Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Viewing and responding to notifications on the Consent for Non-compliance Dashboard related to Unique Device Identification (UDI) Consent to Supply applications

User guide for viewing and responding to notifications for devices that are part of a UDI CtS application

Version 1.0, June 2026

Contents

Introduction

This guide explains how to view and respond to notifications about medical devices included in an application for consent to import or supply that do not meet the Unique Device Identification (UDI)-related Essential Principles (EPs).

This document only covers the features available in the **Notifications** tab.

For guidance on drafting and submitting UDI Consent to Supply (CtS) applications, see: Completing an application for consent to import, supply or export medical devices that do not meet UDI-related Essential Principles.

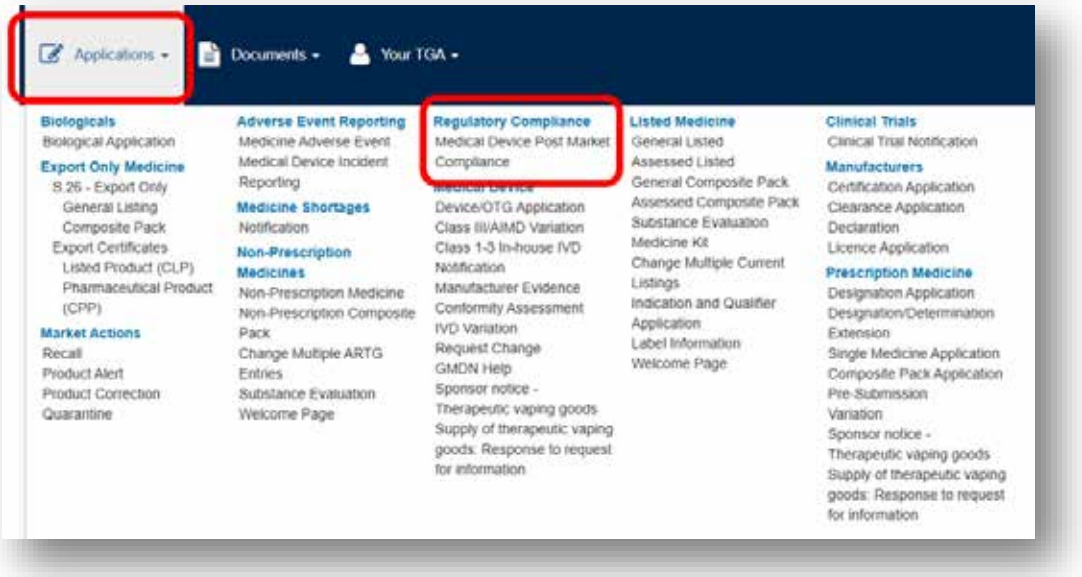
Notifications may include informal requests for additional information, letters advising the outcome of an application, and regulatory letters relating to devices included in an approved consent application.

Accessing the consent for non-compliance dashboard

To access the **Consent for non-compliance dashboard,** log into the TBS portal.

Open the **Applications** drop-down menu and select **Medical Device Post Market Compliance** under **Regulatory Compliance**.

Figure 1: TBS portal

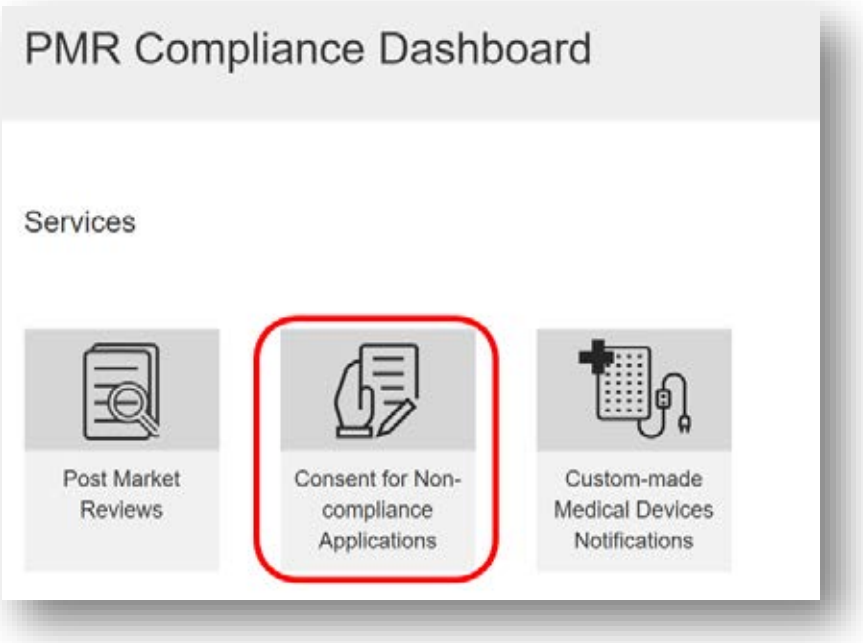


Select **Devices Compliance (PMR).**

Figure 2: Regulatory and Compliance Portal

Select **Consent for Non-compliance Applications** to open the dashboard.

