Response ID ANON-3NHQ-DDSB-Q

Submitted to Proposed refinements to the regulation of personalised medical devices
Submitted on 2021-07-14 00:05:46

Introduction

1 What is your name?

Name:
[redacted]

2 What is your work title?

Work title:
Dental Laboratory Owner

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 - Manufacturing

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.:

The risks are managed due to having only qualified technicians permitted to manufacture the products and a suitably qualified professional insert / provide the product to the customers.

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. :

Temporary dental crowns or bridges, manufactured by a dental technician in a dental laboratory .
The temporary dental crown and bridge by definition is to be inserted only for a short term while waiting for the manufacture of the permanent crown or bridge.
The time frame should be less than 30 days for the permanent crown or bridge to be inserted.

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 risks posed by Class 1 non-sterile, non-measuring patient- matched medical devices will be adequately managed as they have been for many years, ensuring only suitably qualified people are permitted to either manufacture or distribute the product to customers.
TGA approved materials used in the manufacture of the product is key to avoiding most adverse events.

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.:

The qualifications required to manufacture and distribute the devices should meet the requirements for exemption.
TGA approved materials are required to be used by Australian laboratories therefore the risk level should be very low.

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 device is manufactured by a trained, accredited professional who has been recognized as having the required skills to produce the product. When produced in a dental laboratory it will be given to the customer by another trained professional or by the technician who has attained higher qualifications. The quality should be assured and risks should be minimal.
Self assessment and accountability would be assured through documentation that supports their applications.

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.:

Self assessment and documentation to show evidence of accountability should direct responsibility to to the manufacturer of the devices. As with the ATO, the TGA could make site visits on a random, by appointment basis to inspect manufacturing premises to ensure compliance.
At all times disclosure of manufacturing locations should be transparent and recorded.

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

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.:

The regulatory burden will be very expensive and difficult for small laboratories, some boutique laboratories that concentrate on producing custom (patient-matched) devices with intricate, very precise products will have no alternative but to amalgamate with larger business to absorb associated costs and extra time required for compliance e.g. The statement for personalised medical devices and Patient Information sheets, annual reporting, and extra record keeping to name the most time consuming . The costs associated with the extra compliance will need to be passed on to the customer.
Alternative mechanisms that would reduce the burden could be to streamline the process by having the patient invoice double as the statement of personalised medical device as most information is included on the invoice. If an invoice is issued the essentials principles and compliance should be automatically accepted as followed and responsibility for them assured.
Patient Information sheets is a doubling up with the information distributed by dentists to their patients / customers (in the dental laboratory situation). Should the lab be issuing the information sheets or should the operator seeing the customer? In most instances the operator who inserts or distributes the product is the one explaining the use and care of the product.

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.:

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