

## Response ID ANON-3NHQ-DDQB-N

Submitted to Proposed refinements to the regulation of personalised medical devices  
Submitted on 2021-06-25 14:45:38

### 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.:  
health

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.:

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. :

Custom made bolus for radiation therapy should also be on the exclusion list as it is a low risk custom device that is not implanted into the patient, or in place for any length of time. 3D custom bolus for radiation therapy is designed as part of the radiation treatment plan and is placed on the patient only during the course of treatment, under the care of health professionals.

Controls regarding the risks of this device in conjunction to the course of radiation therapy are managed under the radiation safety plan of the department, regulated by radiation protection.

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