Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

EU MDR Transition – Online assessment tool and notification form

User guide for sponsors and agents

Version 2.2, June 2024

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Overview of the online assessment tool

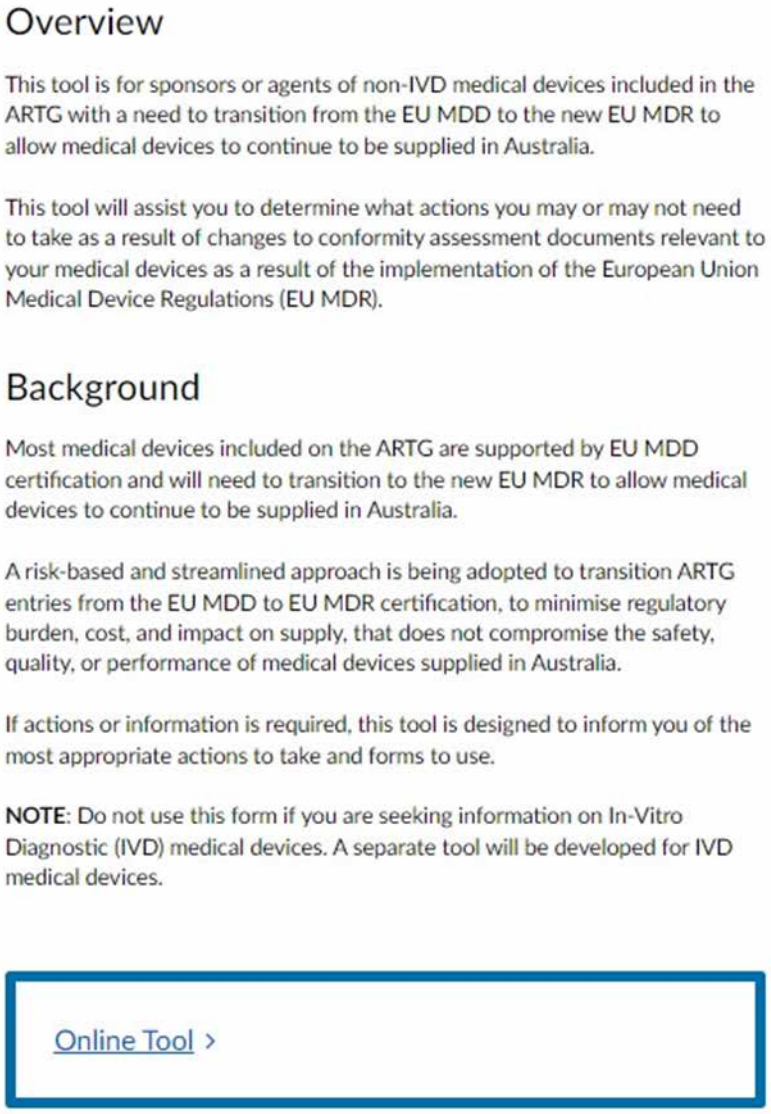
The Online Assessment Tool is optional. You can use it at any time to assist you in determining the appropriate actions required and to assist you to meet obligations for your devices transitioning to the EU MDR.

Note on IVDD to IVDR transition

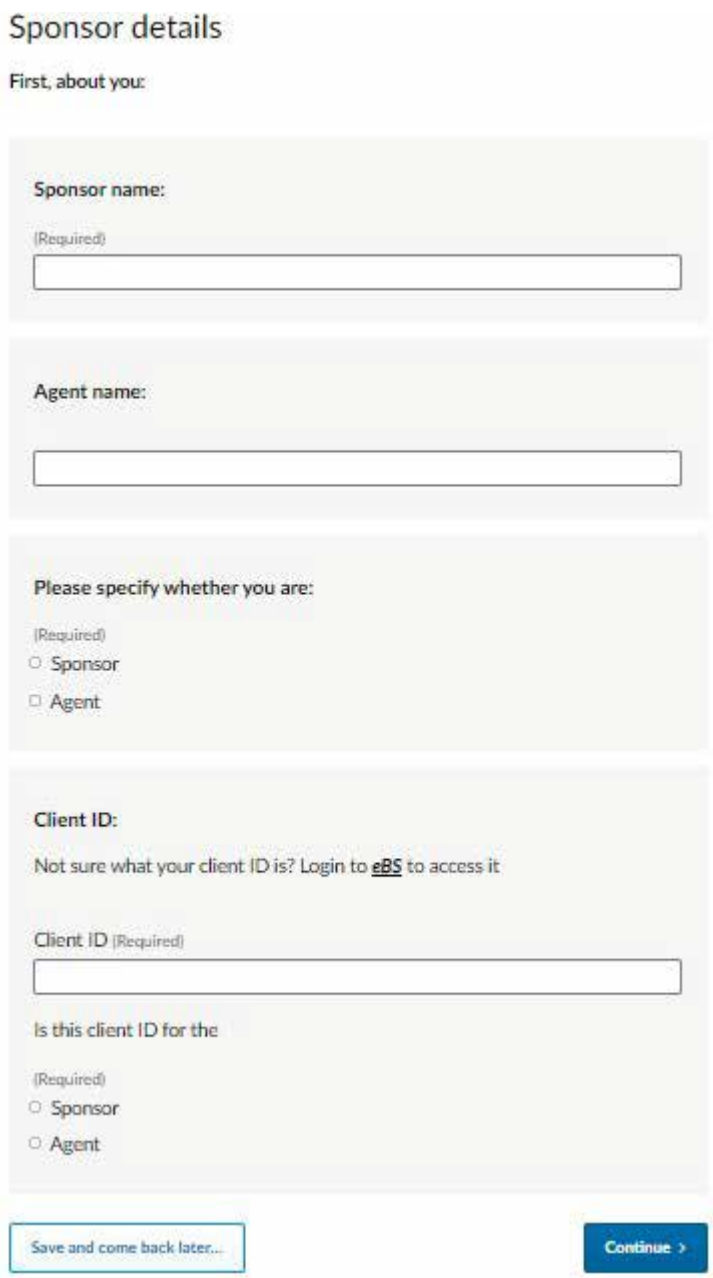
This guidance relates to non-IVD medical devices only and does not cover the transition of IVD medical devices to the EU IVD Regulation (IVDR). A separate guide will be provided for the transition of IVD medical devices to the EU IVDR.

Step by step guide on using the online assessment tool

Access the Online Assessment Tool at the TGA – Citizen Space website.



Click on ‘Online Tool’ to begin.

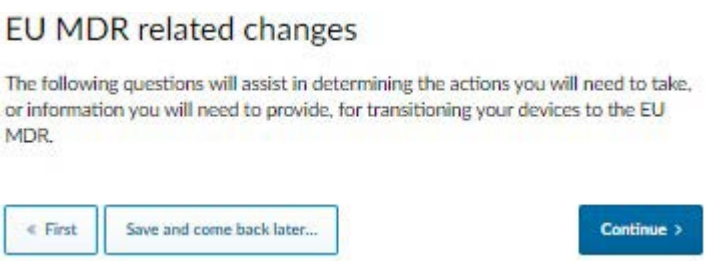


Enter your details, including your TGA eBusiness Services (eBS) client ID. Please contact TGA eBS if you do not know these details.

Click on ‘Continue’ to go to the next page.

If you would like to update your manufacturer evidence in TGA’s certificate repository to your new EU MDR certification, submit an ME variation application.

Click on ‘Continue’ to go to the next page.



This is the start of a questionnaire to help you decide what actions you will need to take to ensure that your devices remain compliant under the Australian regulatory framework as you transition your devices to the EU MDR.

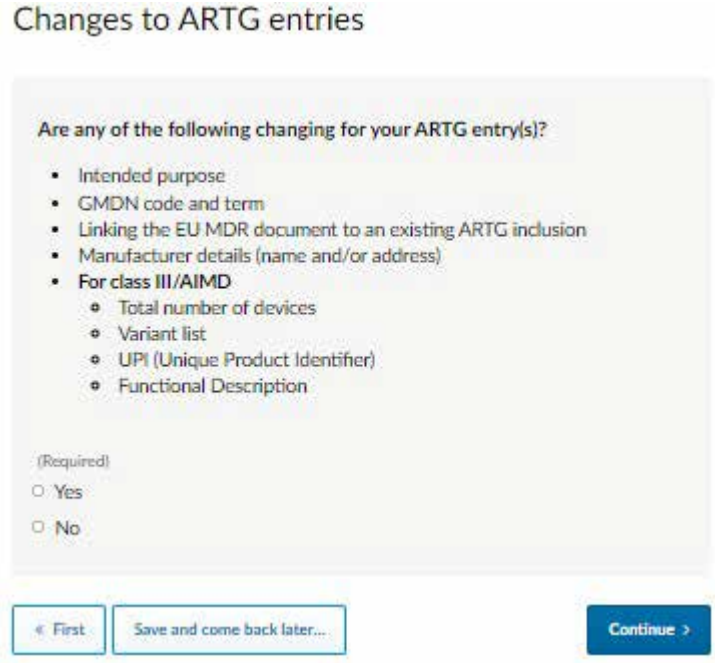
Click on ‘Continue’ to go to the next page.

