TGA – Transitional arrangements

Step-by-step Guide for ASO members

ONLINE FORM AVAILABLE HERE

NOTE: The information provided below does not constitute legal advice.

It is up to each practitioner to determine how and what they report on.

The information provided below are suggestions based on our current understanding of the framework. Please note that this is subject to change and we will notify members immediately if the guidance changes.

NB: These forms **need to be completed for each "kind" of device, not every single device**. For example, if you manufacture removable orthodontic retainers, you would complete the form once regardless of how many variations of a removable retainer you manufacture. See the GMDN Code table and the ASO Fact Sheet for more examples.

Before you complete the application for transitional arrangements form, you will need to have completed the online form notifying the TGA that you are supplying this kind of device. This is a simple form that only requires your contact information and the description, GMDN code and Classification of the kind of device you are supplying. All of this information you can find on the GMDN Code table and the ASO Fact Sheet.

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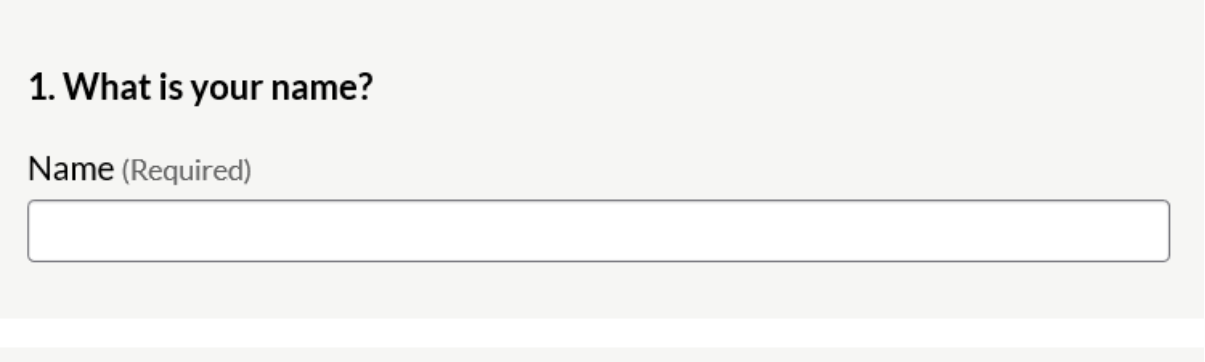
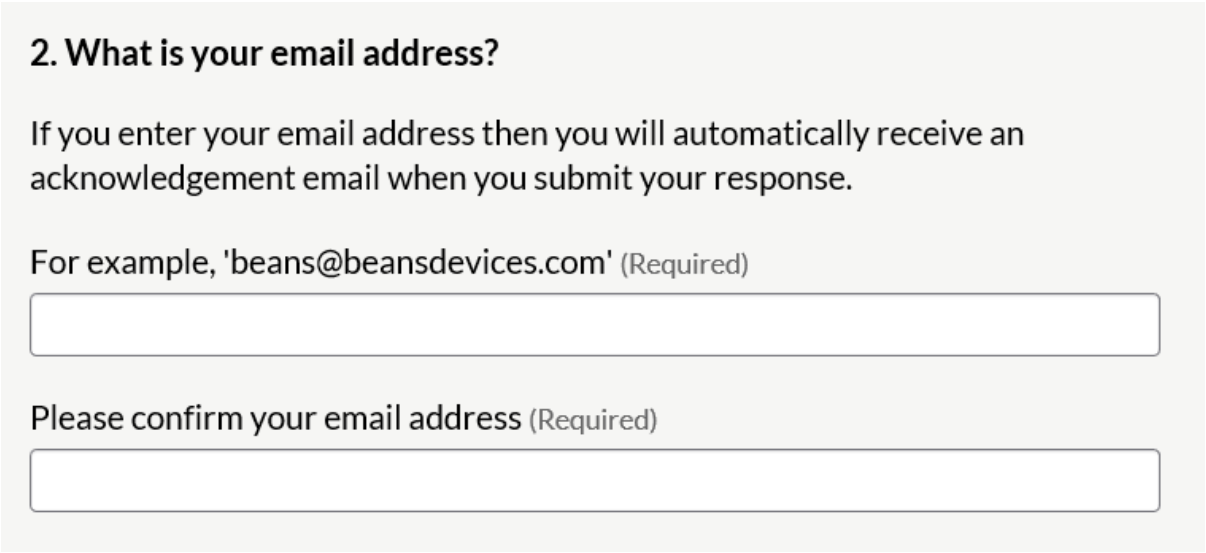
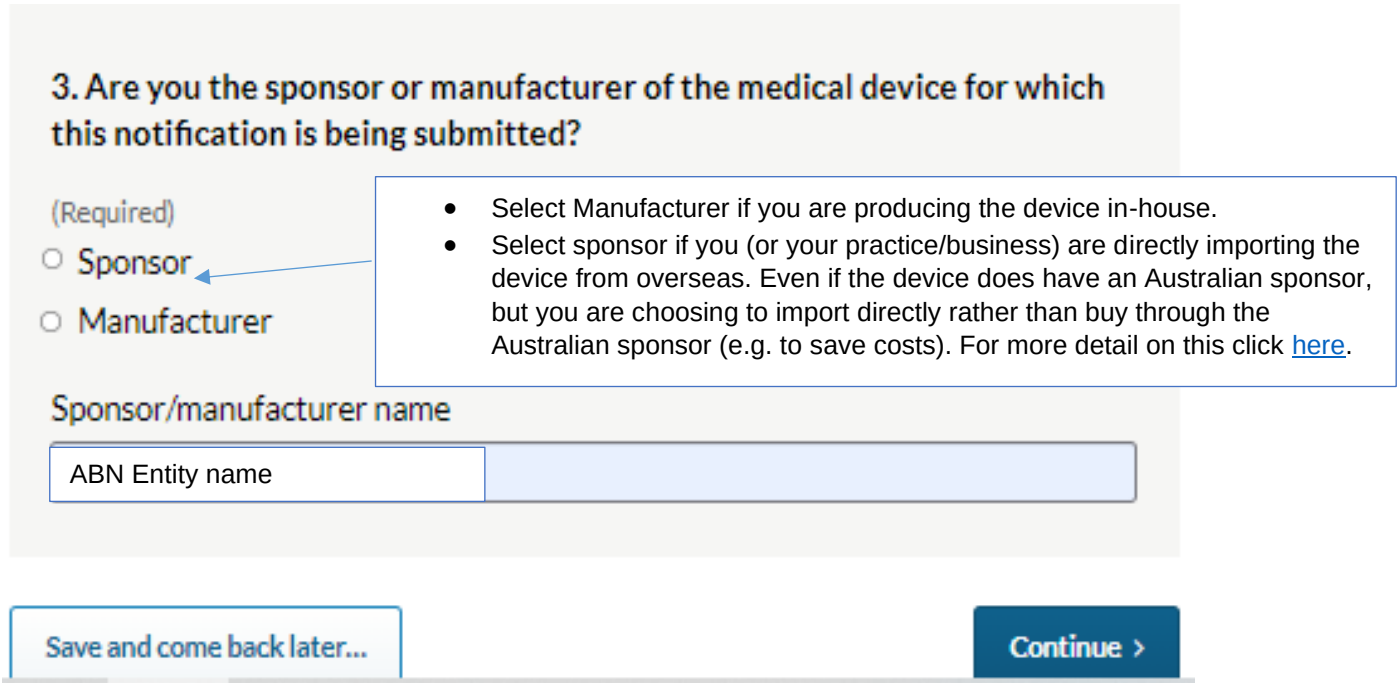


The first question asks about the details of the person submitting the form. This should be the name of the person submitting the form, even if it not the Australian legal entity who is making the declaration.