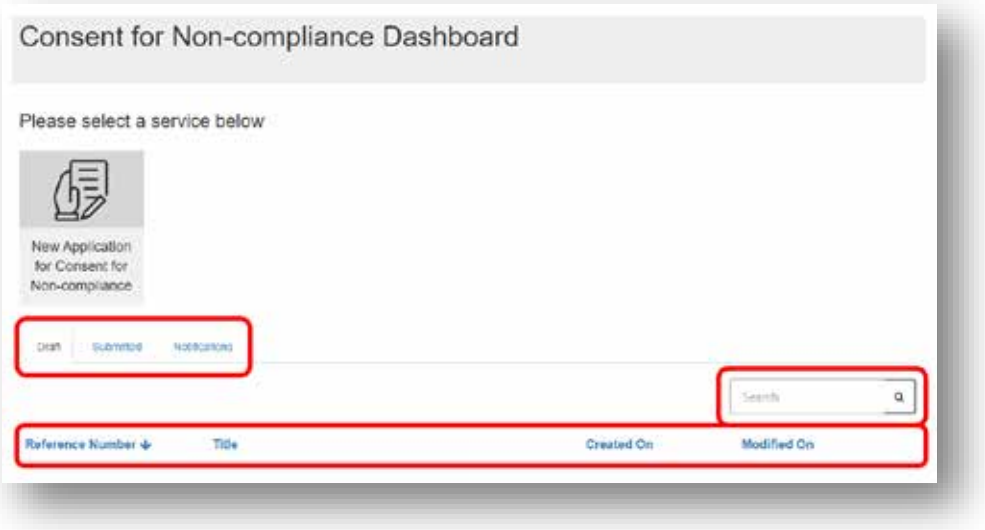
Figure 3: PMR Compliance Dashboard



On the dashboard, you can:

- view **Draft** applications
- view **Submitted** applications
- view **Notifications** related to applications
- search for applications by using the search bar indicated by the magnifying glass symbol [🔍]
- sort the table by selecting the column heading.

Figure 4: Consent for Non-compliance Dashboard



For detailed instructions on the dashboard, including deleting or editing draft applications, see Completing an application for consent to import, supply, or export medical devices that do not meet the Essential Principles

Notifications related to a UDI CtS application

Notifications may include:

- letters advising the application outcome
- confirmation of application withdrawal
- consent expiry or consent revocation notifications
- informal requests for more information
- regulatory letters relating to device(s) that are part of an approved consent application.

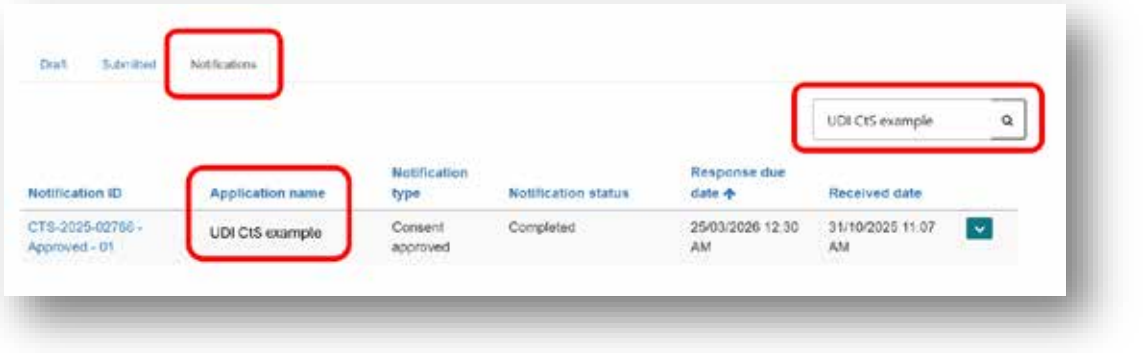
As the UDI CtS process is streamlined and requires less information in the application, we do not expect to request additional information.

All other notifications will continue as normal, including letters about the application outcome and consent expiry.

For general guidance on viewing and responding to notifications related to a consent application, please see: Viewing and responding to a notification from the dashboard about an application for consent to import, supply or export medical devices that do not meet the Essential Principles.

All notifications appear under the **Notifications** tab of the dashboard.

Figure 5: Notifications tab



Viewing notifications for UDI CtS applications

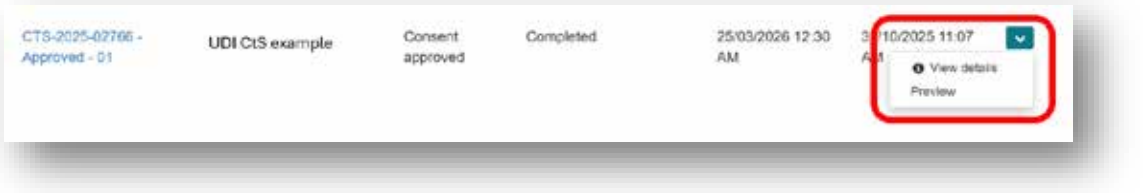
When viewing notifications:

- The notifications table displays in ascending order of Response due date by default.
- The notification with the earliest response due date appears at the top of the list.
- You can search for notifications using the search bar.
- You can sort the table by selecting any column heading.
- You can preview a notification by selecting the down arrow and Preview.
- You can view the full notification by selecting the down arrow and View details.

Previewing a notification

You can preview a notification by selecting the down arrow on the right and choosing **Preview**.