If your ARTG entry requires a change in classification under the Australian regulatory framework, select ‘Yes’. Click on ‘Continue’ to go to the next page, where you will be advised that you will need to lodge a new application of inclusion for your device(s).

A change in classification means your device is a different kind and will require a new ARTG entry.

Click on ‘Continue’ to go to the next page, where you can enter your email address to be sent a copy of your responses. Click on ‘Submit Response’. This will end the session.

If your ARTG entry does not require a change in classification under the Australian regulatory framework, select ‘No’. Click on ‘Continue’ to go to the next page.

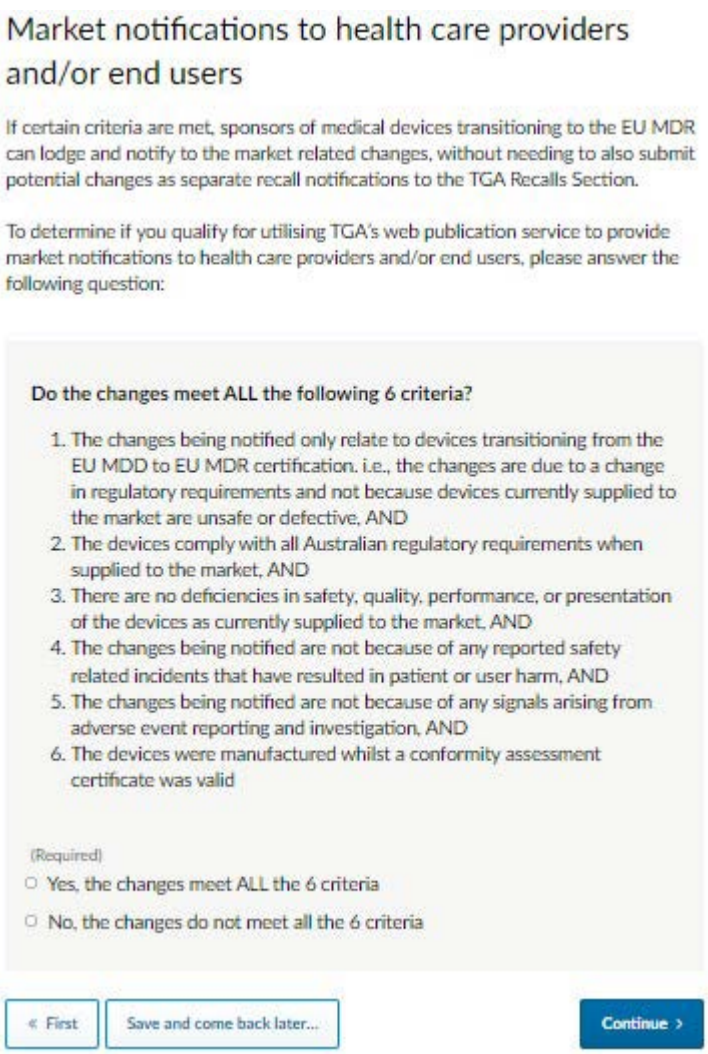


This question helps you to determine if a device change request (DCR) or variation is required for your ARTG entry. Select your response and click on ‘Continue’ to go to the next page.

If you select ‘Yes’, you will be advised that you will need to lodge a DCR or Variation application for your ARTG entry.

If you select ‘No’, you will be advised that no action is required for this response.

Click on ‘Continue’ to go to the next page.

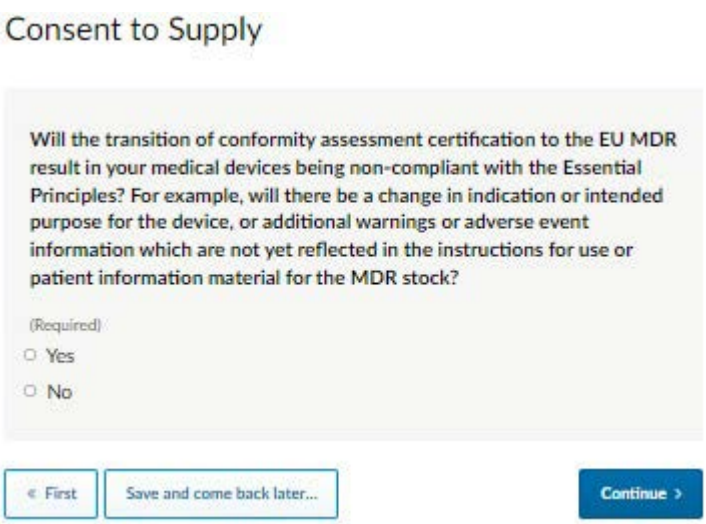


This question helps you to decide whether you qualify for streamlined market notifications for your devices. Select your response and click on ‘Continue’ to go to the next page.

If you select ‘Yes’, you will be advised that you can use the TGA’s EU MDR Transition web publication service to notify end users of device changes, without needing to follow the full TGA recall process.

If you select ‘No’, you will be advised that you need to submit new recall notifications following the TGA’s established recalls procedure.

Click on ‘Continue’ to go to the next page.

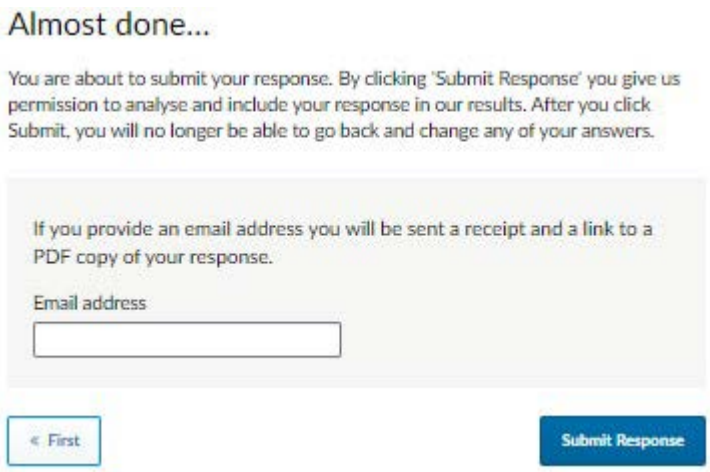


This question helps you to determine whether consent to supply is required for your device. To import, export or supply a product that does not comply with the essential principles, you must submit a consent to supply to the TGA for consideration.

If you select 'Yes', you will be advised that you will require consent to supply your device as your device is non-compliant with the Essential Principles.

If you select 'No', you will be advised that no action is required for this response.

Click on 'Continue' to go to the next page.



To review the entire form before selecting 'Submit Response', click on '<< First' this will return you to the start of your filled out form for review. To go forward through the form, select 'Continue >>' until you get to the final window 'Almost done…'. If you would like to receive a copy of your response, enter your email address and click on 'Submit Response'. This will end the session.

Overview of the online notification form

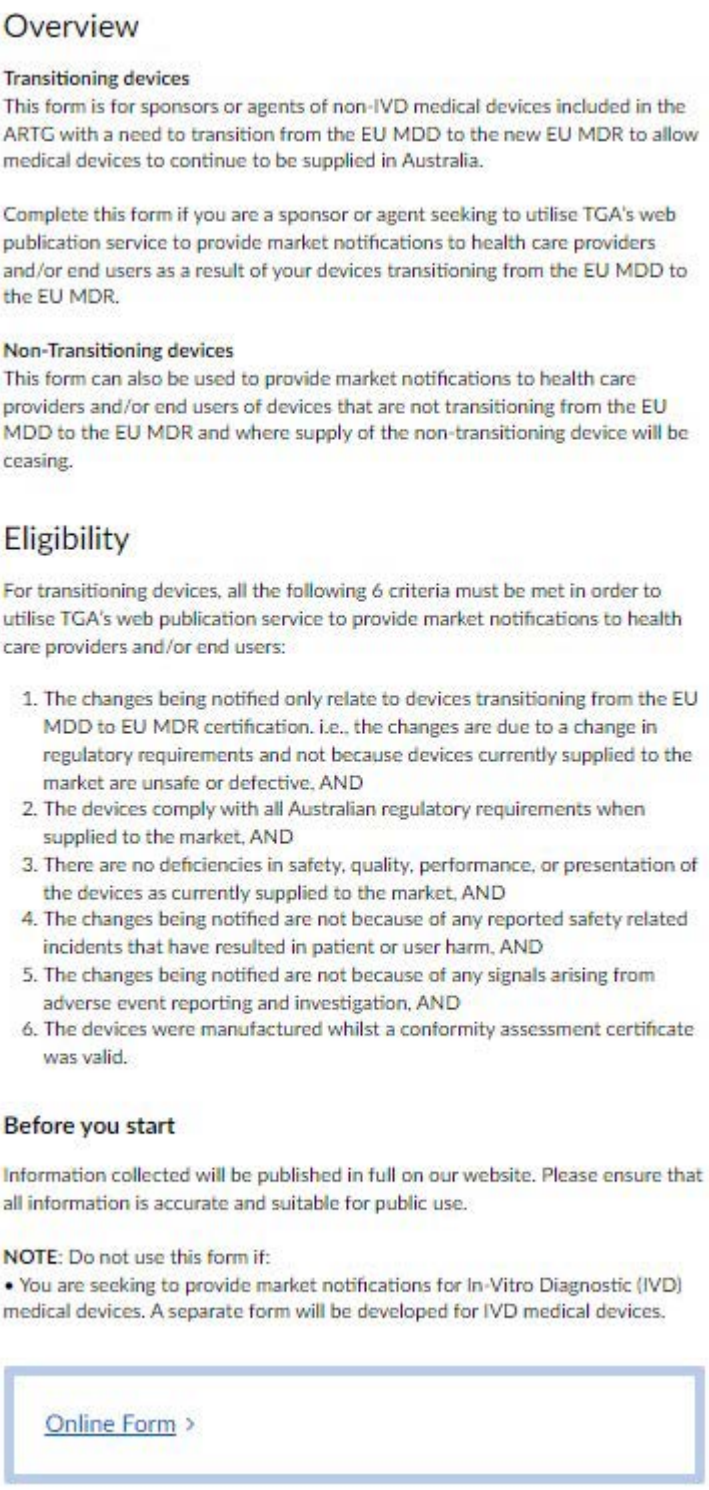
The Online Notification Form is available for sponsors and agents. You can use the TGA's EU MDR Transition web publication service to notify health care providers and users of changes to their devices due to the implementation of the EU MDR and about nontransitioning devices.

