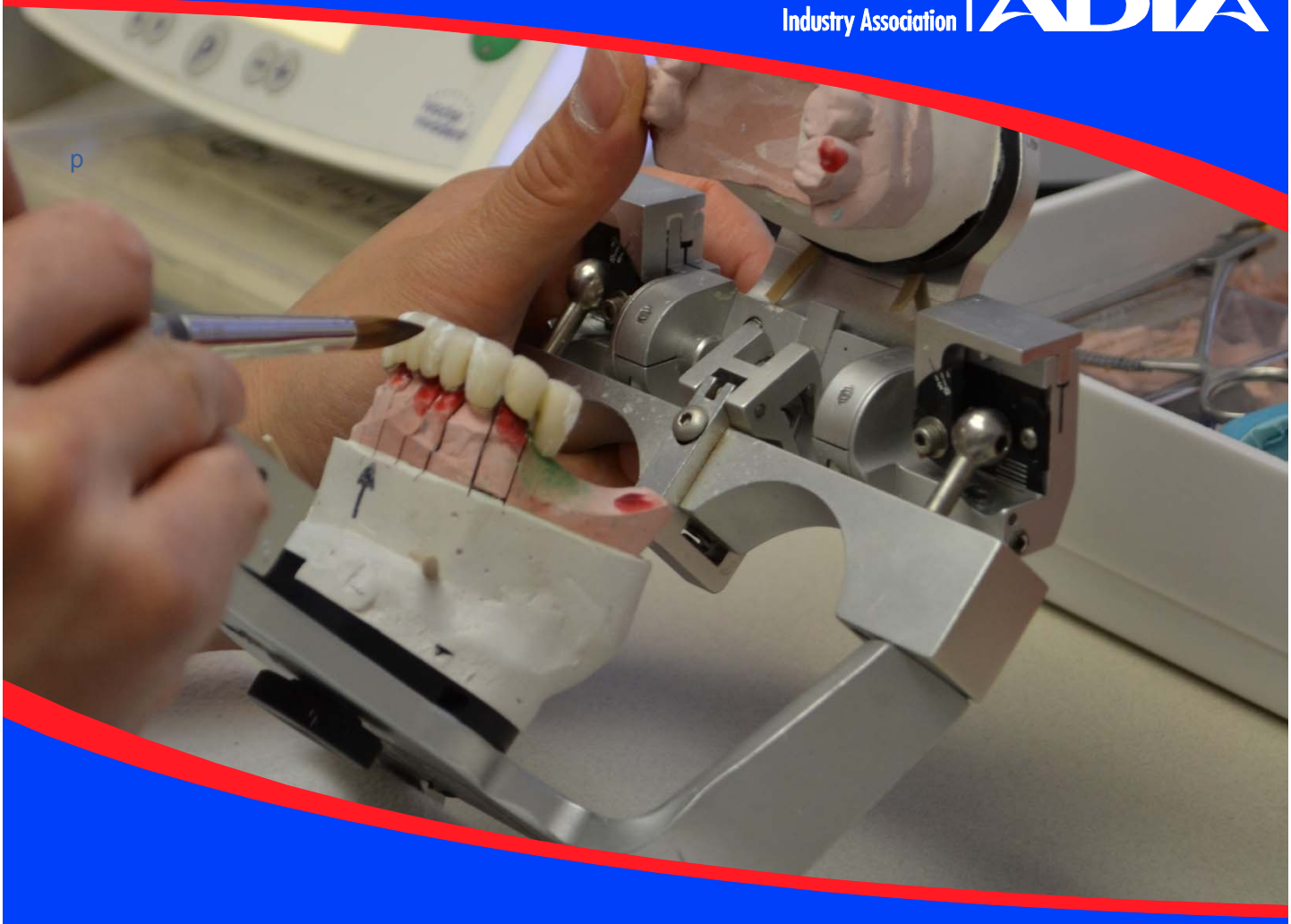
Australian Dental Industry Association | ADIA



— Submission
Inquiry Into Supply of Dental Prostheses

Although there are public concerns about the safety and quality of dental laboratory work from overseas, a comprehensive review of available data does not suggest any elevated degree of risk.

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On 31 July 2014, the Legislative Assembly of the Australian Capital Territory resolved to refer to that chamber's Standing Committee on Health, Ageing, Community and Social Services an inquiry into the sourcing and supply of dental appliances and prostheses used by dental practitioners.

This submission reviews the nature of dental appliances and prostheses (termed custom-made medical devices for regulatory purposes) used in contemporary dentistry, prevailing regulatory standards and recommendations to improve public confidence in this product type.

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Executive Summary

Custom-made dental appliances include crowns, bridges and dentures which are manufactured in dental laboratories by individual dental technicians. Increasingly, in Australia this product is sourced from overseas and there are growing public concerns about the safety of this imported product.

At this point in time, although there are public concerns about the safety and quality of products from overseas, a comprehensive review of available data does not suggest any elevated degree of risk.

In considering this matter, there is a need to consider the existing regulatory standards established by the *Therapeutic Goods Act (Cth) 2009* and subordinate regulations. The regulated manufacturing processes include adherence to conformity assessment procedures which mandate compliance with a defined set of outcomes for the manufacturing, performance and safety of medical devices. All custom-made dental appliances, whether manufactured in Australia or overseas, are required to meet the same regulatory standards. In this context, claims in the media and elsewhere that imports of custom-made dental appliances are "unregulated" have no basis in law. However, ADIA does recognise public concerns with the safety of these products thus readily accepts that limited reform is necessary in order to address such concerns.

As the peak representative business organisation representing manufacturers and suppliers of quality dental products, ADIA is keen to ensure reforms in this area are based on a risk management approach designed to ensure public health and safety, while at the same time freeing dental laboratories and healthcare practitioners from an unnecessary regulatory burden.

Troy R Williams FAIM MAICD
Chief Executive Officer
Australian Dental Industry Association

19 September 2014

Chapter 1 —
Custom-made medical devices in dentistry

Australia has a world-class system to develop, maintain and enforce regulatory standards for medical devices that is administered by the Therapeutic Goods Administration (TGA). By common consensus amongst industry and consumer representatives, the TGA is an able regulator of both medical devices and pharmaceutical products, notwithstanding the agreed need for the organisation to improve aspects of its work (identified in the document *TGA Reforms – A blueprint for TGA's future*). However, there is an argument that when it comes to custom-made medical devices in the dental area, there is a need for reform to address public perceptions associated with alleged substandard product that is manufactured overseas.