Figure 6: Viewing dropdown

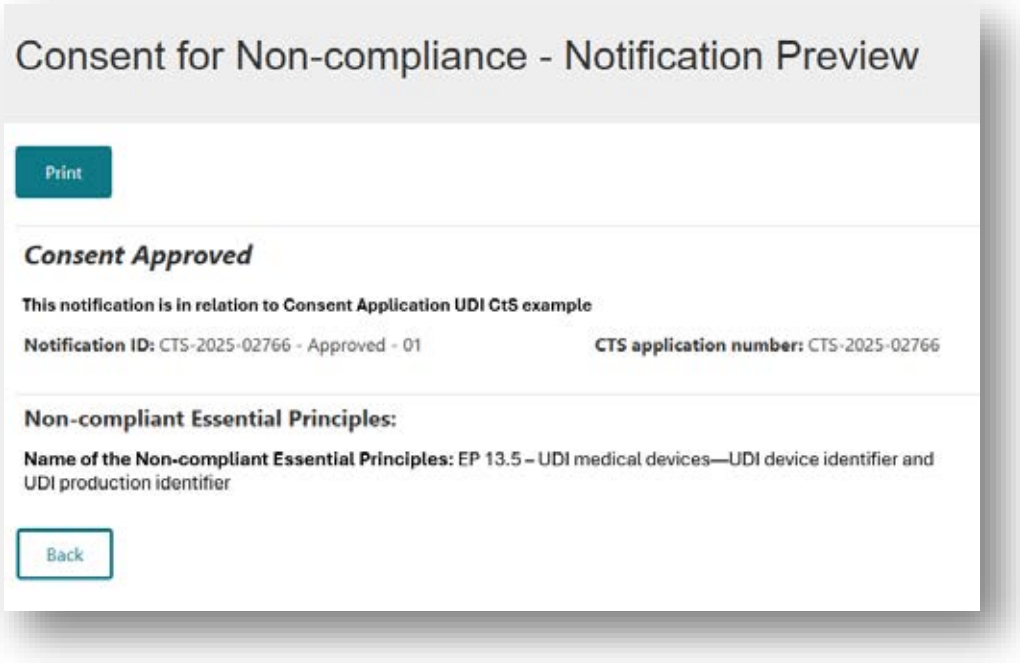


The preview displays:

- an overview of the notification
- the Notification ID
- the CtS application number
- the EPs associated with the application.

Displayed information may differ depending on the notification type.

Figure 7: Notification preview



Viewing details of a notification

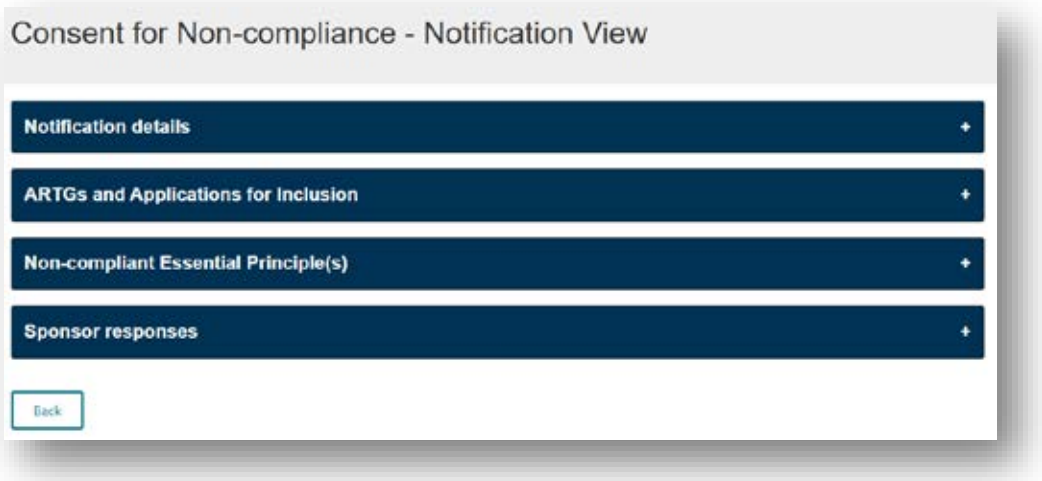
You can view details of a specific notification by selecting the down arrow on the far right of the notification, then selecting **View details.**

Figure 8: Viewing dropdown

You will see 4 non-editable sections:

- Notification details
- ARTGs and Applications for Inclusion
- Non-compliant Essential Principles (EPs)
- Sponsor responses.

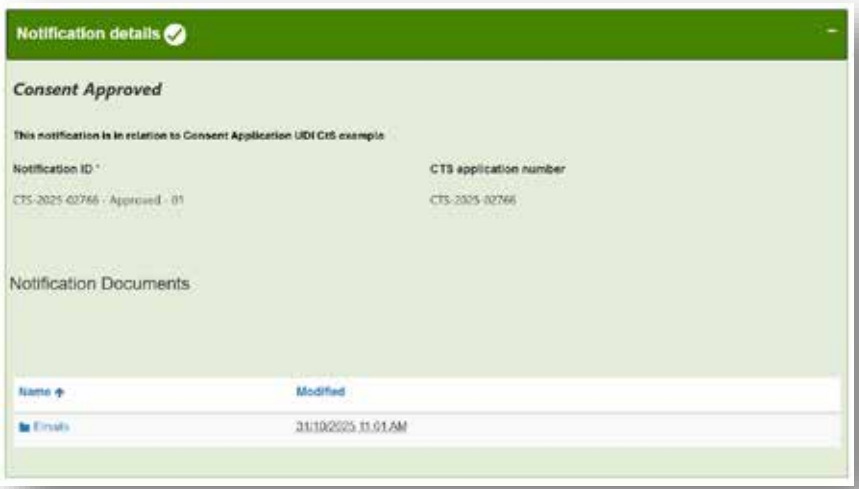
Figure 9: Notification view



Notification details includes:

- Notification ID
- CtS application number
- Notification Documents such as letters, emails, and uploaded documents.

