

# Unique Device Identification Webinar 17

Australian UDI update, workshop summary and  
AusUDID Pre-Production demonstration



**Gary Pascoe**  
UDI Product Manager  
TGA



**Bruce Thomson**  
UDI Business  
Analyst TGA



# Welcome Housekeeping

- This Webinar is being recorded
- The presentation will be made available in the upcoming weeks
- Any relevant links in this event will be broadcasted to you via the Slido app
- Q&A session will occur after today's presentation
- Live poll – how did we go, let us know



## **Difficulties hearing from computer?**

Check your settings located under  
“**Audio & Video**” tab located top of your screen:

OR

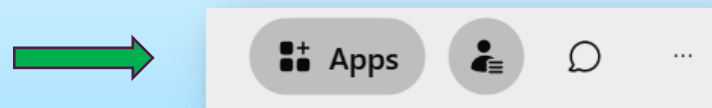
**Dial:** 02 9338 2221 (+61-2-9338-2221 )

**Access code:** 2653 445 3292

# How to ask questions

## SLIDO

### Slido App



- Click on Apps+ icon
- Select “Slido”
- Open “Q&A” tab to ask questions
- Live Poll (use survey tab when prompted)

OR

### Slido QR

Scan the QR  
code to access  
separately from  
your mobile  
device



# Acknowledgement of Country

I would like to acknowledge the Traditional Owners and Custodians of the lands on which we meet today and pay my respects to Elders past, present and emerging.

I would like to extend that acknowledgement and respect to any Aboriginal and Torres Strait Islander peoples here today.

# Agenda

**Australian UDI project update**

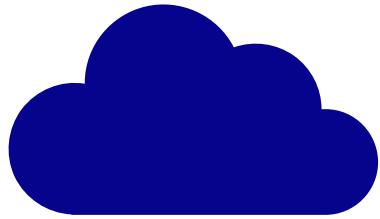
Face-to-face workshop summary

AusUDID Pre-Production demonstration

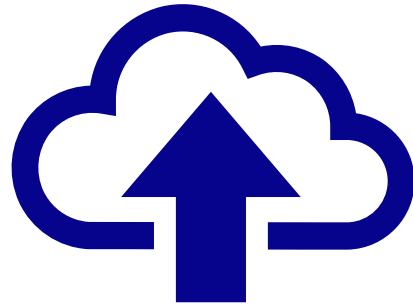
Questions and Answers



# UDI Project Update



AusUDID  
Pre-production  
environment released  
in April to groups of  
sponsors



Commenced testing of  
the National Product  
Catalogue (NPC) and  
preparations for testing  
of Machine to Machine  
(M2M) data submission



Updates to UDI Hub  
on TGA Website,  
including responses  
to third UDI  
consultation paper



Hosted face-to-face  
workshops in Sydney  
and Melbourne for  
sponsors of medical  
devices

# Australian Issuing Agencies



- Three Issuing Agencies will be supported by Australia
  - GS1
  - Health Industry Business Communications Council (HIBCC)
  - International Council for Commonality in Blood Banking Automation (ICCBBA)
- Manufacturers to liaise with issuing agency if their devices do not currently have UDI issued by one of these agencies



# Agenda

Australian UDI project update

**Face-to-face workshop summary**

AusUDID Pre-Production demonstration

Questions and Answers





# Face-to-face sponsor workshop summary

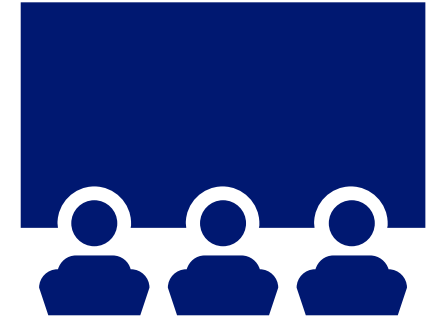


Hosted two face-to-face workshops in Sydney and Melbourne



Agenda:

- UDI regulations and policy position
  - Implementation
- AusUDID, data and submission
  - Guidance and support



