# Response ID ANON-3NHQ-DDQS-6

Submitted to Proposed refinements to the regulation of personalised medical devices
Submitted on 2021-06-24 15:27:19

## 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.:
Radiation Therapy

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.:

For radiation therapy Bolus I believe 'yes' as there is a mandatory reporting system within the industry which can account for any issues with the production of these moulds.

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. :

In relation to a Bolus that is made in a radiation therapy setting, using a 3D printer and Silicon based material. I believe that the current standards required for each department would cover this without TGA management.
The bolus being produced is to be placed on the patient surface to attenuate the radiation dose optimising how this dose is delivered. To produce this an individual CT scan of the patient is taken and the mould is designed within the radiation planning system. This ensures a high standard of accuracy and

makes the product very patient specific posing little risk to be used on the wrong person.
The products used to make the bolus are of no risk to the patient as they are only used externally and not introduced into the patient.
The QA around these devices will vary from department to department however all will have a checking process to ensure that these are generated correctly. This will vary from set measurements to additional CT scans.
Additional to this QA there are already stringent guidelines established for radiation therapy and any missed/incorrect treatments. If a patient was to receive treatment with an incorrect bolus made then mandatory reporting would be undertaken and the error reported

## 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