Your email address allows the TGA to contact you to discuss the form you have submitted. If you would like this to be a generic email for the business you are submitting the request on behalf of, please use that address. This is also the email address where you will be sent a copy of your notification for your records.



4. Provide a description of the kind of medical device that you intend to supply as a patient-matched medical device on or after 01 November 2024, and that you are supplying this notice for.

For example, 'The device is a patient-matched dental aligner that is intended to be used to straighten a patient's teeth over time.' (Required)

A removable artificial replacement (denture) for one or more teeth.

Description – Note: need to include for each “kind” of device in the GMDN code table that you supply. See the ASO GMDN code table for description wording.

5. State the intended purpose of the medical device you intend to supply as patient-matched on or after 01 November 2024, and that you are supplying this notice for.

For example, 'The device is intended to provide a hydrophobic barrier between a wound on the skin and any applied dressing to decrease wound adherence.'

(Required)

The device is intended to be used to replace a patient's missing teeth for functional and/or aesthetical reasons.

Intended purpose - Note: need to include **for each "kind"** of device in the GMDN code table that you supply. See the ASO GMDN code table for intended purpose wording

6. What is the GMDN code for this kind of medical device (if known)?

For example, '10089 Amniotome'

GMDN – see ASO GMDN code table

38587

7. What is the current classification of this kind of medical device? You can use the TGA classification tool to confirm the classification of the device: https://www.tga.gov.au/sme-assist/what-classification-my-medical-device

(Required)

Classification – Class I or Class IIa depending on intended use. See ASO GMDN Code table

- (●) Class I
- ( ) Class Is
- ( ) Class Im
- ( ) Class IIa
- ( ) Class IIb
- ( ) Class III
- ( ) AIMD

8. Have you previously notified the TGA that you are manufacturing or supplying these devices under the custom-made medical devices exemption?

(Required)

- (•) Yes
- ( ) No

Yes –notifying the TGA of your custom-made medical device/s is an existing regulatory requirement. If you have not done this, click here to submit it online.

9. What is the name of the sponsor of this medical device? (Please write, 'Not applicable' if the legal manufacturer is also the sponsor)

For example, 'Bean's Devices Pty Ltd'

Not applicable

"Not applicable" if you are the manufacturer. Or include the legal entity that is acting as the sponsor.

10. What is the physical business address of the sponsor of this medical device? (Please write, 'Not applicable' if the legal manufacturer is also the sponsor)

For example, '123 Bean's Rd, Beantown VIC 3333'

"Not applicable" if you are the manufacturer. Or include the address of the legal entity acting as the sponsor.

11. What is the name of the manufacturer of this medical device?

For example, 'Bean's Devices Pty Ltd' (Required)

ABN Entity Name

12. What is the physical business address of the manufacturer of this medical device?

For example, 'Bean's Street, Beantown VIC 3333' (Required)

ABN registered address of the manufacturer (physical address if it's outside Australia)