Defining custom-made medical devices in dentistry

In the Australian context, custom-made medical devices are defined in the *Therapeutic Goods (Medical Devices) Regulations 2002* as medical devices that are made specifically in accordance with a request by a health professional specifying its design characteristics or construction. Such products are intended to be used only in relation to a particular individual, or by a health professional to meet special needs arising in the course of his or her practice.

Examples of custom-made medical devices include: Prosthetic and / or glass eyes, orthopaedic or pedorthic footwear, prosthetic limbs, and prescription glasses.

With respect to dental product, custom-made medical devices include crowns, bridges and dentures. For ease of reference, throughout this submission they will be referred to as custom-made dental appliances.

Custom-made medical dental appliances are manufactured by dental laboratories employing dental technicians. A dental technician may make models of the mouth and teeth from impressions of the patient's mouth (taken by the dental prosthetist, dentist, dental hygienist or dental therapist) and use models and moulds to make dental restorations such as inlays, onlays, veneers, crowns and bridges. Currently, there is no need for the dental laboratory to be registered as a business (beyond standard requirements for any other business or company operating in Australia) nor is there a need for individual dental technicians to register with the Dental Board of Australia (DBA) within the framework administered by the Australian Healthcare Practitioner Regulation Agency (AHPRA).

The rationale for not registering dental technicians is that rather than fulfilling the role of a healthcare professional treating a patient, they are product fabricators

manufacturing to the requirement of a dental professional registered by the DBA. In terms of the role of a dental technician in the supply chain, this is a valid assessment and the rationale for registering dental professionals is not strong.

Declining market for locally made product

Whereas twenty years ago, most custom-made dental appliances were made in Australia, there is strong anecdotal evidence to suggest that a significant percentage is now manufactured overseas. At this point in time, there is no authoritative source to provide specific data on the quantities and value of locally manufactured product and the product that is sourced overseas. However, the percentage of product manufactured overseas is thought to be increasing and the Senate's Community Affairs References Committee observed:

> *The committee notes that custom made dental devices appear to escape TGA scrutiny, with dental professionals and patients alike unaware that up to 50 per cent of custom made dental prostheses are manufactured overseas, with no validation at the source of manufacture.*
>
> Report: The regulatory standards for the approval of medical devices in Australia
> Senate Community Affairs References Committee (11 November 2011)

The professional body for the individuals dental technicians employed by dental laboratories, the Oral Health Professionals Association (OHPA) has surveyed its members and has drawn a similar conclusion:

> *From our recent survey, some members have stated they have lost between 5 and 50% of their business since July 2010. The offshore market is penetrating our industry at a reported 60%.*
>
> Article: Securing Your Business' Future
> The Denticulator, Oral Health Professionals Association (Volume 3, Number 6 – July 2012)

This changing pattern in procurement is not unique to Australia and the American domestic dental laboratory sector also faces challenges from overseas sourced product as noted by the US National Association of Dental Laboratories (NADL):

> *Although dentists prescribe the type of device they need for a dental patient, the product is actually manufactured by a dental technician employed by a dental laboratory, which could be located in the United States or anywhere in the world. Due to the growing number of Americans seeking dental restorative treatment and the growing pressure by dentists to cut costs and increase profit margins, much of the dental work Americans carry in their mouths is now imported from countries such as China, Pakistan, the Philippines and India.*

> *Those products are not tested or inspected for sterilization, for the long-term safety or quality of their components, or for the precision of the fit as required for proper dental care.*
>
> Media Release: Industry Asks FDA to Improve Regulation of Dental Restorations to Protect Patient Safety
> US National Association of Dental Laboratories (14 September 2007)

In some respects, the trend to source custom-made dental appliances from overseas simply mirrors the pattern across the remainder of the dental sector. ADIA estimates that of the dental product used in Australia more than 95% of dental product by value is imported. That the dental laboratory sector is replicating the supply patterns across the entire dental sector does not in any way diminish the very real commercial pressures that Australian dental laboratories face. It is understandable that individual dental technicians feel that their livelihoods are threatened.

From the outset, it must be stated that ADIA has a firm commitment to Australian manufacturers of dental product, including that produced by domestic dental laboratories. However, ADIA also believes in an open, internationally competitive market for dental product in which locally manufactured and imported product compete on a level playing field, thus it is not felt appropriate to establish technical barriers to trade (*i.e.* regulation) to protect the domestic market, notwithstanding any moves in this area would contravene Australia's international trade obligations to the World Trade Organisation (WTO) and certain treaties.

Safety concerns with imported custom-made dental appliances

Given that custom-made dental appliances reside in a patient's body, it is understandable that there are public concerns that such product may not be safe. Similarly, it is understandable that this concern is often heightened when the product is purchased from overseas. This sentiment is shared by many politicians:

> *Every dental patient should be confident that the crown, bridge or denture going into his or her mouth is safe regardless of where it is made, but this is not the case in Australia, where unregulated imports of dental prosthetics potentially contain toxic heavy metals like nickel, cadmium or lead. Whether it is a crown for a damaged tooth, a bridge for a missing one, a set of dentures or a mouthguard, up to 40 per cent of dental prostheses are thought to be manufactured overseas. This manufacture takes place in countries across Asia, including China, where labour and materials are cheap, and health and safety standards are lax. For example a $1,300 crown can be manufactured in China for as little as $25.*
>
> Hansard: Speech On Dental Prostheses Imports, The Hon. Lee Rhiannon MLC
> NSW Legislative Council (1 September 2009)

The OHPA has defined the increasing trend to sourcing product off-short as "dental import crisis" a term that is misleading as it is also suggests that there

may be a problem with the safety of such devices. Although isolated examples of problem product are not unknown, the recorded incidence of faulty or substandard product is rare. Research undertaken by the American Dental Association (ADA-US) addressed widespread but apparently unfounded concerns about lead within custom-made dental appliances:

> *Lead can be found in a number of porcelain products such as dinner plates and figurines. Feldspathic porcelain is a natural mineral that is mined from the earth and refined for dental use. As such, porcelain will contain naturally occurring trace elements of lead in varying concentrations, depending on the source and refining process.*
>
> *In assessing for total lead content, ADA scientists completely dissolved the powders and finished crowns, and measured the amount of lead remaining in the solution, finding only trace amounts of the naturally occurring element. The results ranged from below detectable to 113 parts per million (ppm) in the 44 porcelain powders, and an average of 46 ppm in the 102 porcelain dental crowns.*
>
> *Second, but more importantly, the researchers also tested the finished crowns for the release of lead (to test the potential body exposure to the element) under laboratory conditions far more extreme than could occur in the mouth. This testing yielded no measureable lead escaping from the porcelain crown (with a limit of detection at one ppm), even under accelerated acidic conditions at elevated temperatures.*
>
> Media Release: ADA Laboratory Tests Find Lead Not Released From Dental Crowns
> American Dental Association (24 March 2009)

It is acknowledged that this ADA-US study only looks at the lead concentrations within custom-made dental appliances and not other metals ill-suited for implantation within a patient's body. That said, the recorded incidence of such substances being used in custom-made medical devices is rare, notwithstanding the risks associated to any one patient when they are exposed to such undesirable substances.

In 2012 the OHPA surveyed its members and asked the question "are you personally aware of any dental work from any country around that world that has been fitted in Australia that has cause [sic] dental or medical problems." Although it is difficult to place too much weight on this survey as the published version does not provide guidance on methodology nor sample size, and the question does not indicate whether the problem product was manufactured in Australia or overseas (the reference is simply to "any" country in the world), it is interesting to note that only one-quarter answered in the affirmative. This is significant as the question simply asked respondents whether they were "aware" of any problem work as opposed to having first-hand experience, thus if there problem was as widespread, as many believe it is, it is reasonable to believe that the reported number of

dental technicians being “aware” of faulty product should have been significantly higher.

The Incident Reporting and Investigation Scheme (IRIS) maintained by the TGA is focused on adverse events or incidents related to the use of medical devices. Investigations of reports of adverse events or potential adverse events from medical device users (including patients and caregivers), sponsors and manufacturers can lead to actions such as product recalls, safety alerts, product improvement, user education and compliance testing. With respect to custom-made dental appliances, ADIA understands that the TGA has not received a quantity of reports concerning custom-made dental appliances that warrants a review. That said, ADIA is advised that the number of dentists and patients aware of the IRIS system is not large nor is its use fully understood within the dental industry, thus the absence of reported problems with custom-made medical devices on the IRIS system should not be used as a definitive argument to support the safety of custom-made dental appliances, whether locally manufactured or imported.

There is no doubt that the dental laboratory sector is facing considerable adverse commercial pressure resulting from the trend towards off-shore sourcing of custom-made dental appliances. However, the documented evidence does not suggest that overseas sourced product is consistently inferior to locally manufactured product. In this context, it is appropriate to couch further reforms in the context of a regulatory framework that is based on a risk management approach designed to ensure public health and safety, while at the same time freeing dental laboratories and healthcare professionals from an unnecessary regulatory burden.

Chapter 2 —
Regulatory framework for custom-made dental appliances

The regulatory standards for custom-made medical devices are set and enforced by the TGA pursuant to the provisions of the *Therapeutic Goods Act (Cth) 1989.* This legislation provides a framework for a risk management approach that allows the Australian community to have timely access to therapeutic goods which are consistently safe, effective and of high quality.

As a result of ADIA's advocacy efforts and growing concerns within the community about the safety of custom-made dental appliances, the TGA has provided considerable guidance concerning the regulatory standards for medical devices. ADIA commends the TGA for the provision of this advice in a timely manner. A key document is entitled *Custom-Made Medical Devices – Information for sponsors, health professionals and manufacturers* a copy of which is reproduced at Appendix A.

Current regulations for custom-made dental appliances

It is important to note that all custom-made dental appliances, whether manufactured in Australia or overseas, are required to meet the same regulatory standards in terms of product design, performance and safety. The regulated manufacturing processes include adherence to conformity assessment procedures prescribed in the *Therapeutic Goods (Medical Devices) Regulations 2002* which mandate compliance with the relevant "Essential principles", a defined set of outcomes for the manufacturing, performance and safety of medical devices.

With respect to custom-made dental appliances, product manufactured both in Australia and overseas is required to meet a range of criteria set out in the Essential Principles. There are six general Essential Principles that apply to all medical devices which include:

- Use of a medical device not to compromise health and safety;
- Design and construction of medical devices to conform with safety principles;
- Medical devices to be suitable for intended purpose;
- Long-term safety;
- Medical devices not to be adversely affected by transport or storage; and
- Benefits of medical devices to outweigh any undesirable effects;

There are a further nine Essential Principles about design and construction that apply to medical devices on a case-by-case basis. These provide minimum chemical, physical and biological properties in addition to a range of

matters not related to custom-made medical devices such as requirements for medical devices connected to or equipped with an energy source.

A common concern held by many within the community is that custom-made dental appliances may contain injurious substances, for instance heavy metals. The regulatory standards specifically prohibits this:

> *Choice of materials: In ensuring that the requirements of Part 1 are met in relation to a medical device, particular attention must be given to:*
>
> *a. the chemical and physical properties of the materials used in the device; and*
> *b. the compatibility between the materials used and biological tissues, cells and body fluids and specimens;*
>
> *having regard to the intended purpose of the device.*
>
> Therapeutic Goods (Medical Devices) Regulation 2002 – Schedule 1, Part 2
> Commonwealth of Australia (2002)

In ADIA's view, the regulatory standards governing the design, performance and manufacturing of custom-made medical devices are appropriate to the currently identified level of risk thus require no further revision at this point in time. That said, there is the need to consider revision to regulations governing the supply of custom-made medical devices that are set out in Chapter 4 of this submission.

Advice available to ADIA suggests that the importation of custom-made dental appliances is being driven by two sectors. The first sector are dental professionals (*e.g.* dentists) sourcing product directly from overseas. The second are businesses taking orders from dental professionals and utilising the services of an overseas dental laboratory to manufacture the custom-made dental appliance and then returning the finished product to the dental professional. As both elements in the supply chain are relatively new, it is appropriate to consider current regulatory enforcement obligations act activities.