295 attendees



# Considerations arising from Sponsor Workshops

## DEEP DIVE

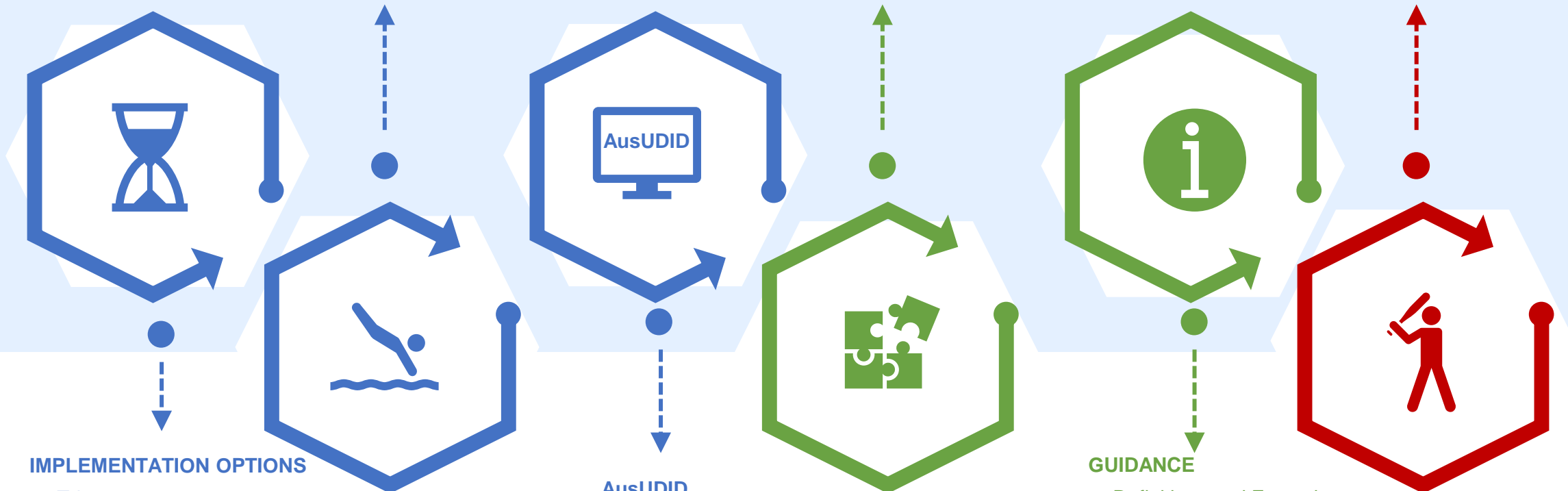
- Surgical loan kits (SLKs) and Systems or Procedure Packs (SOPPs)
- Retail Products
- Labelling from other countries (e.g Japan)

## TGA INTEGRATION

- Medical Device Single Audit Program
- Consent to Supply

## VOLUNTARY COMPLIANCE SUPPORT

- Support Team
- User Guides
- Guidance Documents
- Data Dictionary



## IMPLEMENTATION OPTIONS

- Triggers
- Data elements
- Consent to Supply/ Notifications
- Supply considerations
- Compliance dates for IVDs