When to use the online notification form

You can use this form when you know the details of changes to your devices following European regulatory changes. You will need to be ready to enter details of the changes, for health professionals and consumers. These will be published on the TGA's website.

Step by step guide on using the online notification form

Access the Online notification form at the TGA – Citizen Space website.



Overview

Transitioning devices
This form is for sponsors or agents of non-IVD medical devices included in the ARTG with a need to transition from the EU MDD to the new EU MDR to allow medical devices to continue to be supplied in Australia.

Complete this form if you are a sponsor or agent seeking to utilise TGA's web publication service to provide market notifications to health care providers and/or end users as a result of your devices transitioning from the EU MDD to the EU MDR.

Non-Transitioning devices
This form can also be used to provide market notifications to health care providers and/or end users of devices that are not transitioning from the EU MDD to the EU MDR and where supply of the non-transitioning device will be ceasing.

Eligibility

For transitioning devices, all the following 6 criteria must be met in order to utilise TGA's web publication service to provide market notifications to health care providers and/or end users:

1. The changes being notified only relate to devices transitioning from the EU MDD to EU MDR certification. i.e., the changes are due to a change in regulatory requirements and not because devices currently supplied to the market are unsafe or defective, AND
2. The devices comply with all Australian regulatory requirements when supplied to the market, AND
3. There are no deficiencies in safety, quality, performance, or presentation of the devices as currently supplied to the market, AND
4. The changes being notified are not because of any reported safety related incidents that have resulted in patient or user harm, AND
5. The changes being notified are not because of any signals arising from adverse event reporting and investigation, AND
6. The devices were manufactured whilst a conformity assessment certificate was valid.

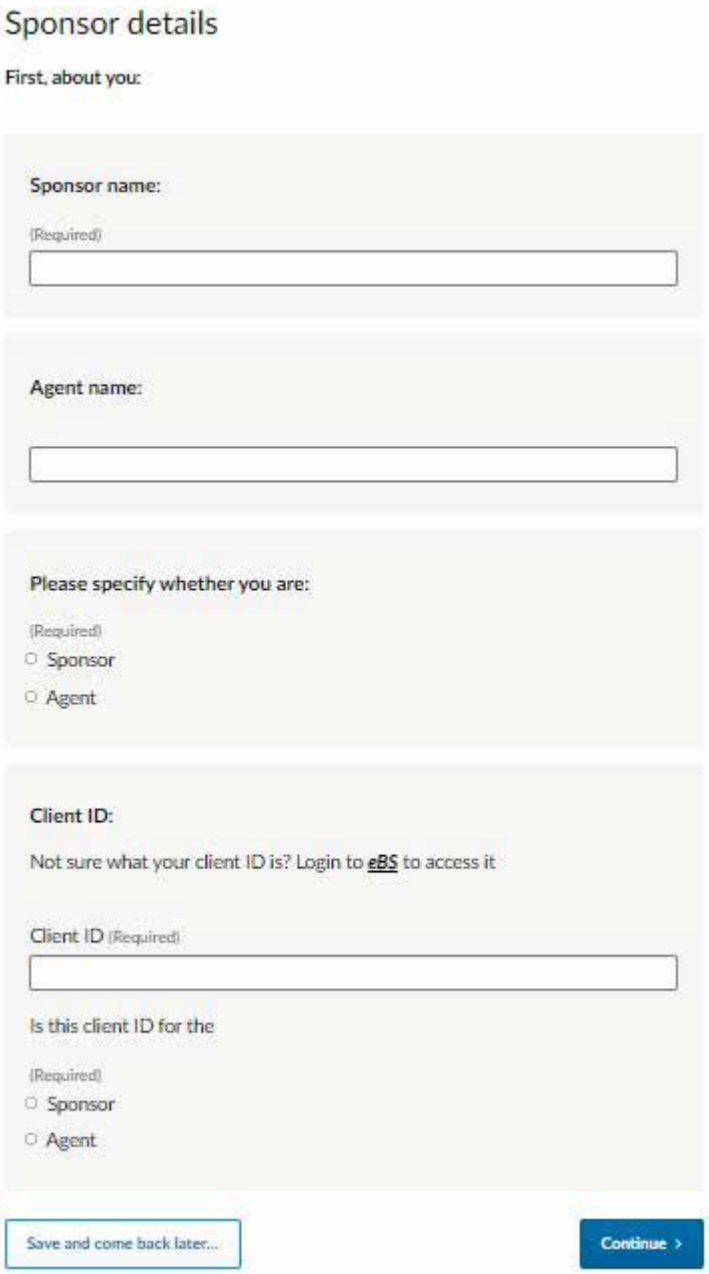
Before you start

Information collected will be published in full on our website. Please ensure that all information is accurate and suitable for public use.

NOTE: Do not use this form if:
• You are seeking to provide market notifications for In-Vitro Diagnostic (IVD) medical devices. A separate form will be developed for IVD medical devices.

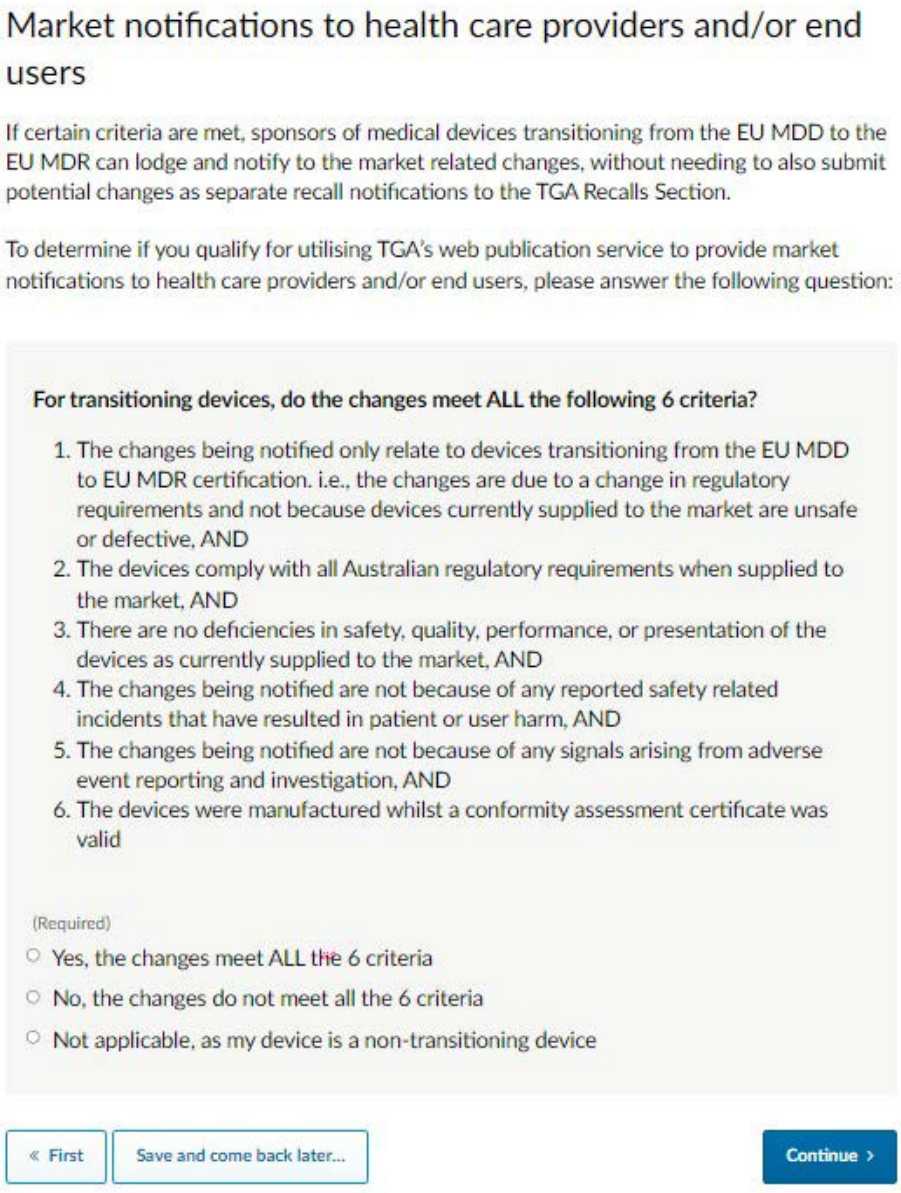
Online Form ›

Click on 'Online Form' to begin.



