# Response ID ANON-3NHQ-DDSM-2

Submitted to Proposed refinements to the regulation of personalised medical devices
Submitted on 2021-07-13 18:49:23

## Introduction

1 What is your name?

Name:
[redacted]

2 What is your work title?

Work title:
[redacted]

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.:
Dental

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.:

the examples in the consultation paper relating to dental products indicates that they meet the definition of a medical devices but the level of risk posed by these devices is considered to be very low.
Also it is likely that the materials used to produce these devices are included in the ARTG

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. :

Yes , please consider [redacted] suck down' orthodontic retainers to be excluded from regulation. The rationale being that they are a passive retention device without any medicament. they are usually worn only at night and they have very low risk of complications.
If bleaching trays are excluded, then so too should these retainers be considered for exclusion.

## 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?

Yes

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

The dental devices listed in the consultation papers as examples of exempted from inclusion in the ARTG are of low risk and this is because of their limited duration of use and low level of invasiveness. they are also manufactured by qualified staff following clear instructions / prescriptions from registered health practitioners. Also, they are issued to the patients by qualified health professionals.
Finally, the listed examples of exempted dental devices are manufactured using materials approved by the TGA and listed in the ARTG .

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.:

No the circumstances listed in the consultation paper are sufficient. However it would be beneficial to clearly articulate the what the specific labelling expectations?

## 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?

Yes

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

The dental devices listed as examples of class IIa PMD suitable for alternative conformity assessment are manufactured using material approved by the TGA, manufactured through a standardised process by qualified technicians and with oversight from registered health practitioners

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

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.:

Yes, dental crowns and bridges manufactured by “Medical Device Production Systems” wherein an end-to-end system for the manufacture of patient-matched medical devices is currently included in the ARTG, thereby allowing medical devices to be manufactured within healthcare facilities without the need to undergo full conformity assessment and application for inclusion in the ARTG.

## 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.:

Yes please, we need clarifications about the requirements for dental devices ( e.g. crowns and bridges ) manufactured by “Medical Device Production Systems” which are currently registered in the ARTG as a medical device system (e.g. Cerec CAD/ CAM which is currently listed in the ARTG as a medical device 287358 )

## 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.:
N/A

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