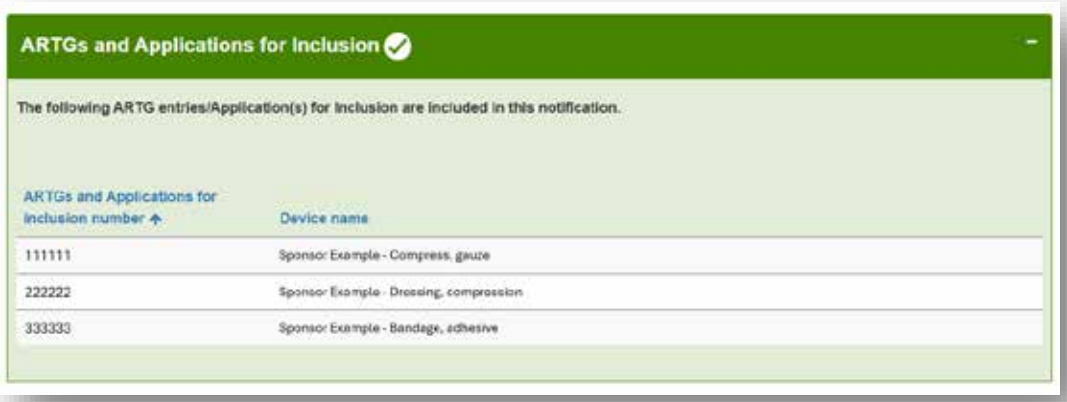
Figure 10: Notification details section



A notification may apply to all or only some devices in the application.

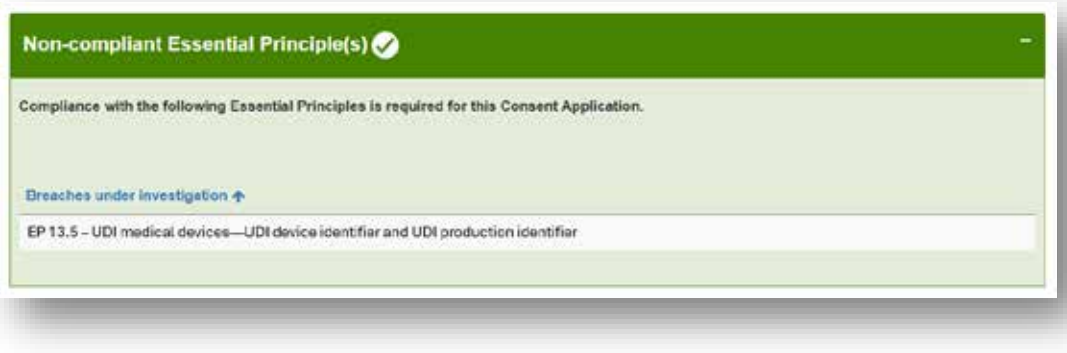
Under **ARTGs and Applications for Inclusion**, you can view ARTG(s) or Applications for Inclusion included in the notification.

Figure 11: ARTGs and Applications for Inclusion section



Under **Non-compliant Essential Principles**, you can view EPs related to the notification.