Enter your details, including your TGA eBusiness Services (eBS) client ID. Please contact TGA eBS if you do not know these details.

Click on ‘Continue’ to go to the next page.



Market notifications to health care providers and/or end users

If certain criteria are met, sponsors of medical devices transitioning from the EU MDD to the EU MDR can lodge and notify to the market related changes, without needing to also submit potential changes as separate recall notifications to the TGA Recalls Section.

To determine if you qualify for utilising TGA's web publication service to provide market notifications to health care providers and/or end users, please answer the following question:

For transitioning devices, do the changes meet ALL the following 6 criteria?

1. The changes being notified only relate to devices transitioning from the EU MDD to EU MDR certification. i.e., the changes are due to a change in regulatory requirements and not because devices currently supplied to the market are unsafe or defective, AND
2. The devices comply with all Australian regulatory requirements when supplied to the market, AND
3. There are no deficiencies in safety, quality, performance, or presentation of the devices as currently supplied to the market, AND
4. The changes being notified are not because of any reported safety related incidents that have resulted in patient or user harm, AND
5. The changes being notified are not because of any signals arising from adverse event reporting and investigation, AND
6. The devices were manufactured whilst a conformity assessment certificate was valid

(Required)

- ○ Yes, the changes meet ALL the 6 criteria
- ○ No, the changes do not meet all the 6 criteria
- ○ Not applicable, as my device is a non-transitioning device

« First | Save and come back later... | Continue ›

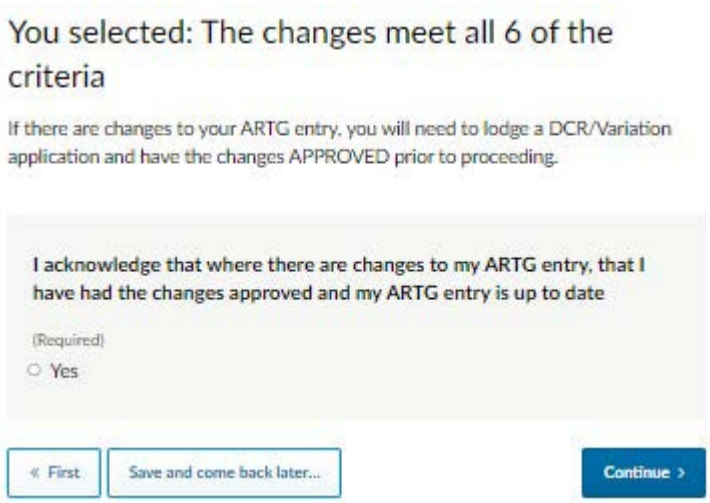
This question helps you in deciding whether changes made to your device are suitable to use the streamlined market notifications for your devices. Select your response and click on 'Continue' to go to the next page.

For transitioning devices, if you select 'No', you will be advised you do not qualify to use the TGA's EU MDR Transition web publication service to provide market notifications to health care providers and/or end users. You will need to submit a new recall notification(s) following the TGA's established recalls procedure.

Click on 'Continue' to go to the next page, where you can provide your email address to be sent a copy of your responses. Click on 'Submit Response'. This will then end the session.

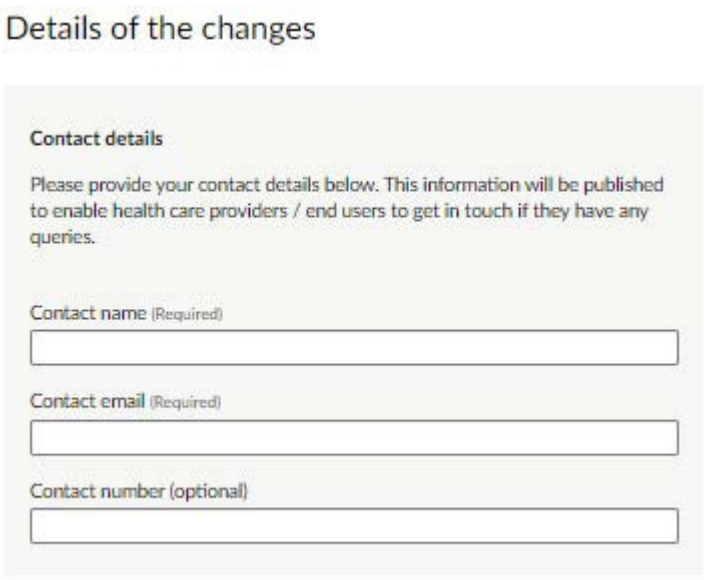
If you select 'Yes', you will qualify to use the TGA's EU MDR Transition web publication service to provide market notifications to health care providers and end users. Click on 'Continue' to go to the next page.

For non-transitioning devices, please select 'Not applicable'. Detailed instructions can be found on page 24 of this document.

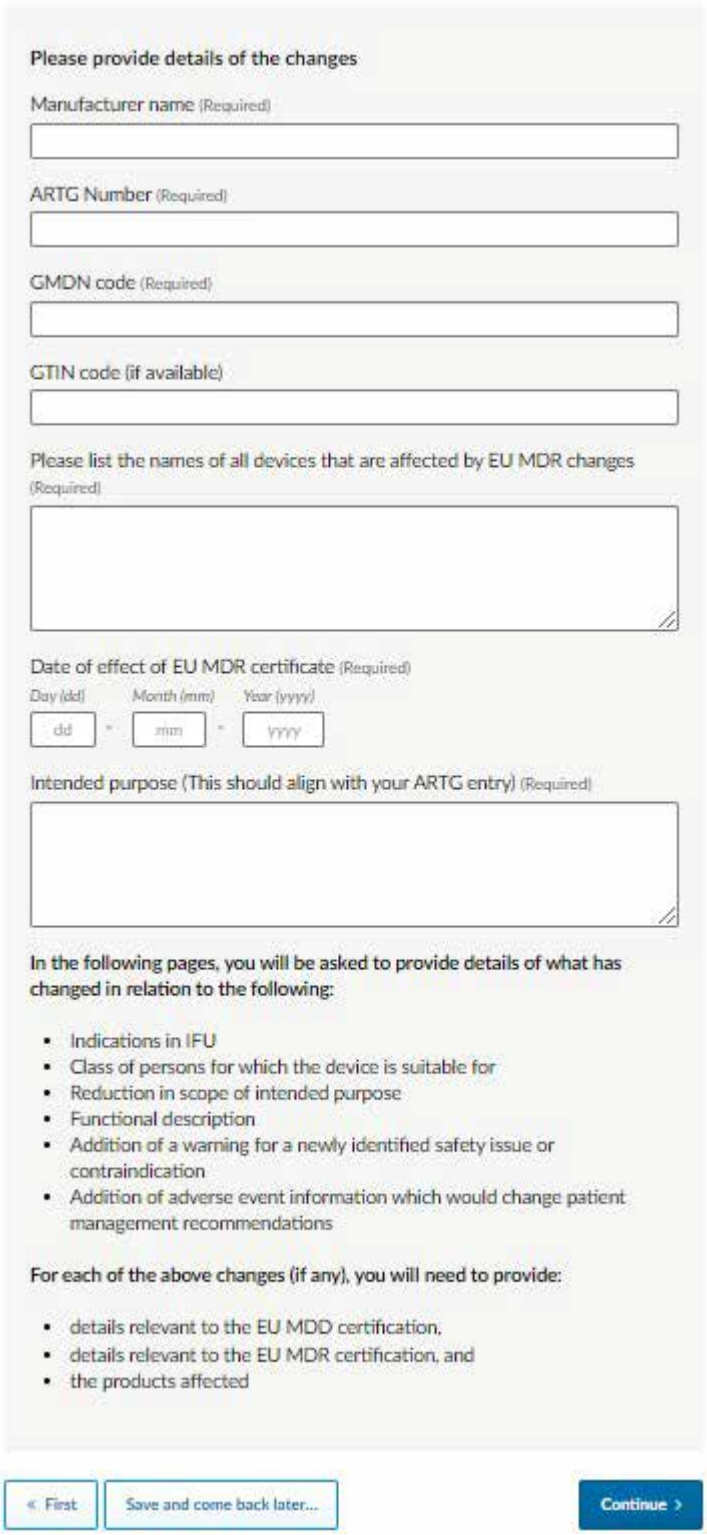


You are asked to confirm that if there are changes to your ARTG entry, you have had the changes approved (e.g., via a device change request application) and that your ARTG entry is up to date. If there are changes to your ARTG entry and your changes have not been approved, please exit the form. Return to this form, after your changes have been approved.

