# Response ID ANON-3NHQ-DDC6-U

Submitted to Proposed refinements to the regulation of personalised medical devices
Submitted on 2021-07-09 16:26:27

## Introduction

1 What is your name?

Name:
Richard Salter

2 What is your work title?

Work title:
Managing Director

3 What is your email address?

Email:
[redacted]

4 What is your company/organisation?

Organisation:
Avant Dental Pty Ltd

5 What is your company/organisation address?

Please provide the business address of your company or organisation.:

[redacted]

6 Which industry do you work in, or represent?

Please state the industry that you work in, or are representing in your submission.:
Dental Laboratory

7 Are you responding:

On behalf of an organisation

## Exclusion

8 Do you agree with the rationale for the proposed exclusion of products?

Yes

If you answered 'no' to the above question, why do you disagree with the rationale for the proposed exclusion of the products listed?:

9 Are the risks posed by the products adequately managed if they are excluded from regulation by the TGA?

Yes

Please explain your response, including by providing examples that illustrate and/or support your position.:

These products are generally lighter touch and not long term devices in the dental laboratory industry e.g. special positioning tray, denture repair kits, whitening trays. Although they can ultimately be risks with these devices as they are devices we believe the practical approach suggested and the fact protections to consumers are covered by ACCC and state or territory consumer protection laws. This is a good idea to exclude and we are supportive of this.

10 Are there further products that meet the principles proposed for exclusion? What are they and why should they be excluded?

Ensure your answer directly addresses (1) why the products pose no, or insignificant, levels of risk or (2) why the product does not meet the definition of a medical device. :

We support the exclusion of very low risk devices such as the examples given
above. We do not support the definition of a medical device as there is less importance then on the materials used to make the devices. There is scope for increased scrutiny on the materials in which labs use but less so on the actually devices we produce as ultimately this should be the responsibility of the practitioner.

## Exemption

11 Do you agree with the rationale for the proposed exemption of Class I non-sterile, non-measuring patient-matched devices when produced under the circumstances listed in the consultation paper?

Yes

If you answered 'no' to the above question, please explain why it is that you disagree with the rationale for the proposed exemption of Class I non-sterile, non-measuring patient-matched medical devices?:

We support the exception rules. This seems like a practical solution given to the risk of the products listed.

12 Can the risks posed by Class I non-sterile, non-measuring patient-matched medical devices when produced under the circumstances listed in the consultation paper be adequately managed if they are exempted from inclusion in the ARTG?

No

Please explain your response, including by providing examples that illustrate and/or support your position.:

Although I do believe in exempting Class I non sterile from inclusion on the ARTG we DO NOT support the criteria for a trained or accredited professional is fair or suitalbe for dental laboratory industry in practicality for a number of reasons.

Australian Qualification disagreement
Dental technicians are not registered in Australia. There have been no regulatory requirements to practice as a dental technician since 2010. The industry was deregulated in 2010. In 2010, with the establishment of the Dental Board of Australia, the national registration requirement for Dental Technicians was not implemented, and all State requirements removed. The Dental Technician is now classified as an Unregistered Health Practitioner. There is no federal body overseeing their practice. Like many trades the quality of work is often learnt through internal training programmes and experience on the job. Normal practice in Australia is that technicians learn there skills on the job. A quality device is not necessarily decided by whether a technician is Qualified in Australia. This is especially relevant in Australia due to most dental technicians not having Australian qualification yet trained overseas. As an example inside our organisation, we have employed many technicians over the past decade and the overwhelming majority were trained overseas and of a higher quality technician than many trained in Australia.
The Australian Health Professionals Regulatory Authority (AHPRA) AND The Dental Board of Australia (DBA) are The two national bodies that provide direction, standards, policies and guidelines for the registered practitioners, those relevant to this discussion are Dentists and Dental Prosthetists. Through the registration process and other mechanisms, they can effectively manage and monitor: Workforce numbers and locations of operation, Codes and Scopes of Practice, Advertising and Patient Disclosure requirements. The dental laboratory industry are commissioned by these professionals to manufacture custom made products under the specifications of these trained professionals. Quality is ultimately determined by these professionals not by where a technician has been trained.
All dental laboratories are already required to comply with the Therapeutic Goods (Medical Devices) Regulations 2002 (the Regulations) under the guiding principals.
Business regulations for Dental Laboratories are already covered across numerous jurisdictions and areas just like any business operating in Australia these include but are not limited to
• Environmental Protection (EPAs) – for the management of fumes and dust from the manufacturing process
• Fair Work Ombudsman – for the application and management of the Award, MA000027 Health Professional and Support Services Award
• Work, Health and Safety Regulation
• Australian Consumer Law
• Other Local, State and Federal

The Oral Health Professionals Association not a relevant and current organisation to the Dental Laboratory industry. The majority of Laboratories in Australia are not represented by this organisation nor are they an authority of best practice or quality standards. Our laboratory manufactures both onshore and offshore and the quality of product is determined by the quality procedures of the lab and of the technician not whether they were trained in Australia or a member. I would like to make a note that according to their website the last AGM held was on the 20th November 2014 to elect a new President. More evidence to say they are not a current or relevant authority in the industry.