Figure 12: Non-compliant Essential Principles section

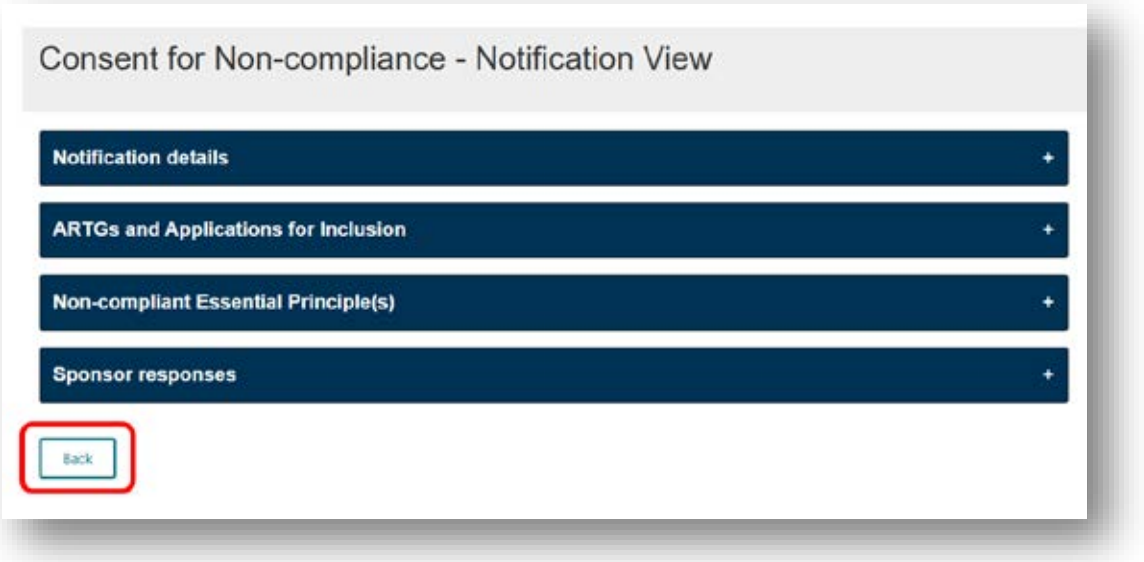


Under **Sponsor responses**, you can view responses to the notification provided by the sponsor.

Figure 13: Sponsor responses section

Select **Back** to return to the dashboard.

Figure 14: Back button



Responding to notifications for UDI CtS applications

Only users with the TGA Business Services (TBS) system role of **Submitter** can submit a response. Users with the **Drafter** role can draft and save responses but cannot submit them.

Consent approved notification

A notification and approval letter is issued when a consent application is approved. It appears in the **Notifications** tab.

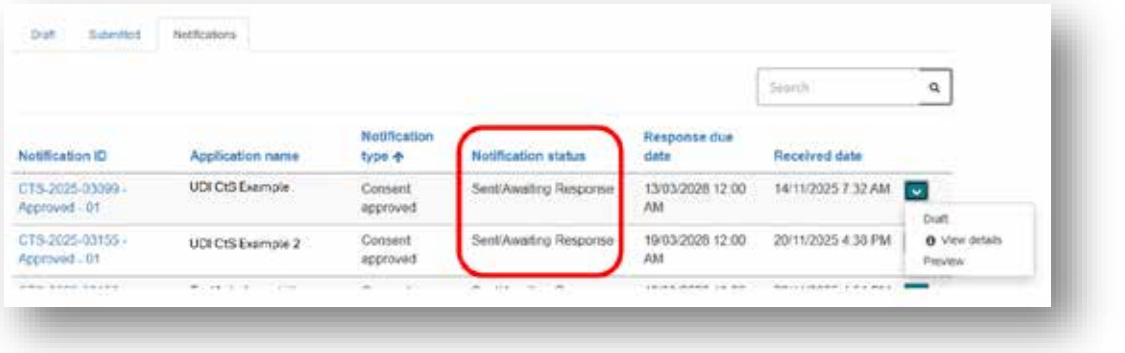
As part of the consent process, sponsors must provide evidence of compliance with the EPs before the end of the consent period.

This evidence must be provided as part of your response to the **Consent approved** notification.

	You may submit compliance evidence multiple times during the consent period; however, this is optional. As part of the UDI CtS application process, we do not expect you to submit compliance evidence multiple times. You may choose to submit evidence only before the end of the consent period.

You can only respond to a **Consent approved** notification where the **Notification status** is **Sent/Awaiting Response**.

Figure 15: Sent/Awaiting Response status

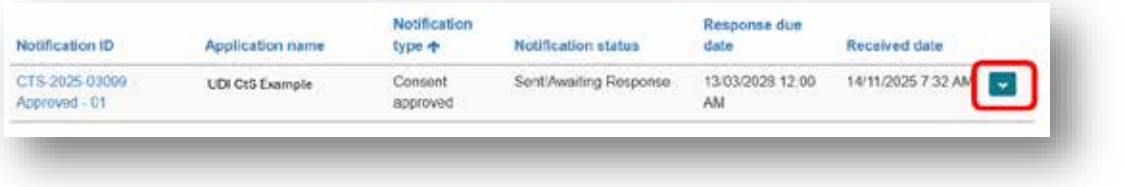


If the notification displays **Complete** but you need to submit evidence, contact the TGA at mdconsent@health.gov.au.

Drafting a response

Select the down arrow on the right-hand side of the notification.

Figure 16: Notification dropdown



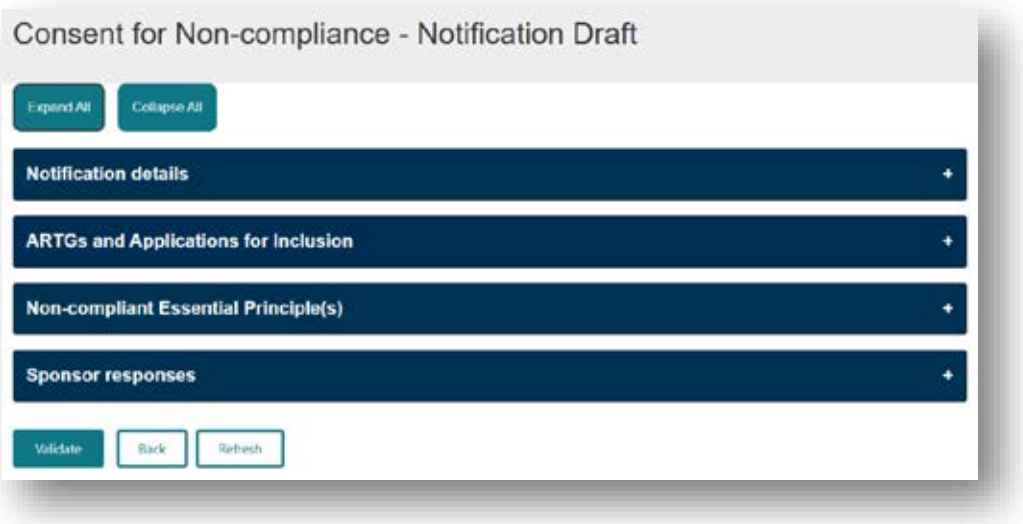
Select **draft**.