Click on ‘Continue’ to go to the next page.



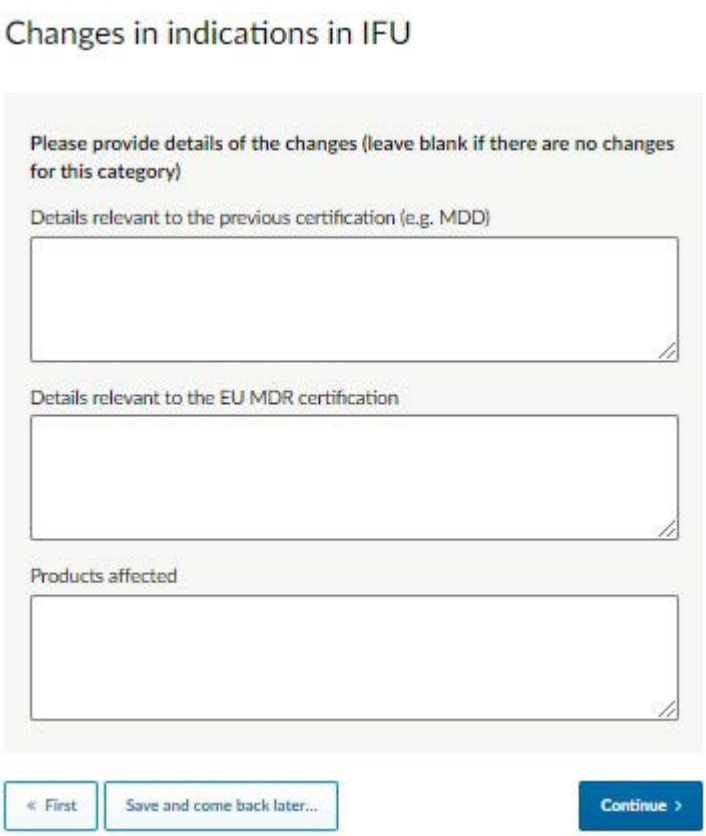
Provide a contact name, email address and phone number (optional) that health service providers or end users can contact for any further details or enquiries on the changes.



Enter your Manufacturer name, ARTG number, GMDN code, and GTIN code (if available).

You are also required to list the names of all devices which are affected by the EU MDR changes. Also enter the issue date of the EU MDR certificate, along with the intended purpose which aligns with your ARTG entry.

Click on ‘Continue’ to go to the next page.

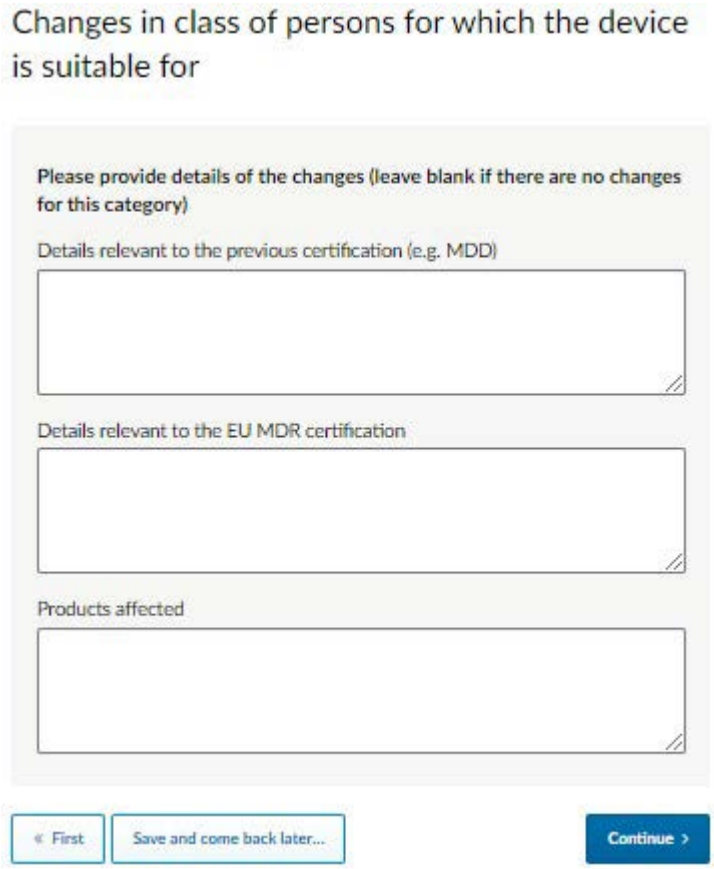


This question allows you to input what has changed regarding the indications in the Instructions for use (IFU).

If nothing has changed, leave all fields blank.

If indications in the IFU have changed after new certification was received, provide details on what the indications in the IFU were under the previous (MDD) certification, what the indications in the IFU are under the current (MDR) certification, and which products are affected (all or certain model numbers).

Click on ‘Continue’ to go to the next page.

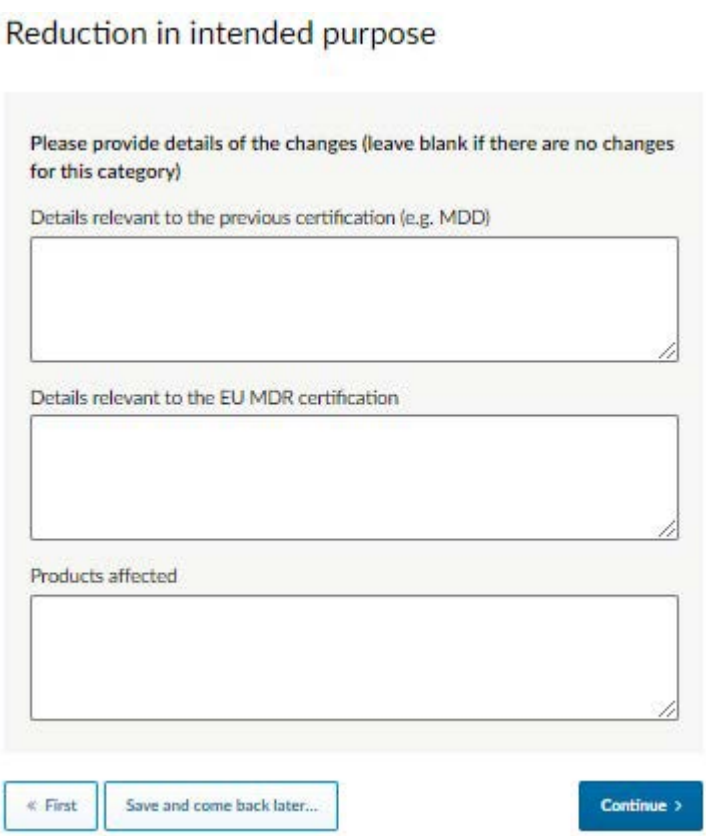


This question allows you to input any change to the class of persons for which the device is suitable for. For instance, the device was previously suitable for adult and paediatric patients under the EU MDD certification but is only suitable for adult patients under the EU MDR certification.

If there is no change, leave all fields blank.

If there are changes to the class of persons for which the device is suitable for, provide details on what was in the previous certification (MDD), what is in the current certification (MDR), and which products are affected. Enter ‘all’ or certain model numbers.

Click on ‘Continue’ to go to the next page.