Having products exempted due to the qualifications of the person making the product rather than the quality of the product and or the manufacturing process creates an unfair playing field. This precedent will cause difficulty for Australian manufacturers when exporting devices to other markets that rely on International medical device regulatory requirements.

13 Are there further circumstances where Class I non-sterile, non-measuring patient-matched devices could be exempt? If so, what measures are in place to manage the risks associated with the devices?

Ensure your answer directly addresses the specific circumstances that are in place (such as qualifications, accreditation, certification, etc) to ensure that the risks associated with the manufacture of the devices have been managed and the Australian regulatory requirements for medical devices have been met before they are supplied.:

We DO NOT support the further circumstances listed above such as qualifications,
accreditation, certification, etc as being suitable or a relevant. We have voiced our opinion above and agree with advice and perspective given

Having products exempted due to the qualifications of the person making the product rather than the quality of the product and or the manufacturing process creates an unfair playing field as mentioned earlier. This precedent will cause difficulty for Australian manufacturers when exporting PMD's to other markets that rely on International medical device regulatory requirements.

I would like to reiterate the qualifications, accreditation, certification IS NOT relevant to the current industry.

## Alternative conformity assessment procedures

14 Do you agree with the rationale for the proposed alternative conformity assessment procedures for Class IIa patient-matched medical devices when produced under the circumstances listed in the consultation paper?

No

If you answered 'no' to the above question, please explain why you disagree with the rationale for the proposed alternative conformity assessment procedures for Class IIa patient-matched medical devices?:

We DO NOT support the rationale with proposed rationale for IIa devices on the same merits of mentioned earlier in question 11.. I do not believe the TGA have a real understanding of how the industry is made up and the role in which offshore manufacturing through hybrid manufacturing processes where products are made by sponsors and finished locally or made wholly by offshore manufacturers is understood. The proposed changes also do not take into considerations what exporters of PMD's to other international markets will need to do and makes them less competitive.

I would like to reiterate the list qualifications, accreditation, certification especially the OHPA are not suitable.

15 Do you agree that the risks associated with the Class IIa patient-matched medical devices when produced under the circumstances listed in the consultation paper could be adequately managed through the proposed alternative conformity assessment procedure?

No

Please explain your response, including by providing examples that illustrate and/or support your position.:

We DO NOT support the rationale. This is on the same reasons outlined above and in previous question 12.

16 Are there further circumstances where an alternative conformity assessment procedure for Class IIa patient-matched devices would be appropriate?

Please ensure that your answer directly addresses what measures are in place to manage the risks associated with the devices.:

We DO NOT support the rationale which was outlined in previous response to Q13 and reasons relevant.

17 Are there any Class IIa patient-matched medical devices that should not be subject to an alternative conformity assessment procedure? What are they, and why not?

Please outline your reasoning.:

We DO NOT support the rationale as previously answered. As we have previously detailed in question. We believe that a consistent regulation should be applied across all IIa as to create an even playing field for both manufacturers, sponsors and exporters.

## Alternative approaches we should consider

18 Are there alternative mechanisms for minimising the regulatory burden for patient-matched medical devices without compromising patient health and safety that you would like to propose?

If applicable, please write your response in the text box below.:

We feel as if a level playing field must be maintained across all fields. These compliance requirements puts pressure on the limited resources of laboratories and adding more layers of compliance and cost could make it unfair on smaller laboratories or laboratories where technicians may be trained oversees. The majority of dental laboratory products are Class IIa therefore exception wouldn't really help the administrative burden and create a burden which will result in less quality of products due to limited resources put towards regulation rather than quality of products.

Given we are a full service dental laboratory we would need to include a number of GMDN codes for very similar products. The introduction of some generic categories would simplify and reduce the costs and be a happy compromise. Also a requirement of more scrutiny on the raw materials used would add another layer of safety without creating a greater burden on administration.

## Required final step - Publishing my response

19 Do you consent to the Department collecting the information requested in Citizen Space about you, including any sensitive information, for the purposes of this consultation?

I consent

20 I consent to the submission made by me being published on the Department's website, and accessible to the public, including persons overseas, in accordance with the following preference:

Publish response, including both my name and organisation's name

21 If there are specific answers you have provided that you do not wish to be published, please indicate these below.

Please state below any specific questions that you do not wish to have your answers to published.:

22 May we contact you for further information or to seek feedback about how the consultation was undertaken?

Yes

23 By making a submission, I acknowledge that:

I acknowledge the above