Figure 17: Draft button

A new page opens with 4 sections:

- Notification details
- ARTGs and Applications for Inclusion
- Non-compliant Essential Principle(s)
- Sponsor responses.

Figure 18: Notification draft



You cannot edit **Notification details**, **ARTGs and Applications for Inclusion**, or **Non-compliant Essential Principle(s).**

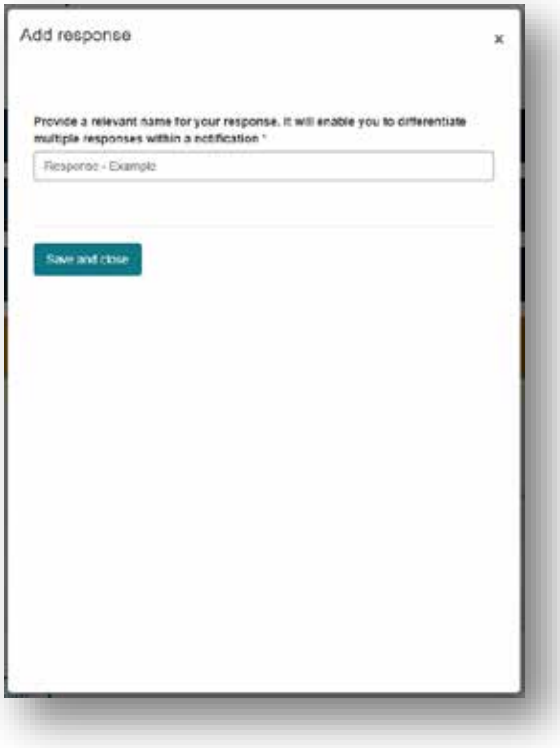
To add a response, open **Sponsor responses** and select the **Add response** button.

Figure 19: Add response button

You can include multiple ARTGs, Applications for Inclusion and EPs in a single response if the evidence is relevant to all selections.

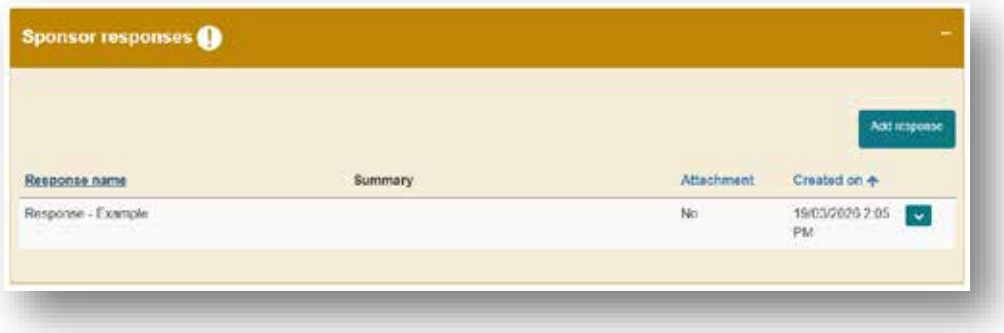
Provide a meaningful response name and select **Save and Close**.

Figure 20: Response name text box



Your response will appear in the **Sponsor responses** list.

Figure 21: Sponsor response list



To edit the response, select the down arrow and choose **Edit**.

Figure 22: Sponsor response edit dropdown

The ARTG(s), Application(s) for Inclusion and EP(s) for this notification are included by default.

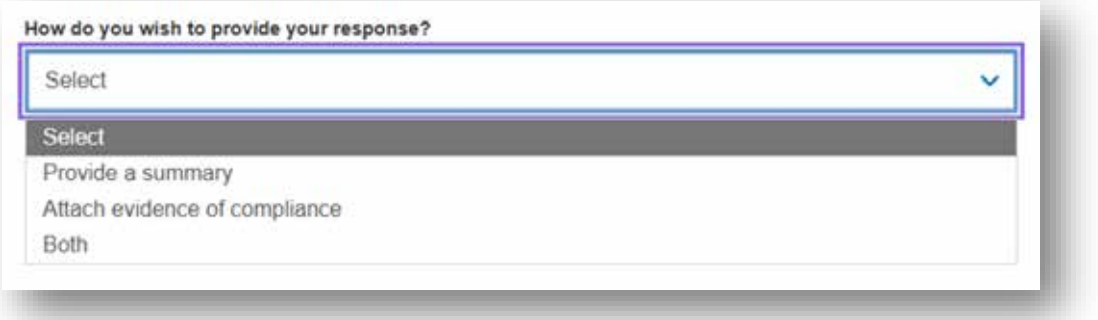
If these do not appear, refresh the table by selecting the blue column header.