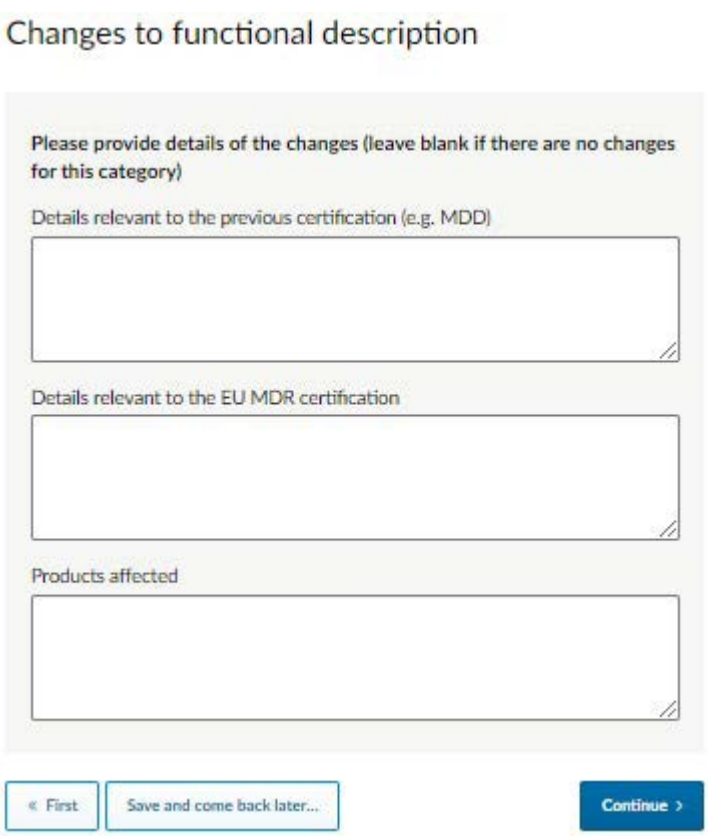


Enter any change to the intended purpose.

If there is no change, leave all fields blank.

If there is a reduction in the scope of the intended purpose, provide details on what was in the previous (MDD) certification, what is in the current (MDR) certification, and which products are affected (all or certain model numbers).

Click on ‘Continue’ to go to the next page.

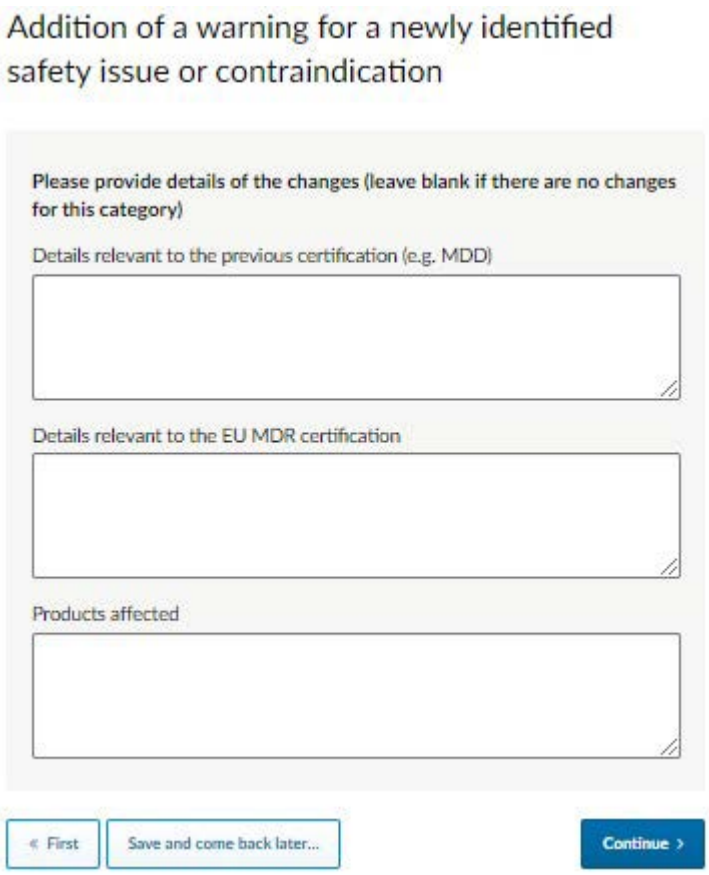


This question allows you to input any changes to the functional description (for a class III/AIMD device only).

If there is no change, leave all fields blank.

If there is a change to the functional description, provide details on what was in the previous (MDD) certification, what is in the current (MDR) certification, and which products are affected (all or certain model numbers).

Click on ‘Continue’ to go to the next page.

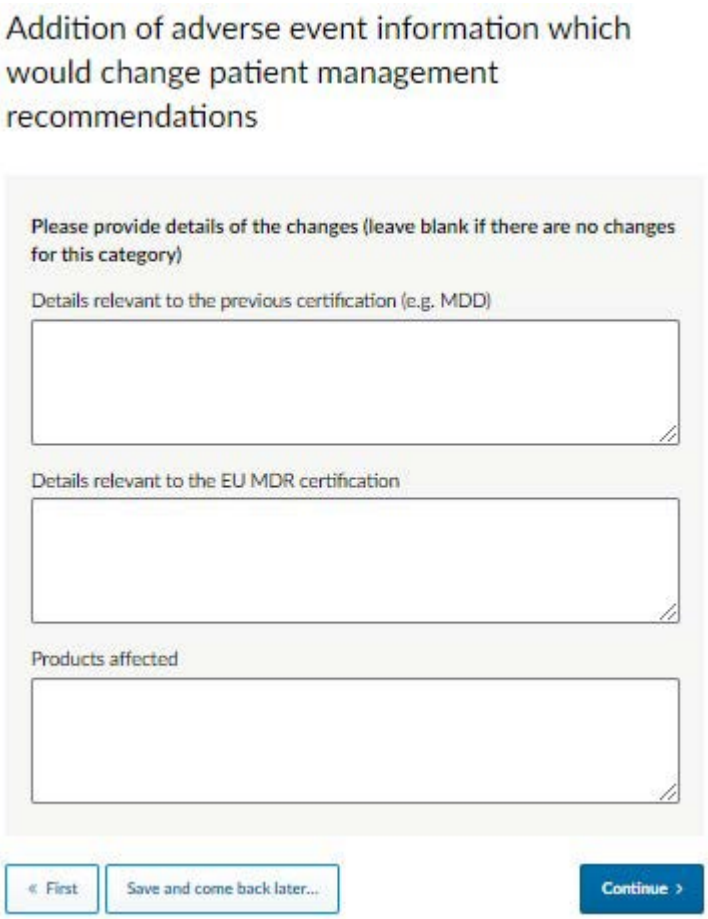


Enter any additional warnings for a newly identified safety issue or contraindication.

If there are no additions of a warning for a newly identified safety issue or contraindication, leave all fields blank.

If there are additions of a warning for a newly identified safety issue or contraindication, provide details on what was in the previous (MDD) certification, what is in the current (MDR) certification, and which products are affected (all or certain model numbers).

Click on ‘Continue’ to go to the next page.



Enter any additional adverse event information which would change patient management recommendations.

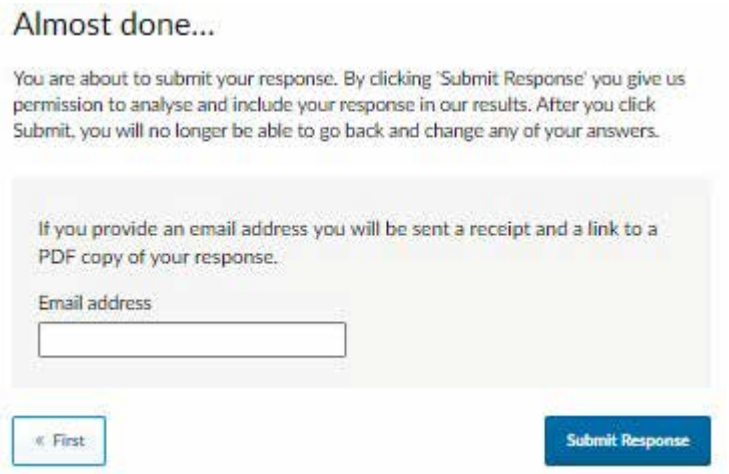
If there are no additions of adverse event information which would change patient management recommendations, leave all fields blank.

If there are additions of adverse event information which would change patient management recommendations, provide details on what was in the previous (MDD) certification, what is in the current (MDR) certification, and which products are affected (all or certain model numbers).

Click on ‘Continue’ to go to the next page.

Tick the box if you acknowledge that you have the authority and provide your consent to the information you have provided being shared publicly.

Click on ‘Continue’ to go to the next page.



If you would like to review the information you have provided before you select 'Submit Response', please click on '<< First' to return to the start of your filled out form for review, then select 'Continue >>' to move through the form.
If you would like to receive a copy of your response, enter your email address and click on 'Submit Response'. This will then end the session.