Responsibility for statutory compliance

Given the complex supply arrangements in which dental products can be manufactured in Australia, ordered from dental professionals directly from overseas dental laboratories and also ordered by laboratories in Australia that then source the product from overseas, it is not surprising that there is considerable confusion concerning where responsibility rests for statutory compliance.

However convoluted the supply chain may seem, the TGA maintains a relatively straight-forward view as to where responsibility for statutory compliance rests. Under the provisions of the *Therapeutic Goods Act (Cth)*

1989 it is the Sponsor of a custom-made dental appliance who is responsible for statutory compliance. The TGA notes:

> *A sponsor is the person or organisation that imports or supplies medical devices in Australia, or exports medical devices from Australia. The sponsor can be the manufacturer, a health professional, or someone else.*
>
> *For example where a manufacturer in Australia also supplies their custom made devices directly to the market rather than through a third party, they will also be a sponsor under the Regulations.*
>
> *Or if a health professional obtains custom made devices directly from the manufacturer for supply to his or her patients, then they will be a sponsor under the Regulations.*
>
> Custom Made Medical Devices – Information for sponsors, health professionals and manufacturers
> Therapeutic Goods Administration (2 July 2012)

In layman's terms, responsibility for statutory compliance can be summarised as resting with the individuals who is responsible for originating the custom-made dental appliance within Australia. If the product was manufactured by an Australian dental laboratory, the principal of the laboratory will be nominally responsible (unless the business has designated a specific individual as having responsibility for statutory compliance). Similarly, when a custom-made dental appliance is ordered by a dental professional in Australia directly from an overseas laboratory, the dental professional is responsible for statutory compliance. This is recognised by the Australian Dental Association (ADA) which has published the following guidance:

> *Dental imports that are custom-made such as removable dentures, fixed dental prostheses, crowns, and bridges must also have a "sponsor" in order to enter Australia. A dentist may be listed as a "sponsor". By becoming a sponsor, the dentist becomes responsible for ensuring the dental device meets TGA requirements. For customised devices, the standard off-the-shelf components are required to be included on the ARTG. However, custom-made components and the assembled devices are currently not required to be included on the ARTG.*
>
> Brochure: National Dental Update – Imported Dental Devices, The Facts
> Australian Dental Association (October 2009)

Finally, if the custom-made dental appliance is ordered by an Australian business which then commissions an overseas dental laboratory to manufacturer the product, the principal of the Australian business is nominally responsible for statutory compliance (unless the business has designated a specific individual as having responsibility for statutory compliance).

At this point in time, ADIA believes that the regulatory standards for custom-made medical devices are appropriate and create a level playing field insofar as they apply equally to product manufactured in Australia or overseas. However, this is not commonly understood with many believing that import custom-made dental appliances are supplied outside the regulatory framework.

Incorrect perceptions of an unrelated market

As custom-made dental appliances are not required to be entered on the Australian Register of Therapeutic Goods (ARTG) and the TGA has no statutory responsibility for off-shore dental laboratories, there is the misconception that imported custom-made medical devices are "unregulated". This perception is widespread, even amongst key stakeholders:

> *Isn't it true that the Therapeutic Goods Administration has banned the use of heavy metals such as lead and nickel in the manufacture of dental prosthetics made in Australia but it is still perfectly legal to import cheap products from overseas that contain these dangerous metals? And don't these imported dental products end up in the same place as Australian made products — that is, in the patient's mouth?*
>
> Hansard: Question without Notice form Senator Fielding
> Australian Senate (28 October 2009)

As previously noted, the *Therapeutic Goods (Medical Devices) Regulation 2002* clearly prohibit imported custom-made dental appliances using dangerous toxic metals however misunderstanding on this point remains widespread. Beyond this misunderstanding concerning product standards, there is also confusion about who is responsible for statutory compliance. When referring to dentists who import custom-made dental appliances, the OPHA incorrectly concluded:

> *They are a totally ungoverned market selling crowns, cobalt-chrome castings and other work into Australia at alarming rates and now have an estimated market share of 50 – 60%.*
>
> Brochure: Dental Technicians – Call to Arms
> Oral Health Professionals Association (July 2011)

That the representative body for individual dental technicians could incorrectly draw this conclusion that dentists directly importing product are "completely ungoverned" highlights the complexity of the regulatory standards for custom-made dental appliances. However, over the course of the past year the TGA has made considerable efforts to increase awareness of, and compliances with, the regulatory standards and ADIA highly commends the organisation for this outcome.

Chapter 3 —
Senate Inquiry Into Regulatory Standards

On 16 June 2011 the Senate referred to the Senate Community Affairs References Committee for inquiry the regulatory standards for the approval of medical devices in Australia. Amongst the issues to be considered by the committee was the role of the TGA in regulating the quality of devices in Australia. Although the committee was primarily concerned with the TGA's role in enforcing regulatory standards for hip implants, at the urging of ADIA and member businesses the committee reviewed issues related to the importation of dental product. ADIA was the only association (industry or professional) in the dental sector to make representations to the committee.

The Senate Committee received advice that that custom-made dental prostheses such as crowns, bridges, dentures and some implants are sourced from overseas markets such as China, India and Vietnam. Senators observed:

> *The committee notes that custom made dental devices appear to escape TGA scrutiny, with dental professionals and patients alike unaware that up to 50 per cent of custom made dental prostheses are manufactured overseas, with no validation at the source of manufacture.*
>
> Report: The regulatory standards for the approval of medical devices in Australia
> Senate Community Affairs References Committee (11 November 2011)

Advice tendered to the Senate Committee was that the regulatory model used in the United Kingdom merited review. Under this model, patients in the United Kingdom receiving a custom-made dental appliance are offered a statement of manufacture. The advice was that practitioners are obligated to retain this statement for the lifetime of the prosthesis and record whether this was provided to the patient or not.