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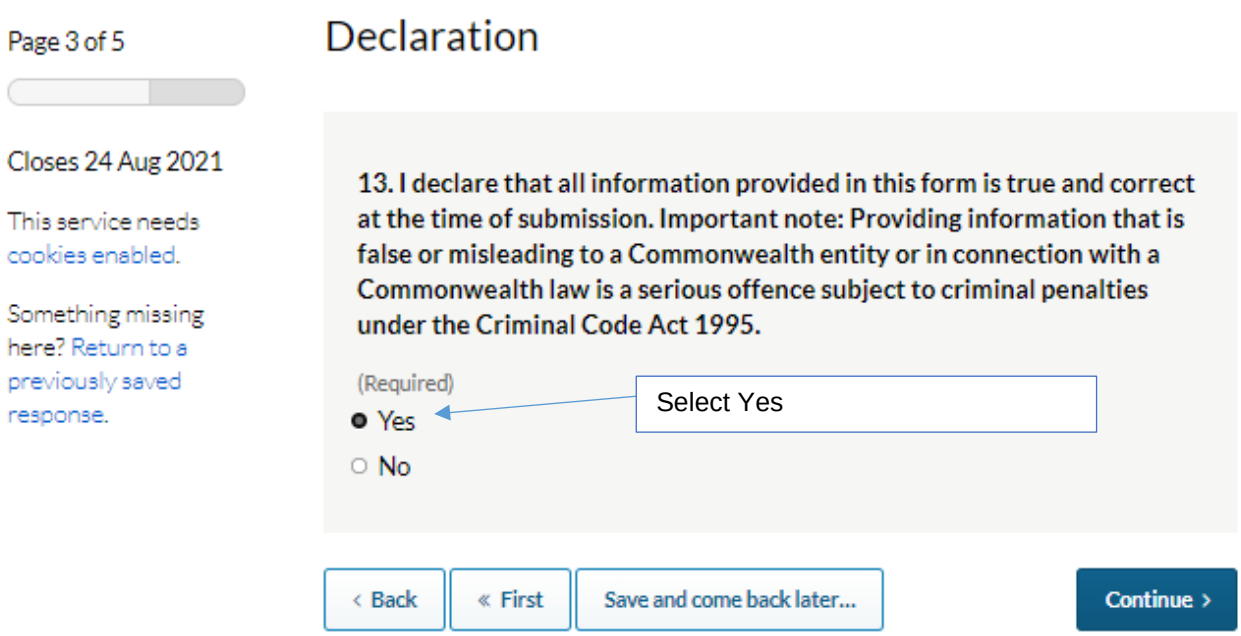

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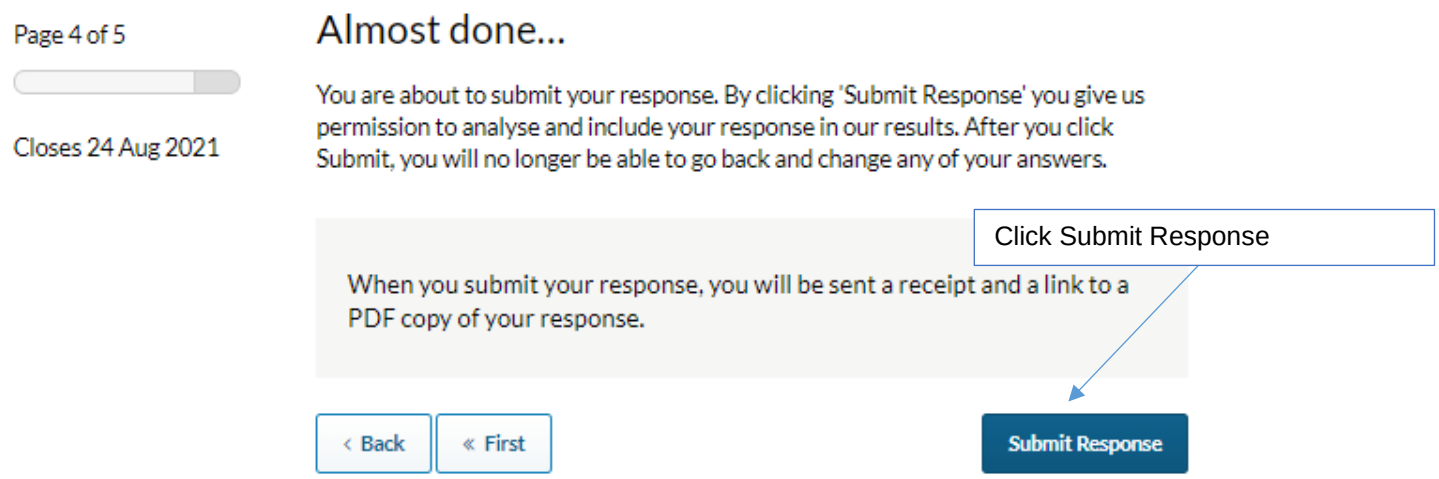

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