## AusUDID

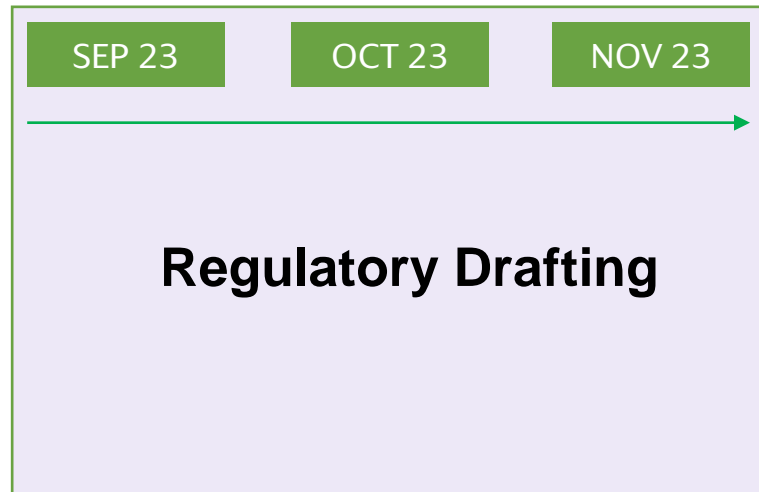
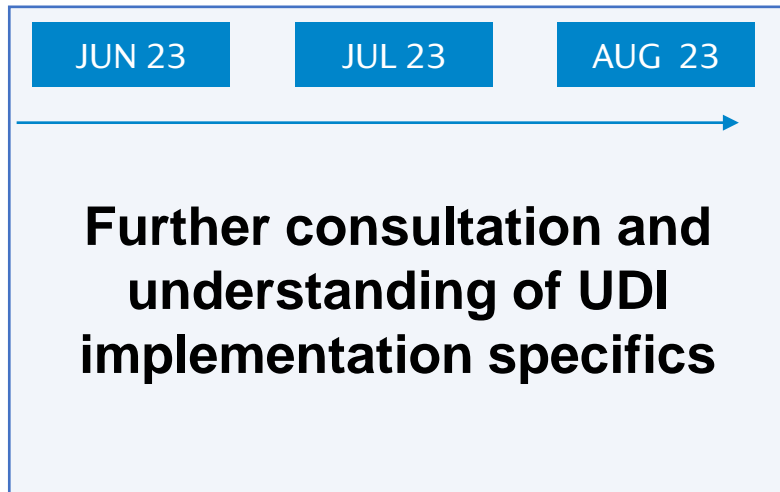
- Multiple sponsors of the same device
- Corrections
- Global Medical Device Nomenclature

## GUIDANCE

- Definitions and Examples
- Device type breakdown
- Responsibilities
- Labelling
- Patient Information Cards

## From Sponsor Workshops to Voluntary Compliance

- Aiming for UDI Regulations and Guidance to be in effect late December 2023



# Agenda

Australian UDI project update

Face-to-face workshop summary

**AusUDID Pre-Production demonstration (Bruce)**

Questions and Answers



# AusUDID – Login via TBS (Production)

**Australian Government**  
Department of Health and Aged Care  
Therapeutic Goods Administration

Login to TGA Business Services

Username or login ID

Password


Login

Forgotten your password?

[Reset Password](#) | [Privacy](#) | [Help](#)



# AusUDID – Login (Pre-Production)

 **Australian Government**  
**Department of Health and Aged Care**

[Login](#) [Sign Up](#)

Use the myGovID login below if you are Australian business or individual

Login with myGovID

Don't have a myGovID? [Sign up here](#)

Use the TGA login below if you have previously used any TGA service portal (e.g. SAS, etc...)

Login with TGA

Use the log in below only if you are not an Australian resident or not eligible for a myGovID

Email Address


Password

[Forgot your password?](#)

[Sign in](#)

Are you an international user and not associated with an Australian Business. Don't have an account?  
[Sign up now](#)

# AusUDID – Sponsor Home Page



**Australian Government**  
Department of Health and Aged Care  
Therapeutic Goods Administration

## AusUDID

Search the device database

ACC ENVIRONMENT

AusUDIDTest\_BectonDickinson AusUDIDTest\_BectonDickinson  
[Back to Business Portal](#)  
Becton Dickinson Pty Ltd (621) (Agent)  
**Current Session**  
Becton Dickinson Pty Ltd (621) (Sponsor)  
[Change](#)  
**Roles**  
Submitter

**Home** | **Devices** | **Scan a barcode** | **Downloads** | **Find Supporting Documents**

### UDI Management Centre

**Overview** | My UDI Records | Add UDI Record | Link ARTG Details | Drafts | Bulk Edit UDIs | Manage Documents

#### Welcome to the UDI Management Centre

You can view your profile and manage your UDI records.