Senate committee recommendation

Senate standing order 38(1) requires the chair of a committee to prepare a draft report and submit it to the committee for consideration. After a final report has been agreed to Senators attached conclusions plus recommendations and with respect to its inquiry into the regulatory standards for custom-made medical devices, the committee made one recommendation:

> *Recommendation 12:*
> *The committee recommends that the Therapeutic Goods Administration consider whether custom made dental devices are adequately regulated; and whether the approach used in the United Kingdom of*

requiring a statement of manufacture to be provided to patients, and retained by the dental practitioner, has merit.

Report: The regulatory standards for the approval of medical devices in Australia
Senate Community Affairs References Committee (11 November 2011)

ADIA supports this recommendation. This submission is tendered to the Chair of the TGA Medical Device Reforms Reference Group with the objective of giving impetus to the implementation of the Senate Committee's recommendation. ADIA encourages the TGA to elevate this specific reform as a matter of priority.

The recommendation is significant insofar as it recognises that there is a problem and signals a course of action to address public perceptions associated with the safety of custom-made dental appliances. This course of action is supported by ADIA.

Australian Government response

Governments give careful consideration to Senate Committee reports and frequently act on committee recommendations. Since 1978, successive governments have undertaken to respond to committee reports within a specified period, currently three months. The Australian Government's response to the Senate Committee's response was tabled in the Senate on 13 September 2012, beyond the three-month timeframe.

The Australian Government's response addressed all eighteen recommendations contained within the Senate Committee's report. With respect to the regulatory arrangements for custom-made dental appliances, the Government responded to recommendation twelve on the following terms:

The Australian Government notes the recommendation.

Custom-made medical devices are not required to be included on the Australian Register of Therapeutic Goods. However, there are a number of requirements that must be met.

The therapeutic goods legislation requires that the importers of custom-made dental devices hold certain information about the device including information identifying the manufacturer, the device and any special characteristics of the device.

The Australian Government will consult with the Dental Board of Australia on this recommendation, as the governing body with the authority to regulate the dental profession.

Government Response: Report on the regulatory standards for the approval of medical devices in Australia
Australian Government (August 2012 – Tabled In The Senate 13 September 2012)

ADIA welcomes the commitment to engage with the DBA in order to increase awareness of, and compliance with, the regulatory standards for custom-made

medical devices. Further, ADIA believes it appropriate that it should follow the leadership of its counterpart in the United Kingdom, the General Dental Council (GDC), in clearly articulating that compliance with regulatory standards is a mandatory requirement for registration as a dentist. The GDC states:

> *All GDC registrations must comply with the GDC standards guidance. With regards to the commissioning and manufacturing of dental appliances, the following principle has particular relevance:*
>
> > *"Find out about laws and regulations which affect your work, premises, equipment and businesses, and follow them" (Principle 5.4L Standards for dental professionals).*
>
> *When commissioning and manufacturing dental appliances this includes compliance with the Medical Devices Directive 93/42/EC.*
>
> Brochure: Standards on commissioning and manufacturing dental appliances
> UK General Dental Council (March 2011)

ADIA is committed to working with the DBA in order to ensure that it is aware of the Australian Government's response to the Senate Committee's recommendations with a view to obtaining an outcome where the DBA publishes guidance for dental professionals that reflects Australian Government policy and reflects the position of the GDC.

As the peak representative body for suppliers of quality dental product, including a growing number of dental laboratories, ADIA was pleased to make representations to the Senate Community Affairs References Committee inquiry into the regulatory standards for dental product. ADIA believes that the committee's investigation and report, in addition to the Australian Government's response, represents a milestone in efforts to achieve improved regulation of custom made dental appliances.

Chapter 4 — Conclusions & Recommendations

There is an increasing trend to source custom-made dental appliances from off-shore dental laboratories, an outcome that is adversely affecting the commercial interest of the dental laboratory sector. In itself, this does not provide the need for regulatory reform. However, there are also growing public perceptions about the safety of imported custom-made dental appliances and a review of the current arrangements is justified in this context.

The understanding of the current regulatory standards for custom-made dental appliances is not understood, indeed the perception that imported product is "unregulated' does appear to be common. This perception has no basis in law as the TGA clearly establishes a level playing field by requiring all custom-made dental appliances meet the same mandated principles for design, performance and safety. For this reason, ADIA does not recommend any change to the regulatory standards for custom-made dental appliances from a product viewpoint; however there are two recommendations that are made:

Manufacturing and importation standards

The current regulatory standards for the approval of custom-made medical devices are essentially sound and broadly reflect risk management approach designed to ensure public health and safety, while at the same time freeing dental laboratories and healthcare practitioners from an unnecessary regulatory burden; however it could be improved by requiring a statement of manufacture to be provided to patients, and retained by the dental practitioner.

The implementation of this recommendation would address the calls for many of 'country of origin' labelling.

This is consistent with Recommendation 12 from the Senate Community Affairs References Committee's 2011 report into the regulatory standards for the approval of medical devices in Australia.

ARTG Improvements

Although Sponsors of custom-made medical devices are required to notify the TGA that they are supplying such products to the Australian market, there is no established process to do so. ADIA and the TGA have identified a pathway to improve the process by improving the ARTG's online eBusiness portal to allow Sponsors to register that they are supplying custom-made medical devices. Nothwithstanding TGA assurances that such an

improvement is under consideration, to date there are no signs of progress. A recommendation from this Legislative Assembly inquiry that the TGA expedite the required ARTG eBusiness upgrades would enjoy ADIA's unqualified support.

It is acknowledged that some stakeholders in the dental community have argued for a complete ban on imported custom-made medical devices used in dentistry. Notwithstanding the absence of demonstrable actual risk – as opposed to perceived risk – with such a move, it would be incompatible with Australia's World Trade Organisation (WTO) obligations.

ADIA welcomes the interest of the Standing Committee in this matter and looked forward to providing appropriate advice and guidance as appropriate.

Appendix A —

Therapeutic Goods Administration
Fact Sheet: Custom Made Medical Devices

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Custom made medical devices

Information for sponsors, health professionals and manufacturers

Definitions

What are custom made medical devices?

Custom made medical devices are defined in the Therapeutic Goods (Medical Devices) Regulations 2002 (the Regulations) as medical devices that are:

- made specifically in accordance with a request by a health professional specifying its design characteristics or construction.
- intended to be used only in relation to a particular individual, or by a health professional to meet special needs arising in the course of his or her practice.