If you are submitting partial evidence or wish to provide multiple responses, exclude ARTG(s), Application(s) for Inclusion or EPs by selecting the down arrow and **Exclude.**

Figure 23: Exclude button

For UDI CtS applications, select **Provide a summary** to generate a text field.

Figure 24: Method of response dropdown



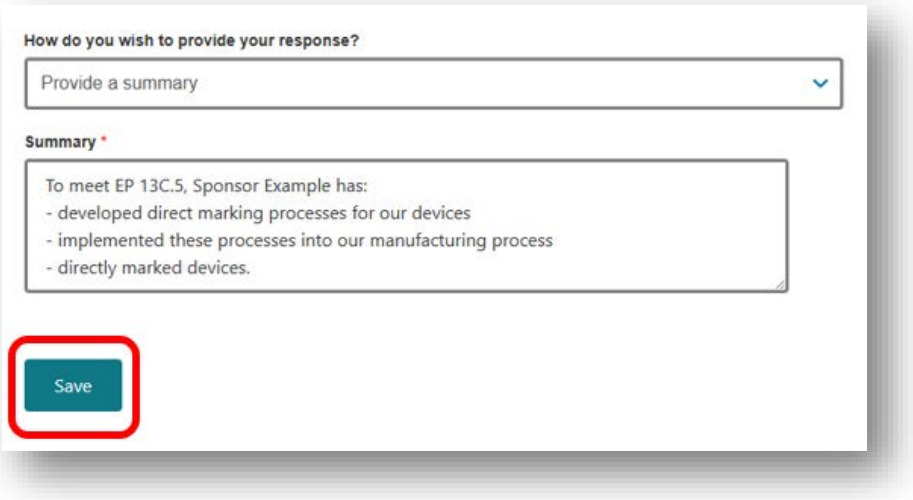
Provide dot-point details describing how you have met the EPs for the selected devices.

Figure 25: Provide a summary option and text box

You may attach evidence, but it is not required. For guidance on attaching evidence, see Viewing and responding to a notification from the dashboard about an application for consent to import, supply or export medical devices that do not meet the Essential Principles.

Select **Save** when complete.

Figure 26: Example of response and save button

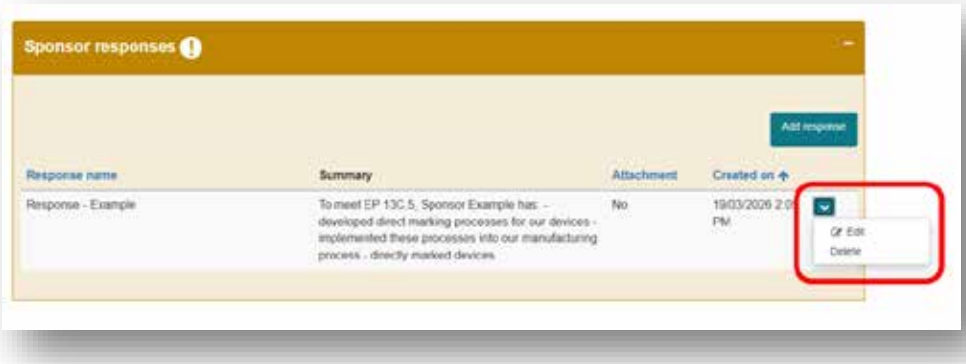


Your response will appear in **Sponsor responses.**

Figure 27: Response appearing in sponsor responses

You may edit or delete your response using the down arrow menu.

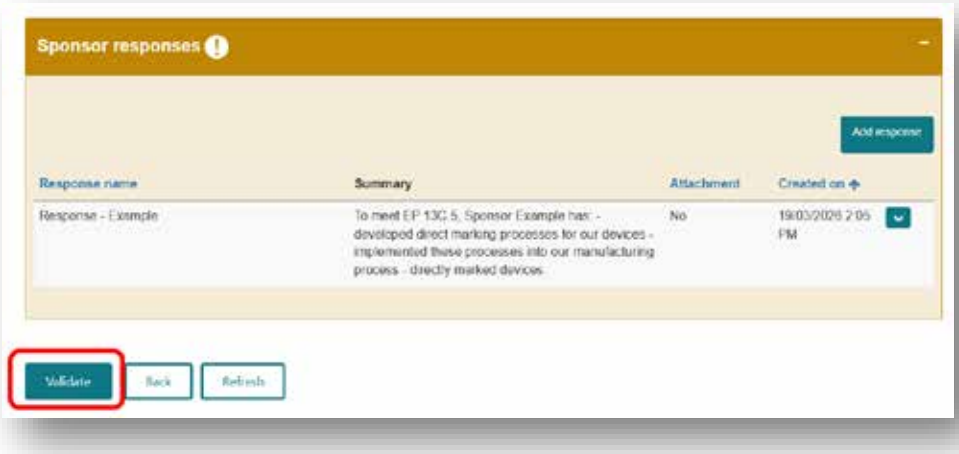
Figure 28: Edit and delete dropdown



Repeat the process to add additional responses.

When ready, select **Validate**.

