Response ID ANON-3NHQ-DDSP-5

Submitted to Proposed refinements to the regulation of personalised medical devices
Submitted on 2021-07-13 20:30:36

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.:

6 Which industry do you work in, or represent?

Please state the industry that you work in, or are representing in your submission.:
Medical Engineering / Patient Specific Products

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?

No

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

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. :

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.:

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.:

I would suggest an addition :

Examples where Class I (low-risk) patient-matched medical devices could be exempted are where they are being manufactured:
By an accredited Biomedical Engineer registered with Engineers Australia (as a Biomedical Engineer) [who holds a recognised qualification under the Australian Qualifications Framework] AND
The devices they produce are intended to be used by a patient of a healthcare facility, registered provider or AHPRA-registered health professional.

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.:

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.:

I would suggest an addition :

Examples where Class IIa (low-medium risk) patient-matched medical devices could be subject to alternative conformity assessment procedures are if they are being manufactured:
By an accredited Biomedical Engineer registered with Engineers Australia (as a Biomedical Engineer) [who holds a recognised qualification under the Australian Qualifications Framework] AND
The devices they produce are intended to be used by a patient of a healthcare facility, registered provider or AHPRA-registered health professional.

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.:

I agree with the reclassification of anatomical models for diagnostic purposes to IIa, however I believe they should be exempt from ARTG similar to Class I non-sterile, non-measuring PMMD with alternative mechanisms of oversight for the manufacture and use of the device.

Anatomical models do not enter oral cavities and do not pernitrate skin, have any anchorage to the body or require health care professionals for removal. The function they have in addition to Class I is a "measuring" which when manufactured by a by an accredited professional (Biomedical Engineer included, as above). They are also a duplicate of a real patient so verification of accuracy can be done by the health care provider in real time (relatively).

The accuracy of anatomical models (thus, measuring function) has more to do with the experience of the professional CREATING the model prior to production rather than the way at which it is produced. Materials and manufacturing techniques are of course important but generally these models are produced with the same material and same machines as the majority of Class I devices. Certification of software and process to convert patient data to 3D model need to be followed and validated by accredited professional (Biomedical Engineer).

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.:

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