- [+ Create a new UDI record](#)
- [🔗 Continue working on a draft record](#)
- [📄 Link ARTG Details](#)

#### Support

Phone: [02 6289 8557](tel:0262898557)  
Email: [udi@health.gov.au](mailto:udi@health.gov.au)

#### Organisation Details

Name: Becton Dickinson Pty Ltd  
ABN: 92005014706



# AusUDID – Sponsor: My UDI Records

## UDI Management Centre

Overview **My UDI Records** Add UDI Record Link ARTG Details Drafts Bulk Edit UDIs Manage Documents

Filter by keyword...   Filters:    Missing ARTG ID

Primary DI	Brand	Manufacturer	Commercial Distribution Status	ARTG ID
<a href="#">00801741077692</a>	Phasix™ Mesh	Becton Dickinson & Company	In Commercial Distribution	<a href="#">225406</a> <input type="button" value="external"/>
<a href="#">00801741061066</a>	Atlas® Gold	Becton Dickinson & Company	In Commercial Distribution	<a href="#">177789</a> <input type="button" value="external"/>

Page  of 1 pages   items per page

2 total matching items found



# AusUDID – Sponsor: My UDI Records

Roles  
Submitter

Home Devices Scan a barcode Downloads Find Supporting Documents

## UDI Management Centre

Overview My UDI Records Add UDI Record Link ARTG Details Drafts **1** Bulk Edit UDIs Manage Documents

*i* Test2 ×

### Welcome to the UDI Management Centre

You can view your profile and manage your UDI records.

- [+ Create a new UDI record](#)
- [🔄 Continue working on a draft record](#)
- [📄 Link ARTG Details](#)

### Support

Phone: [02 6289 8557](tel:0262898557)  
Email: [udi@health.gov.au](mailto:udi@health.gov.au)

### Organisation Details

Name: Becton Dickinson Pty Ltd  
ABN: 82005914796  
NPC Supplier GLN: *Not provided*

Postal Address:  
Locked Bag 3200  
NORTH RYDE NSW 2113  
Australia



# AusUDID – Add UDI Record

## UDI Management Centre

Overview My UDI Records **Add UDI Record** Link ARTG Details Drafts Bulk Edit UDIs Manage Documents

### Assign device identifiers

All devices in the Australian UDI database require at least one unique identifier issued by an authorised agency. If you have more than one identifier, add as many as you can here. This will help users find your device when searching.

Primary DI \*

Device Count \*

Unit of Use DI  
 ISSUER  
GS1

Device Exempt from Direct Marking requirements?

Direct Marking DI Different from Primary DI?

- Doing **Device Identifiers**
- To do Device Information
- To do Clinical Characteristics
- To do Manufacturer Details
- To do ARTG Details
- To do Global Medical Device Nomenclature
- To do Package DIs
- To do Production Information
- To do Supporting Documents
- To do

# AusUDID – Add UDI Record

## UDI Management Centre

Overview **My UDI Records** Add UDI Record Link ARTG Details Drafts **1** Bulk Edit UDIs Manage Documents

Filter by keyword...  Filters: **Any Status**  Missing ARTG ID

Primary DI	Brand	Manufacturer	Commercial Distribution Status	ARTG ID
<a href="#">00801741077692</a>	Phasix™ Mesh	Becton Dickinson & Company	In Commercial Distribution	<a href="#">225406</a>
<a href="#">00801741061066</a>	Atlas® Gold	Becton Dickinson & Company	In Commercial Distribution	<a href="#">177789</a>

Page  of 1 pages  items per page  
2 total matching items found

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Therapeutic Goods Administration



# AusUDID – Search for Package

Home Devices Scan a barcode Downloads Find Supporting Documents

## UDI Management Centre

Overview **My UDI Records** Add UDI Record Link ARTG Details Drafts **1** Bulk Edit UDIs Manage Documents