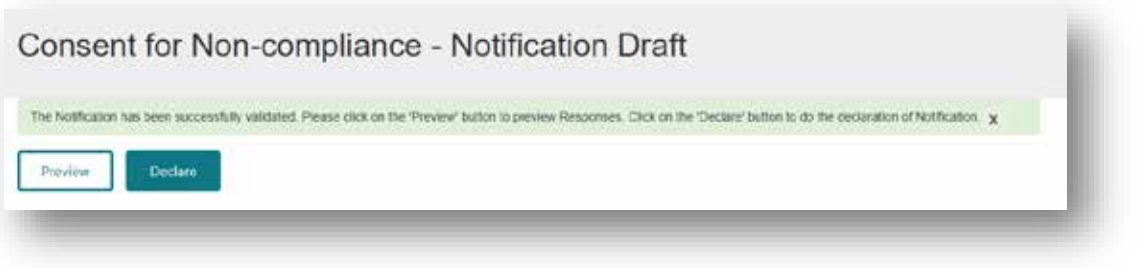
Figure 29: Validate button



The system confirms successful validation.

You may **Preview** your response or select **Declare** to submit it.

Figure 30: Successful validation notification



Complete the declaration by selecting **Yes** and then **Submit**, followed by **OK**.

Figure 31: Declaration pop-up

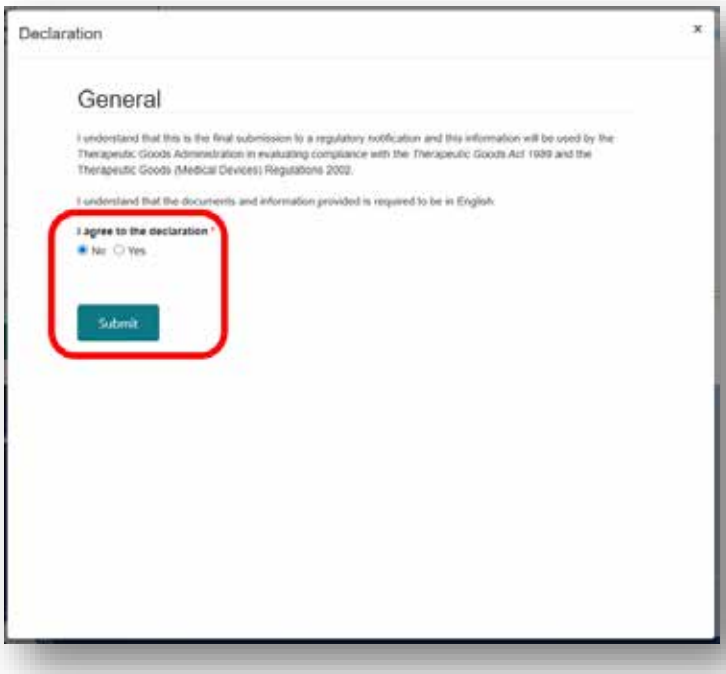
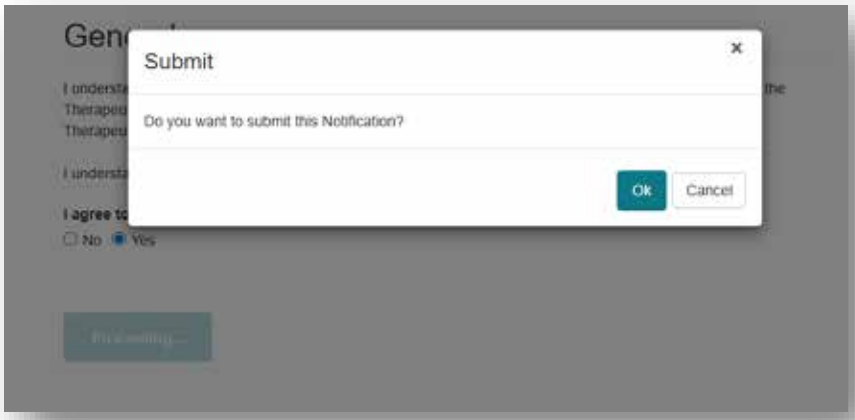


Figure 32: Submit pop-up



Once submitted, the notification displays as **Completed**.

Figure 33: Notification with completed status

Consent not-approved notification

These notifications do not require a response.

Additional information notification

Requests for additional information are **not** expected under the streamlined UDI CtS process.

If requested, follow the process in Viewing and responding to a notification from the dashboard about an application for consent to import, supply or export medical devices that do not meet the Essential Principles.

Regulatory notifications

Regulatory notifications that do not require a response

No response is required.

For details on viewing these notifications, see Viewing and responding to a notification from the dashboard about an application for consent to import, supply or export medical devices that do not meet the Essential Principles.

Regulatory notifications that require a response

These are not expected under the streamlined UDI CtS process.

If requested, follow the process in Viewing and responding to a notification from the dashboard about an application for consent to import, supply or export medical devices that do not meet the Essential Principles.

Extension requests

Extension requests are **not** permitted under the UDI CtS process.

If additional time is required to meet UDI-related EPs, you must submit a new UDI CtS application.

Resources

For resources specific to UDI, see: Unique Device Identification (UDI) hub | Therapeutic Goods Administration (TGA).

Contact us

For help submitting your application, contact the **Medical Device Consent Team**:

	mdconsent@health.gov.au
	1800 141 144

For UDI-specific assistance, contact the **UDI Support Team**:

	UDI@health.gov.au

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Device Reforms Taskforce Devices Application and Triage Section	June 2026

Therapeutic Goods Administration

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