Are medical devices that are adapted for an individual considered to be custom made?

Custom made medical devices do not include medical devices that have been adapted or modified to accommodate an individual patient. However, the device that requires modification is also required to be included on the Australian Register of Therapeutic Goods (ARTG) before it is supplied.

It is important to note that the person who adapts a medical device for an individual patient is not considered to be a manufacturer of a medical device if the adaptation does not alter its intended purpose. This exclusion is covered under subsection 41BG(3) of the *Therapeutic Goods Act 1989* (the Act).

Regulation—general

How are custom made devices regulated?

Manufacturing of custom made devices must at a minimum, meet conformity assessment procedures regulated by the TGA. These include conformity assessment procedures prescribed under Part 7, Schedule 3 of the Regulations that comply with the relevant Essential Principles in Schedule 1 of the Regulations.

Custom made devices are not required to undergo premarket assessment by the TGA or to be included on the ARTG before supply. This is because of the relatively low risk associated with the use of custom made devices such as prescription glasses and dental crowns, as well as the impracticalities of the TGA assessing such devices.

Can the TGA prevent custom made devices from being imported?

The TGA regulates the supply and exportation of medical devices to ensure they meet required standards of quality, safety and performance. So long as a custom made medical device meets these requirements, the TGA will not prevent their importation.

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TGA Health Safety Regulation

Examples of custom made medical devices

- dental appliances such as crowns, bridges and dentures
- prosthetic or glass eyes
- orthopaedic or pedorthic footwear
- prosthetic limbs
- prescription glasses

Requirements for sponsors

What or who is the sponsor of custom made medical devices?

A sponsor is the person or organisation that imports or supplies medical devices in Australia, or exports medical devices from Australia. The sponsor can be the manufacturer, a health professional, or someone else.

For example where a manufacturer in Australia also supplies their custom made devices directly to the market rather than through a third party, they will also be a sponsor under the Regulations.

Or if a health professional obtains custom made devices directly from the manufacturer for supply to his or her patients, then they will be a sponsor under the Regulations.

What are the requirements for sponsors of custom made medical devices?

The sponsor:

- must ensure that the manufacturer is aware of their responsibilities for manufacturer custom made devices under the therapeutic goods legislation
- have the same reporting obligations as the manufacturer (see below).
- must notify the TGA under section 41MP of the Act of the following:
  - any malfunction or deterioration in the characteristics or performance of the device
  - any inadequacy in the design, production, labelling, instructions for use or advertising material for the device
  - any use of the device that has led to, or potentially may lead to, the death or serious deterioration in the health of the patient or user of the custom made device
  - any information relating to technical or medical reason for a malfunction or deterioration of a custom made device that has led the manufacturer to recover the device
  - any information that indicates the device does not comply with the essential principles.

It is mandatory for medical device sponsors and manufacturers to report adverse events associated with a medical device. If there is any doubt about whether an adverse event report should be submitted, then the report should be submitted.

Requirements for health professionals

What are the responsibilities of health professionals prescribing custom made devices?

The health professional prescribing the custom made device is responsible for specifying its design characteristics or construction. If they are also the manufacturer or sponsor of the medical device, then they must also meet the relevant responsibilities.

Can health professionals import custom made medical devices?

Health professionals can import custom made medical devices from overseas, but in doing so they become the sponsor and are subject to the sponsor's obligations as outlined above.

Are health professionals obliged to tell patients if custom made device are manufactured overseas?

This is a matter for the health professional to decide and is not covered by therapeutic goods legislation.

Requirements for manufacturers

What are the requirements for manufacturers of custom made medical devices?

Manufacturers of custom made medical devices are required to apply appropriate conformity assessment procedures and should refer to the Australian regulatory guidelines for medical devices (ARGMD). In addition to this, the TGA provides the Essential principles checklist to assist manufacturers to ensure that any custom made devices meet safety and performance requirements.

What must be reported to the TGA?

Manufacturers are required to notify the TGA about:

- malfunctions or deteriorations in the characteristics or performance of the device
- any problems with the design, production, labelling or instructions for use of the device that has led to, or potentially may lead to, the death or a serious deterioration in the health of the user of the custom made device
- information relating to the technical or medical reason for a malfunction or deterioration of custom made devices that has led to the recovery of that device.

These reporting requirements are detailed in Schedule 3, Part 7(7.5)(4)(c) of the Therapeutic Goods (Medical Devices) Regulations 2002.

Suspect devices

What do I do if I find a suspect medical device?

If you have concerns about the safety or performance of a custom made medical device, you can submit a report to the TGA. The act of reporting an event is not an admission of liability for the event or its consequences.

This can be done via the TGA Internet site, or the forms can be posted to:

Office of Product Review
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Appendix B(i) —

UK Medicines & Health Products Regulation Agency
Sample Mandated Form – Patient Prescription Information (Type 1)

A N Other Dental Laboratory
44 Wollaton Road
Nottingham NG9 2NR
0115 9254888
REGISTERED WITH THE UK COMPETENT AUTHORITY GA00000

TWO-PART CUSTOM-MADE DENTAL APPLIANCE PRESCRIPTION

MHRA

Please complete the appropriate sections of this prescription and send both parts to the address opposite. If you have any problems with the use of this prescription then phone us on 0115 9254888.

PATIENT'S NAME | NAME OF PRESCRIBER | CLINIC NAME AND ADDRESS (*if applicable*)

Date sent: | Date required | Lab reference (*where applicable*)

Type of appliance	Orthodontic	Denture	Metal casting	Crown & Bridge	Bite raiser	Splint
Please [Y]	Obturator	Facial prosthesis	Body prosthesis	Nightguard	Implant	Bleaching tray

INSTRUCTIONS AND AMENDMENTS RECORD

OUTLINE OF DESIGN REQUIRED

FIELDS BELOW TO BE COMPLETED BY LABORATORY PERSONNEL ONLY

Approved for manufacture by:
Sign:
Details of materials etc supplied by prescriber
Initials:

Approved for release by:
Sign:
Details of any model approval by prescriber
Initials:

ORIGIN OF MANUFACTURE DECLARATION

This complete appliance has been wholly manufactured within the EU.
☐ Yes
☐ No
(If no, detail manufacturing locations below)
3.
4.

