Response ID ANON-3NHQ-DDD3-S

Submitted to Proposed refinements to the regulation of personalised medical devices
Submitted on 2021-06-24 01:14:34

Introduction

1 What is your name?

Name:
[redacted]

2 What is your work title?

Work title:
Principal Dentist

3 What is your email address?

Email:
[redacted]

4 What is your company/organisation?

Organisation:
[redacted]

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.:
Dentist

7 Are you responding:

As an individual

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.:

Training to fabricate these devices are part of my qualification (BDSc UWA).
Sourced items for fabrication (i.e. thermoplastics) are regulated to Health grade standards already. Other items are manufactured fit for use (e.g. UV cure light materials, specifically for dental use)

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. :

MEDICAMENT trays (for fluoride application, tooth mousse application and home bleaching application) - not described correctly as just 'bleaching trays'; ensure the definition there is accurate. Prescribed use by professional.

"Orthodontic appliance positioning tray" - Not described correctly. It is NOT a tray). Simple PASSIVE orthodontic appliance (i.e. post orthodontic treatment retainer). Prescribed use by professional.

Dental Custom Trays, to take the 'physical impressions of a patient's anatomy and models cast from these'. Used for secondary impression but technically 'made to match the patient'. Prescribed use by professional.

The above items can be accurately fabricated in house by a dentist with relevant training, as well as CERT III/IV dental assistants with correct extended training and Oral Health Therapists with relevant training.

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?:

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.:

Dental prosthetists
• Occlusal splints
• Aligners

Does this fall under their scope?

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.:

Special Custom (to patient) Tray for impressions (dental)
Medicament Trays (dental)
Passive orthodontic appliance (dental)
Custom fit mouthguards (dental) for sport

- provided adequate fabrication training (qualifications, certifications to prove this)
- should exclusion not be permitted

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?

Yes

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?:

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?

Not Answered

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

No comments for or against

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.:

No comments

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.:

No comments

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.:

Official recognition of certification-equivalent training through application or assessment of current Australian accredited courses.
e.g. I have learnt how to fabricate a mouthguard at university as part of my BDSc (UWA). I don't have a document that says that.
I don't know if that is universal to all dentists, all universities, all years of courses etc. Something that can be verified though.

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 without my name or my organisation's name (anonymously)

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.:
No

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

No

23 By making a submission, I acknowledge that:

I acknowledge the above