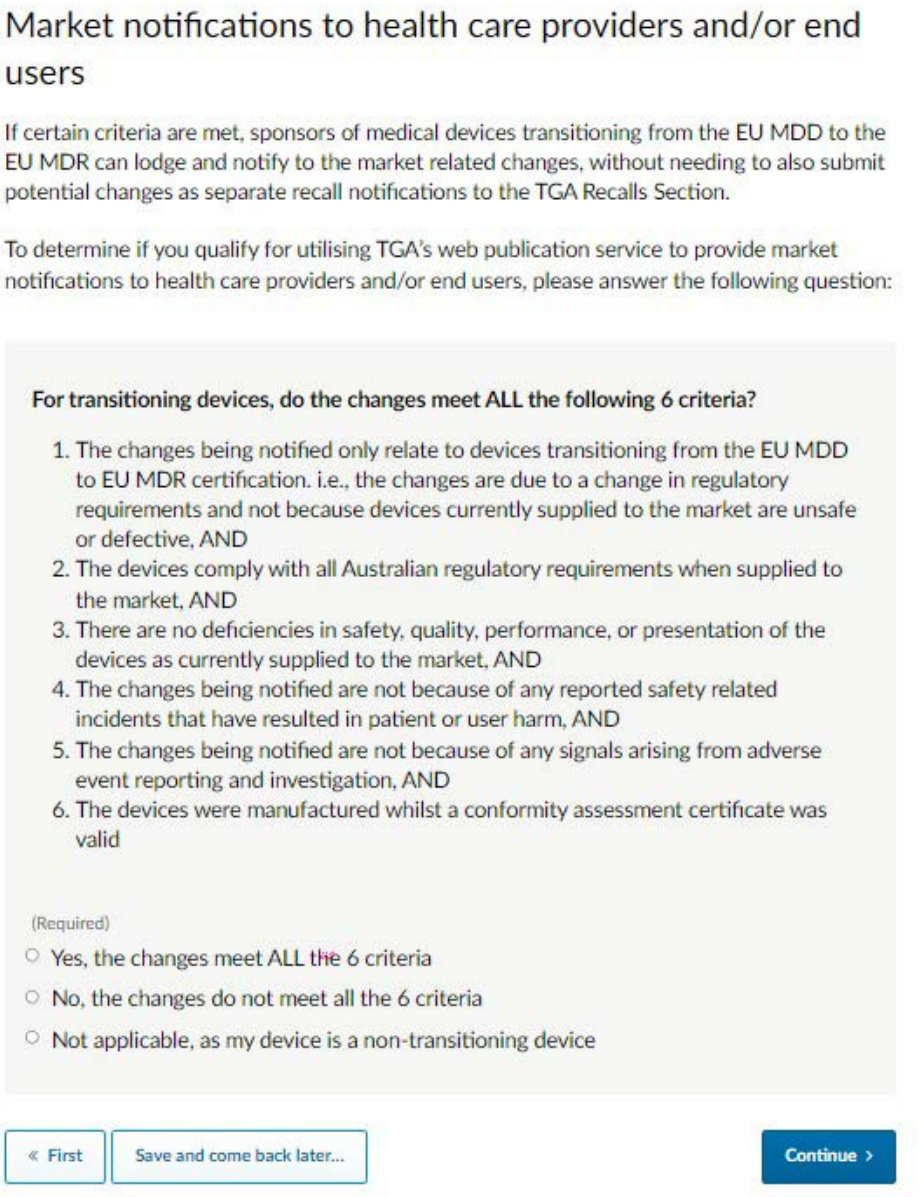
Non-transitioning devices

This form can also be used to provide market notifications to health care providers or end users about devices that are not transitioning from the EU MDD to the EU MDR and where the supply of the non-transitioning device will be ceasing.

Click on 'Online Form' to begin.

Enter your details, including your TGA eBusiness Services (eBS) client ID. Please contact TGA eBS if you do not know these details.

Click on 'Continue' to go to the next page.



Market notifications to health care providers and/or end users

If certain criteria are met, sponsors of medical devices transitioning from the EU MDD to the EU MDR can lodge and notify to the market related changes, without needing to also submit potential changes as separate recall notifications to the TGA Recalls Section.

To determine if you qualify for utilising TGA's web publication service to provide market notifications to health care providers and/or end users, please answer the following question:

For transitioning devices, do the changes meet ALL the following 6 criteria?

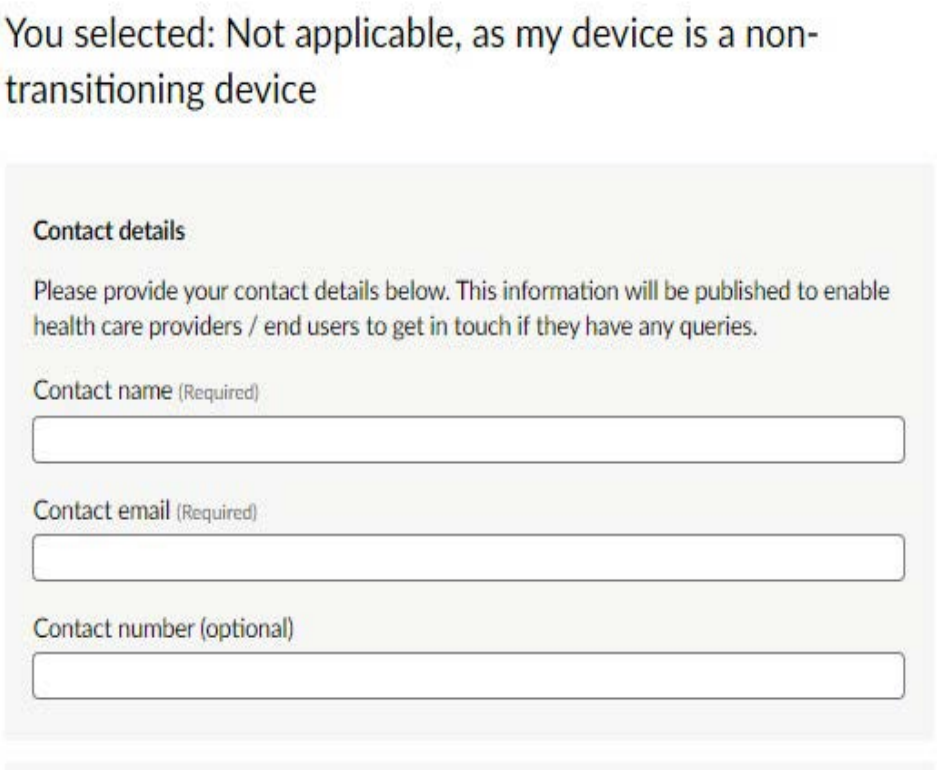
1. The changes being notified only relate to devices transitioning from the EU MDD to EU MDR certification. i.e., the changes are due to a change in regulatory requirements and not because devices currently supplied to the market are unsafe or defective, AND
2. The devices comply with all Australian regulatory requirements when supplied to the market, AND
3. There are no deficiencies in safety, quality, performance, or presentation of the devices as currently supplied to the market, AND
4. The changes being notified are not because of any reported safety related incidents that have resulted in patient or user harm, AND
5. The changes being notified are not because of any signals arising from adverse event reporting and investigation, AND
6. The devices were manufactured whilst a conformity assessment certificate was valid

(Required)

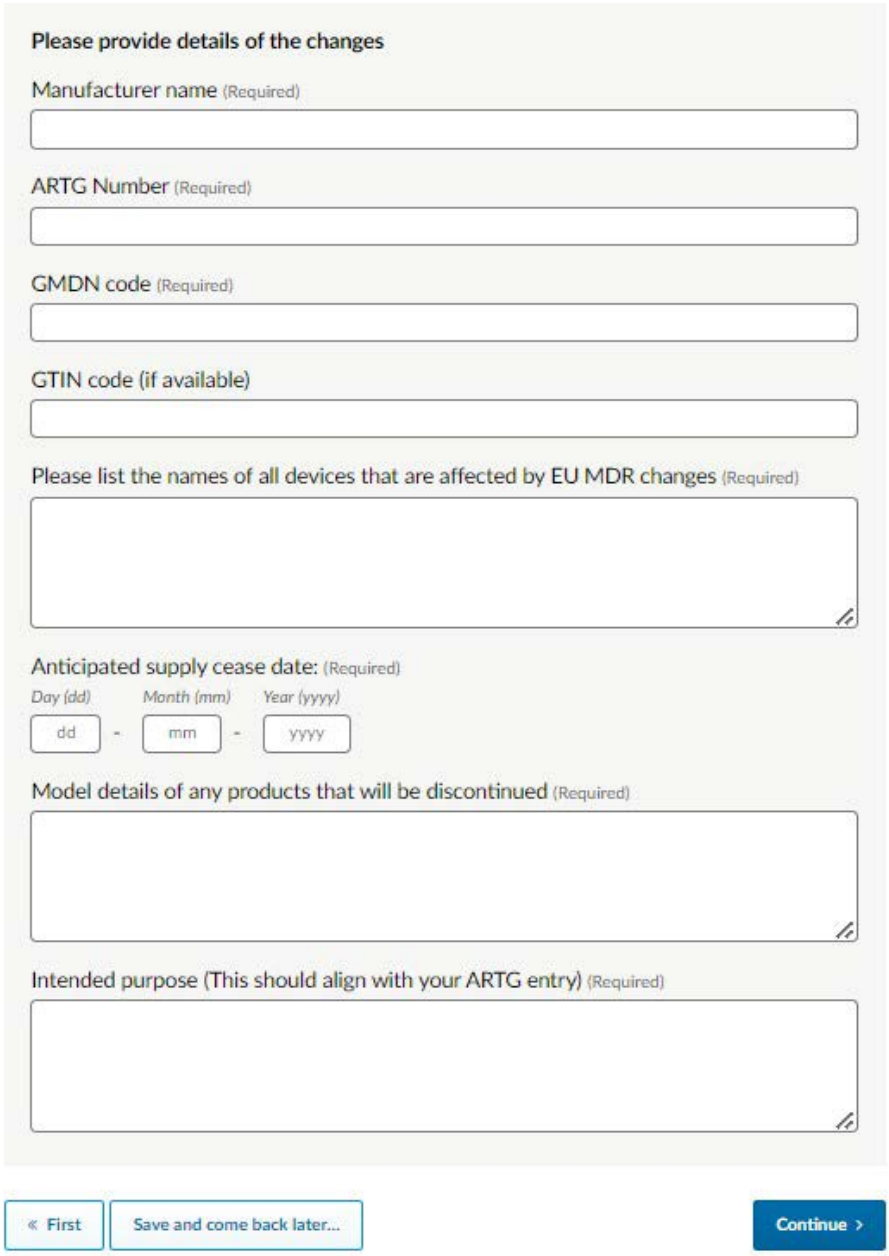
- ○ Yes, the changes meet ALL the 6 criteria
- ○ No, the changes do not meet all the 6 criteria
- ○ Not applicable, as my device is a non-transitioning device

« First | Save and come back later... | Continue ›

If your device is a non-transitioning device, select the third option and click on 'Continue' to go to the next page.