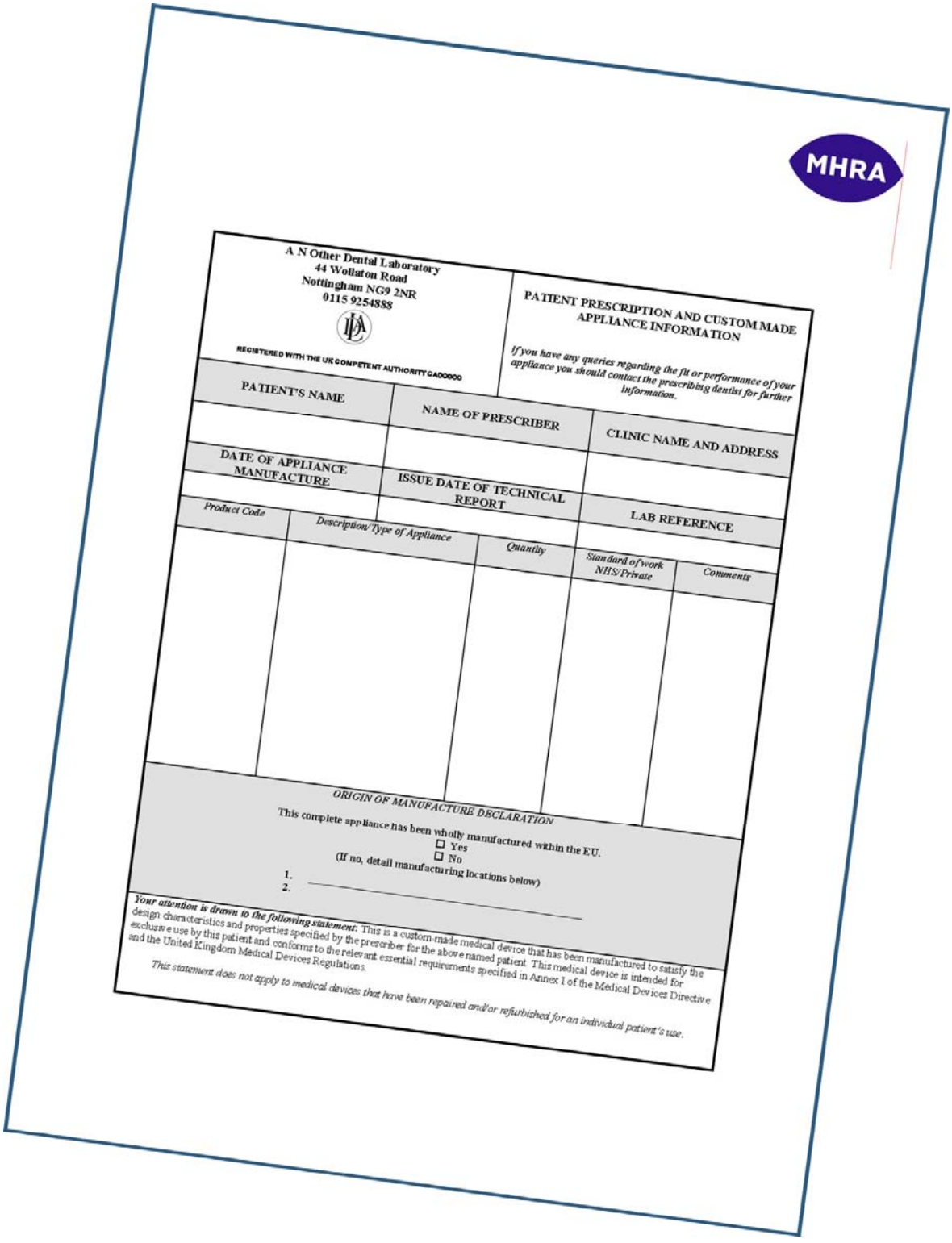
Your attention is drawn to the following statement: This is a custom-made medical device that has been manufactured to satisfy the design characteristics and properties specified by the prescriber for the above named patient. This medical device is intended for exclusive use by this patient and conforms to the relevant essential requirements specified in Annex I of the Medical Devices Directive and the United Kingdom Medical Devices Regulations.

This statement does not apply to medical devices that have been repaired and/or refurbished for an individual patient's use.

Storing, handling and instructions for use: It is recommended that before use, this medical device is stored in a clean and safe environment that prevents it from coming into contact with materials, equipment, acids, alkalies or bleaches that could cause physical or chemical damage to the medical device. The medical device should not be subjected to extremes of temperature during storage. Where applicable, you should take care not to damage the medical device when removing it from its model. Where applicable, instructions on how to use or clean this medical device may be obtained from the prescriber.

Appendix B(ii) —

UK Medicines & Health Products Regulation Agency
Sample Mandated Form – Patient Prescription Information (Type 2)



MHRA

A N Other Dental Laboratory
44 Wollaton Road
Nottingham NG9 2NR
0115 9254888

REGISTERED WITH THE UK COMPETENT AUTHORITY GA00000

PATIENT PRESCRIPTION AND CUSTOM MADE APPLIANCE INFORMATION

If you have any queries regarding the fit or performance of your appliance you should contact the prescribing dentist for further information.

PATIENT'S NAME	NAME OF PRESCRIBER	CLINIC NAME AND ADDRESS
DATE OF APPLIANCE MANUFACTURE	**ISSUE DATE OF TECHNICAL REPORT**	**LAB REFERENCE**

Product Code	*Description/Type of Appliance*	*Quantity*	*Standard of work NHS/Private*	*Comments*

ORIGIN OF MANUFACTURE DECLARATION

This complete appliance has been wholly manufactured within the EU.
☐ Yes
☐ No
(If no, detail manufacturing locations below)
1.
2.

Your attention is drawn to the following statement: This is a custom-made medical device that has been manufactured to satisfy the design characteristics and properties specified by the prescriber for the above named patient. This medical device is intended for exclusive use by this patient and conforms to the relevant essential requirements specified in Annex I of the Medical Devices Directive and the United Kingdom Medical Devices Regulations.

This statement does not apply to medical devices that have been repaired and/or refurbished for an individual patient's use.

