



Welcome to the Australian Unique Device Identification Database

For sponsors and manufacturers of medical devices

AusUDID

You can submit and maintain your **UDI-DIs and related data** in the [Australian Unique Device Identification Database](#) (AusUDID) for medical devices you supply in Australia. The UDI records link to your relevant inclusion(s) in the [Australian Register of Therapeutic Goods \(ARTG\)](#). Patients, consumers, clinical quality registries and health professionals can access this device information, at no cost.

To learn more about the AusUDID, visit the [UDI Hub](#).

AusUDID environments

There are 2 AusUDID environments for you to use:

- **AusUDID Production**, the live version of the database
- **AusUDID Pre-Production**, a version of the database where you and your colleagues can test your UDI data and all types of record submission.

The AusUDID Pre-Production environment is indicated by the **'Pre-Production'** tag in the header.



Access only via TGA Business Services (TBS)

You must use your active [TBS](#) account to submit UDI records to either environment.

What you can do in the AusUDID will then depend on your **TBS system role**:

- To draft UDI records, you can have the TBS system role of **Drafter** or **Submitter**
- To submit and maintain UDI records, you must have the TBS system role of **Submitter**
- To add users to your TBS account for UDI submission purposes, you must have the TBS system role of **Administrator**.

Learn more [here](#).

Submission methods

Select **'Login with TGA'** highlighted in *Figure 2*.

You can submit UDI records in 4 ways:

- **Online Portal** – submit one UDI record at a time
- **Bulk Upload** – submit up to 200 UDI records at a time
- **HL7 SPL** – submit many UDI records at a time from your existing product information management or inventory system, either directly or via a Third Party Data Provider
- **National Product Catalogue (NPC)** – submit UDI records using GS1's NPC.

Learn more [here](#).

The types of access and data submission methods available to you will depend on your organisation's role in the AusUDID.

Data Provider	Submission Methods			
	Online	Bulk Upload	HL7 SPL	NPC
Sponsor	Yes	Yes	Yes	Yes
Manufacturer*^	Yes	Yes	Yes	Yes
Agent^	Yes	Yes	Yes	Yes
Third Party Data Provider^	No	No	Yes	No

Learn more [here](#).

UDI Support

Contact our UDI Support Team at UDI@health.gov.au or visit the [UDI Hub](#) on the TGA website.



*UDI records **published by manufacturers** are **not** publicly available until a sponsor has **linked their ARTG inclusion to the UDI record(s)**.

^Sponsors continue to be responsible for the quality and compliance of the UDI data. They should work with the manufacturer, agent or Third Party Data Provider submitting UDI records on their behalf to maintain this compliance.

- **UDI record – Published**

Published UDI records are records that can be viewed by users from other sponsor organisations. Other sponsors can link their ARTG inclusion(s) to a Published UDI record.

A UDI record must pass all the applicable data validation roles before it can be published. The user creating the record can elect to publish the record immediately or on a date in the future.

- **UDI record - Publicly Available**

Once a published UDI record is associated with an ARTG inclusion, the UDI record is publicly available. This means it can be viewed by all users of the AusUDID including patients and healthcare organisations. The UDI record will remain indefinitely in the AusUDID regardless of the status of the linked ARTG inclusion(s).

UDI record states

UDI records have different states which will impact the actions you can take.

These states will vary depending on whether the UDI record is in '**Grace Period**' and the **role of the user**.

- **UDI record - Draft**

A Draft UDI record is a record still being prepared by the user. It is not visible to other users of the AusUDID and has not been through the full suite of validation checks. Any changes can be made to the UDI record. A Draft record is only accessible to staff in the organisation of the user who created it. If a manufacturer has been linked to a Draft UDI record that was created by a sponsor, TBS users from the manufacturer organisation can also view that Draft record.

Grace Period

The Grace Period is a set time in which you can make any needed changes or fixes to all UDI data without triggering the requirements for a new UDI-DI.

The Grace Period begins once you have published your UDI record.

Once the Grace Period ends the UDI trigger rules will be active.

Learn more [here](#).

UDI Management Centre

**Overview**

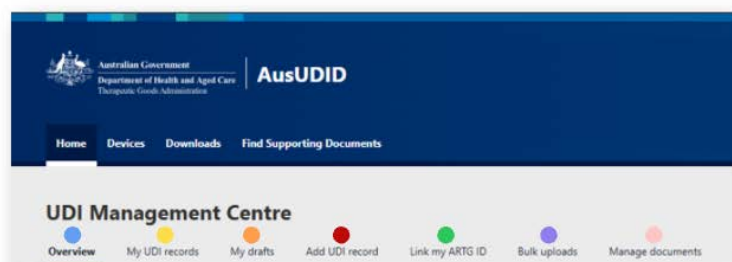
Provides an overview with information about each tab.

**My UDI records**

View your published UDI records.

**My drafts**

View and edit draft UDI records.

**Add UDI record**

Create a new UDI record. Save as a draft or publish.

**Link my ARTG ID**

Link your ARTG ID to a UDI record.

**Bulk Uploads**

Upload a Microsoft Excel template with UDI records or link your ARTG IDs to UDI records.

**Manage documents**

Add and manage documents such as Patient Information Leaflets.