australian Consumer Law (ACL).

ADIA is aware that the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) undertook a review of Intense Pulsed Lights (IPL) for the beauty industry in 2015, identifying that while there was insufficient information to support a national regulatory framework, the key areas of focus should be consumer education and provider competency for the professional sector. The relative risk associated with the use of lights in cosmetic dental procedures is low, highlighting that an assessment of the scope of products with no medical intended purpose proposed for inclusion as medical devices, should be undertaken to ensure that products are not subject to additional regulatory burden unless there is an absence of adequate consumer protection afforded by the current provisions of the ACL.

ADIA has no specific comments on the changes to definitions in the Consultation Paper.

ADIA appreciates the opportunity to engage in this consultation.



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## ADIA An Introduction —

Formed in 1925, the Australian Dental Industry Association (ADIA) is the peak business association representing manufacturers and suppliers of ninety-five percent of the products used in Australian dentistry.

The ADIA membership ranges in size from the local operations of multi-billion-dollar corporations through to small family-owned entities. They share common aspirations for the growth of their business, the creation of jobs and an industry that's sustained through the provision of quality products and services to dental professionals.

ADIA supports a regulatory framework for dental products and services that is based upon a risk-management approach designed to ensure public health and safety, while at the same time freeing business from an unnecessary regulatory burden. To this end, ADIA is a strong advocate for reforms that cut red-tape and allow businesses in the dental industry to grow, create jobs and operate sustainably.

Australia's largest healthcare trade show, *ADX*Sydney, is convened biennially by ADIA and attracts nearly ten thousand stakeholders from across the Asia-Pacific's dental and oral healthcare community. ADIA also convenes regional trade shows in Adelaide, Brisbane, Melbourne and Perth that provide a platform for the growth of member businesses.

Working with members to ensure that the dental industry has ongoing access to a workforce of skilled professionals, the Association supports skills development across the dental industry. A pioneering partnership with MEGT sees the group training model used to employ apprentices and trainees across the industry and the *CSU – ADIA Graduate Certificate in Small Business Management* provides support for mid-career professionals. Consistent with ADIA's role as the peak body for manufacturers and suppliers, ADIA is a member of the Australian Chamber of Commerce & Industry (AusChamber), the nation's foremost grouping of employer organisations. Amongst other affiliations is ADIA's membership of the association of International Dental Manufacturers (IDM), the Swiss-based global body for the dental industry.

The ADIA national office is based in Sydney and the Association is active in all mainland states.

More information can be found online at [www.adia.org.au](http://www.adia.org.au)

## ■ ADIA MEMBER BUSINESSES ■

3DMEDiTech 3M Oral Care 3Shape Australia A.R. Medicom AADFA Acteon Australia / New Zealand A-dec Australia ADR Dental Aesthetic Prosthetics AHP Dental & Medical Ainsworth Dental Air Liquide Healthcare AJ Barber Ajax Dental Supplies Alldent Alliance Medical Finacne Alphabond Dental Amalgadent Dental Supplies Ampac Dental Andent Anthos in Australia ANZ Banking Group Ark Health Australasian Dentist Australian Imaging Australian Medical Suction Systems Babich Maintenance & Steriliser Services Biodegree Biohologic Biomedex Biomil Dental Products Bite Magazine BOQ Specialist Bank Borg Dental Cal-Dent Denture Cleaner Carestream Dental Carl Zeiss Cassins Healthcare Design & Construct Cattani Australia Centaur Software City Dental Supplies Clare Martin & Associates CMA Ecocycle Colgate Oral Care Coltene-Whaledent International Commodore Dental and Medical Fitouts Core3D Credabl Crown Dental & Medical Curaden Swiss Dentacast Australia Dental Axess Dental Concepts Dental Depot (QLD) Dental Education Centre Dental Essentials Dental Fitout Projects Dental Focus Marketing Dental Implant Registries Dental Innovations Dental Installations Dental Premium Engineering & Supplies Dental Profit System Dental Protection Dentalife Australia Dentaurum Australia Dentavision Dentplex Dentpro Dentsply Sirona Designer Surgeries Designs for Vision Dr Mark's HyGenie Durodent Dental Supplies Durr Dental AG East Coast Dental Dental Devices EMS Erkodent Erskine Health Supplies and Services Experien Garfield Refining Co GC Australasia GKWA GlaxoSmithKline Gritter Dental Handpiece Australia Heine Australia Australia Horseley Dental Supplies Australia Independent Dental Supplies Medical Technologies Intellimail International Invisalign Australia INZ Dental Supplies Ivoclar Vivadent Kavo Kerr Kulzer Australia Leading Dental Levitch Design Australia Lorchant Dental LoveSmiles Macono Orthodontic Laboratories Med & Dent (WA) Medfin Australia Medical Dental Solutions NQ Medical Equipment Services Medi-Dent Medifit Design and Construct Minimax Implant (Dentium Australia) MIPS Mocom Australia Momentum Management My Dental Marketing Myofunctional Research Co. NAOL Australia Neoss Australia Nobel Biocare NOVA IT Group novaMED NSK Oceania NuMedical One Dental Optima Healthcare Group Orien Dental Supplies Osseo Dental Osstem Australia Osteon Medical Ozdent Dental Products Australia Pacific Dental Specialties Pegasus Dental Services Perfect Practice Philips Oral Healthcare Practice Sales Search Praktika Presidential Prime Practice Professional Dentist Supplies Race Dental Ray Australia RCR International Rhodium Dental Labs Australia Ridley Dental Supplies RJ Dental Sales & Service Roland DG Australia Rosler International RutiniDent Dental Supplies SDI Ltd Septodont Sieverts Radiation Protection Consultancy Smile Right Software of Excellence South Austral Straumann Supreme Orthodontic Supply (Aust) Teamwork Technology The Dentists Workshop The Health Linc Tomident TrollDental Ultimate Dental Supplies Ultimo Health Technologies Ultradent Products Australia Urban IT Vatech Medical VOCO Australia W&H Wealthpreneur West Coast Dental Depot Westpac Whiteley Corporation William Green Wisbey Dental XAND Innovations Xcellent Dental World Xpress Tex XYZ Dental Zimmer Biomet Dental



**ADIA**

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 twitter: @AusDental  
t: 1300 943 094 f: 1300 943 794

www.adia.org.au