Appendix C —

The following abbreviations are used throughout this submission

ADA	Australian Dental Association
ADIA	Australian Dental Industry Association
ADA-US	American Dental Association (USA)
AHPRA	Australian Healthcare Practitioner Regulation Agency
DBA	Dental Board of Australia
FDA	Food and Drug Administration (USA)
FDI	World Dental Federation (*Fr.* Federation Dentaire Internationale)
IDM	International Dental Manufacturers association
IRIS	Incident Reporting and Investigation Scheme (IRIS)
ISO	International Standards Organisation
OHPA	Oral Health Professionals Association
MHRA	Medial Health products Regulation Agency (UK)
NADL	National Association of Dental Laboratories (NADL)
NEHTA	National E-Health Transition Authority
TGA	Therapeutic Goods Administration
WHO	World Health Organisation

Introduction – Australian Dental Industry Association

Formed in 1925, ADIA is the peak national association representing the suppliers of quality dental product and services to dentists and allied oral healthcare professionals. The ADIA membership represents businesses, including a growing number of dental laboratories, that supply around more than ninety-five percent of the nation's purchases of dental product and consumables which are valued at an estimated $860 million per annum.

ADIA members have the opportunity to contribute to the development of not only the Association, but also the broader dental industry, through a number of national committees that address regulatory, technical, skills and industry promotional issues. A national board of seven leading professionals attends to governance matters and sets the strategic direction of the Association.

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. The Association provides advice to agencies including the TGA and the National eHealth Transition Authority (NeHTA), often nominating industry representatives to government committees and working groups. The Association also supports its members in the development of technical standards for dental products and consumables, nominating industry representatives to committees of both Standards Australia and the International Standards Organisation (ISO).

ADIA builds partnerships between dentists and the suppliers of dental products and services. The Association is the organiser of the nation's premier dental trade show, the highly acclaimed *ADX Dental Exhibition,* which attracts more than four thousand dentists and allied oral healthcare professionals every year.

At an international level, ADIA is a founding member of the International Dental Manufacturers (IDM), the Geneva-based global confederation of national dental trade associations. ADIA is also a supporting member of the World Dental Federation (*Fr.* Federation Dentaire Internationale – FDI).

Working with members to ensure that the dental industry has ongoing access to a workforce of skilled professionals, the Association supports the development of both TAFE and university courses relevant to the dental industry and the Association delivers the widely acclaimed *ADIA Introduction To Dentistry Course*.

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

■ ADIA MEMBER BUSINESSES ■

3M ESPE A.R. Medicom AB Dental Employment Agency Accentu8 Novotecnica Acteon Australia / New Zealand Active Change for Life A-dec Australia AHP Dental & Medical Ainsworth Dental Airport Function Centre AJ Barber Alldent Alphabond Dental Amalgadent Dental Supplies Ampac Dental Anthos in Australia AP Design AR Instrumed Argibond Dental Supplies Ark Health Auspharm Australasian Academy of Dento-Facial Aesthetics Australasian Dental Practice Australasian Dentist Australian College of Dental Education Australian Imaging Australian Medical Suction Systems Bien Air Australasia Biodental Technologies BioHorizons Australia Biomedex Biomet 3i Bite Magazine Body Logic Resources Borg Dental Bourke Dental Supply Bova Compounding Carestream Dental Carl Zeiss Cattani Australia Centaur Software City Dental Supplies Clare Martin & Associates Clark Jacobs Clisby Engineering Colgate Oral Care Coltene-Whaledent International Commodore Joinery Critical Dental Curaden Swiss Dental Axess Dental Burs Australia Dental Concepts Dental Depot (QLD) Dental Fitout Projects Dental Innovations Dental Installations Dentalife Dentaurum Australia Dentavision Dentequip Dentiform Australia Dentist's Choice Dentpro Dentsply (Australia) Designer Project Group Designer Surgeries Designs for Vision Digital Dental DPL Australia Dürr Dental AG East Coast Dental Services Ecocycle Australia Elite Fitout Solutions Empire Dental Devices EMS Erskine Dental Essology Finlease (Aust) First Dental GC Australasia Dental Glamsmile GlaxoSmithKline Gritter Dental Gulmohar Dental Gunz Dental Hayes Handpiece Australia Heine Australia Henry Schein Halas Heraeus Dental Australia HICAPS High Tech Laser Australia Hogies Australia Horseley Dental Supplies Hu-Friedy Mfg Co Inc ID Health IDOZ Medical iMixwell Impulsedent Australia Independent Dental Supplies Inline Medical & Dental Innovatio Dental Supplies Investec Specialist Bank Ivoclar Vivadent Johnson and Johnson Pacific Kerr Corporation Leading Dental Levitch Design Australia Lizard Software Lomax Financial Group Lorchant Dental Marda Investments Med & Dent (WA) Medfin Australia Medi-Dent Medical Dental Solutions NQ Medical Equipment Services Medifit Medilend Melbourne Dental Miele Australia Miniflam Australia Minimax Implant (Dentium Australia) Mobile Clinics Australia [Kuipers] Mocom Australia Momentum Management Myofunctional Research Co NAOL Australia Neoss Australia Nobel Biocare NSK Oceania One Dental Oral-B (Procter & Gamble) Osseo Dental Osstem Australia Pegasus Dental Services Philips Oral Healthcare Presidental Prime Practice Priority Dental Supplies Trust Professional Dentist Supplies Profile Financial Services Purus Health and Medical Technologies RCR International Ridley Dental Supplies Right Time Business RJ Dental Sales & Service Roland DG Australia RutiniDent Dental Supplies RWD Dental Image SDI Ltd Sieverts Radiation Protection Consultancy Siltex (Australia) Sirona Dental Systems Software of Excellence South Austral Southern Implants Australia Specialites Septodont Stoneglass Industries Straumann Suntech Dental Equipment Services Supreme Orthodontic Supply (Aust) The Bambach Saddle Seat The Dental Solution Australia Tri-Dental Implants TrollDental Trustwater Australia Ultimate Dental Supplies Ultimo Health Technologies Ultradent Products Inc Veden Australia VOCO Australia W&H Wellsites West Coast Dental Depot Whiteley Corporation William Green Wisbey Dental Zeno Dental

ADIA
Australian Dental Industry Association Limited
ABN 32 003 0314 396

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