Response ID ANON-3NHQ-DDDP-P

Submitted to Proposed refinements to the regulation of personalised medical devices
Submitted on 2021-06-17 15:23:05

Introduction

1 What is your name?

Name:
Dr. Kieran O'Shannessy dental surgeon

2 What is your work title?

Work title:
Dr. Kieran O'Shannessy dental surgeon

3 What is your email address?

Email:
[redacted]

4 What is your company/organisation?

Organisation:
Dr. Kieran O'Shannessy proprietary limited

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:

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.:

Items are produced by means of personal and direct action performed upon the patient in person and are well regulated by AHPRA.
Items are not of a kind just recently innovated but are of kinds which have been practiced for many years.
Items are not of a kind which has untoward side effects over time. On the contrary they are readily amenable to simple physical adjustments when required.
For example tooth crowns are really not more than an extended dimension of tooth fillings.
Mouthguards, Dental splints and occlusal appliances and dentures fit very well with the above comments.

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. :

n/a

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?:

At this point in time I have not seen in them an application to the Dental appliances mentioned in my earlier response

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.:

I am really not quite sure how to respond to this

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.:

n/a

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.:

As above

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.:

My belief in accordance with my comments above, is that there are no other measures required

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.:
n/a

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