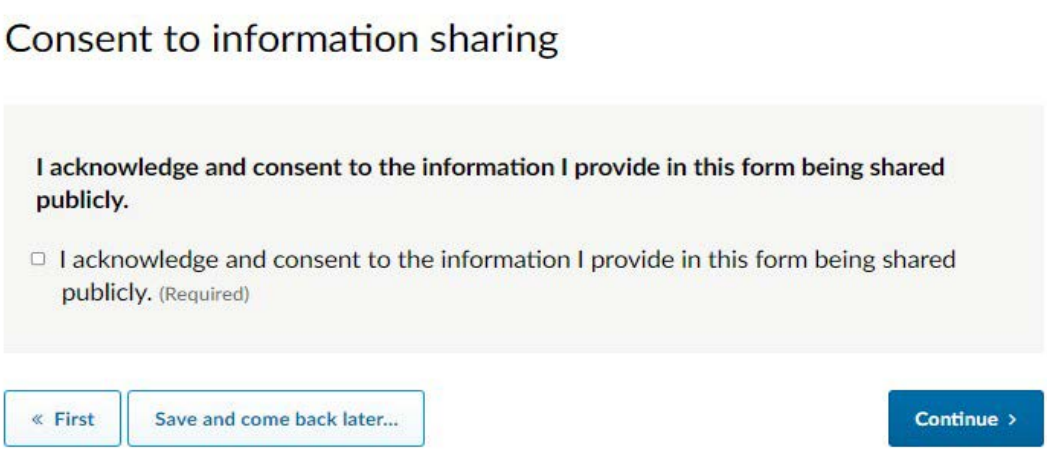
Provide a contact name, email address and phone number (optional) that health service providers or end users can contact for any further details or enquiries on the changes.



Enter your Manufacturer name, ARTG number, GMDN code, and GTIN code (if available).

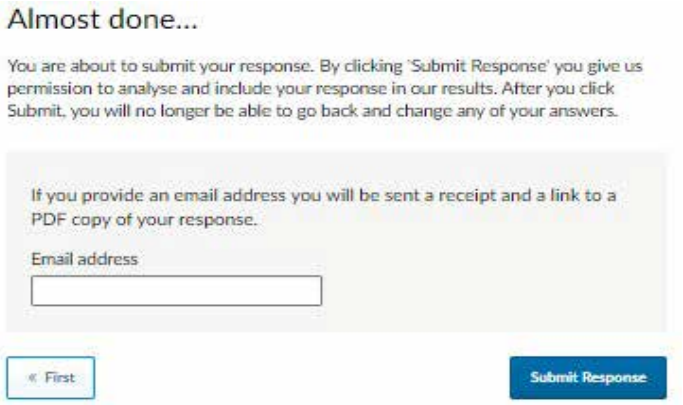
Then list the names of all devices that are affected by the EU MDR changes. Also enter the anticipated supply will cease and the model details and intended purpose of any products that will be discontinued. These details should align with the details in your ARTG entry.

Click on ‘Continue’ to go to the next page.



Tick the box if you acknowledge that you have the authority and provide your consent to the information you have provided being shared publicly.

Click on ‘Continue’ to go to the next page.



If you would like to review the information you have provided before you select ‘Submit Response’, please click on ‘<< First’ to return to the start of your filled out form for review, then select ‘Continue >>’ to move through the form.

If you would like to receive a copy of your response, enter your email address and click on ‘Submit Response’. This will then end the session.

Once you have submitted the form it cannot be amended or changed. To amend or add any details after you have submitted the form, you can contact us by email at the following address devices@tga.gov.au.

Fees and Charges

The online tool and form are provided to assist sponsors and does not incur a fee. If you are required to submit a new device application, a Device Change Request (DCR) application, Variation application or Consent to Supply application, applicable fees will apply.

The information you have submitted will be published on the TGA's EU MDR Transition web publication service when it is next updated. Updates will occur weekly on a Tuesday. Sponsors are responsible for advising health care providers or end users to access the TGA's EU MDR Transition web publication service for information on device changes.

More information about the Online Notification Form

The Online Notification Form is provided to assist sponsors and agents seeking to utilise TGA's EU MDR Transition web publication service to streamline the provision of market notifications to health care providers and users. It is not compulsory.

The Online Notification Form can be used by sponsors who have not undertaken market notification activities and have already transitioned devices and the inclusions in the Register to the EU MDR.

If the market notification is identified as the correct pathway for any changes required, you have fulfilled obligations to notify users about the changes to my medical device. However, if the changes do not meet any of the six eligibility criteria, then sponsors must submit new recall notifications via the TGA Business Systems portal.

You can choose to use this tool if there are multiple ARTG entries covered by one MDD certificate transitioning to the MDR at different times to work through the changes as you become aware of them. You may decide to wait until you have all of the information for the certificates before using the tool. The aim of the tool is to assist you with compliance under the regulatory framework.

Manufacturers and Sponsors have a range of options relating to system or procedure pack (SOPP)that are transitioning to EU MDR certification:

Option 1: The manufacturer of a system or procedure pack may obtain market authorisation evidence, issued by an independent assessment body or regulator for the system or procedure pack; or

Option 2: Use the special conformity assessment procedure set out in clause 7.5 of Schedule 3 of the Therapeutic Goods (Medical Devices) Regulations 2002 (the 'Regulations') if they meet the eligibility criteria defined in Regulation 3.10.

If using option 1, sponsors should use the tool when the MDR certification is received, and they are aware of all device changes.

If using option 2, sponsors must ensure that all relevant conformity assessment procedures are applied to the individual components and if applicable, the sterility aspect of the SOPP, and ensure that other requirements stipulated in the Regulation 3.10 are met. If there are staggered MDR certification of the individual components, whereby there are changes to the kit configurations, there may be multiple changes required to the inclusion in the ARTG and the kit. Sponsors should be aware of all device changes, conformity assessment requirements and SOPP configurations before using the tool.

For further information, please refer to the guidance document EU MDR Transition – Manufacturer evidence – Case studies and scenarios.

Purpose

This user guide is to assist Australian sponsors and agents of non-in vitro diagnostic (IVD) medical devices included in the Australian Register of Therapeutic Goods (the Register) who need to transition to the new European Union Medical Device Regulations (EU MDR) under the Australian regulatory framework. This will allow continued supply of their medical devices in Australia.

This user guide also helps Australian sponsors and agents of non-IVD medical devices who are not transitioning to the new EU MDR and where the supply of the device will be ceasing.

Additional guidance

The TGA has published additional guidance to assist you to manage your obligations under the Australian regulatory framework while transitioning to EU MDR:

EU MDR Transition – Overview and management under the Australian regulatory framework - guidance for manufacturers and sponsors

EU MDR Transition – Manufacturer evidence – case studies and scenarios (pdf)

EU MDR Transition – DCRs and variations – case studies and scenarios (pdf)

EU MDR Transition – Recalls and market notifications - case studies and scenarios (pdf)

EU MDR Transition - Conformity assessment, Essential Principles and consent to supply - case studies and scenarios (pdf)

Version history

Version	Description of change	Author	Effective date
V1.0	Draft publication for feedback	Medical Devices Authorisation Branch	16 June 2022
V1.1	Publication for beta release	Medical Devices Authorisation Branch	29 June 2022
V1.2	Publication for stakeholder review	Medical Devices Authorisation Branch	31 October 2022
V2.0	Publication for final release	Medical Devices Authorisation Branch	1 December 2022
V2.1	Addition of non-transitioning devices	Medical Devices Authorisation Branch	December 2023
V2.2	Updated template	Medical Devices Authorisation Branch	June 2024

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Reference/Publication #