Filter by keyword... Filters: Any Status  Missing ARTG ID

Primary DI	Brand	Manufacturer	Commercial Distribution Status	ARTG ID
<a href="#">00801741077692</a>	Phasix™ Mesh	Becton Dickinson & Company	In Commercial Distribution	<a href="#">225406</a>
<a href="#">00801741061066</a>	Atlas® Gold	Becton Dickinson & Company	In Commercial Distribution	<a href="#">177789</a>
<a href="#">02211122233346</a>	Brand X	Becton Dickinson & Company	In Commercial Distribution	<a href="#">177789</a>

Page  of 1 pages  items per page

3 total matching items found

# AusUDID – Link to ARTG

## UDI Management Centre

Overview **My UDI Records** Add UDI Record Link ARTG Details Drafts **1** Bulk Edit UDIs Manage Documents

Filter by keyword... Filters: Any Status  Missing ARTG ID

Primary DI	Brand	Manufacturer	Commercial Distribution Status	ARTG ID
<a href="#">00801741077692</a>	Phasix™ Mesh	Becton Dickinson & Company	In Commercial Distribution	<a href="#">225406</a>
<a href="#">00801741061066</a>	Atlas® Gold	Becton Dickinson & Company	In Commercial Distribution	<a href="#">177789</a>

Page 1 of 1 pages Showing 20 items per page  
2 total matching items found


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Therapeutic Goods Administration




# AusUDID – Edit Draft Record

## UDI Management Centre

Overview   My UDI Records   Add UDI Record   Link ARTG Details   **Drafts 1**   Bulk Edit UDIs   Manage Documents

Filter by keyword... 

Primary DI	Brand	Model / Version	Manufacturer	ARTG ID	
10885403464072	Jamshidi	EJC6011	Becton Dickinson & Company	<a href="#">177789</a> 	<a href="#">Continue editing</a> →



Page  of 1 pages   Showing  items per page


1 total matching items found

# AusUDID – Edit Draft Record

## UDI Management Centre

[Overview](#)[My UDI Records](#)[Add UDI Record](#)[Link ARTG Details](#)[Drafts 1](#)[Bulk Edit UDIs](#)[Manage Documents](#)

Primary DI	Brand	Manufacturer	ARTG ID
<a href="#">00801741077692</a>	Phasix™ Mesh	<b>Becton</b> Dickinson & Company	<a href="#">225406</a>  <a href="#">EDIT ARTG IDS</a>
<a href="#">00801741061066</a>	Atlas® Gold	<b>Becton</b> Dickinson & Company	<a href="#">177789</a>  <a href="#">EDIT ARTG IDS</a>
<a href="#">02211122233346</a>	Brand X	<b>Becton</b> Dickinson & Company	<a href="#">177789</a>  <a href="#">EDIT ARTG IDS</a>

Page  of 1 pages   items per page

3 total matching items found



# AusUDID – Manage Documents

## UDI Management Centre

Overview   My UDI Records   Add UDI Record   Link ARTG Details   Drafts **1**   Bulk Edit UDIs   **Manage Documents**

Filter by keyword...  Filters   ARTG ID (Exact)   Patient Information Leaflet

URL    Attachment    No Documents

### Add Document

Select a device to add a new Document.

### Replace / Delete Documents

Select a device with the below document to Replace/Delete.

URL    Attachment

Search for URL or Filename

<input type="checkbox"/>	Primary DI	Brand	Manufacturer	ARTG ID
<input type="checkbox"/>	<a href="#">00801741077692</a>	Phasix™ Mesh	Becton Dickinson & Company	<a href="#">225406</a> <input type="button" value="v"/>
<input type="checkbox"/>	<a href="#">00801741061066</a>	Atlas® Gold	Becton Dickinson & Company	<a href="#">177789</a> <input type="button" value="v"/>



# AusUDID – Add document to many devices at once

## UDI Management Centre

Overview My UDI Records Add UDI Record Link ARTG Details Drafts **1** Bulk Edit UDIs **Manage Documents**

Filter by keyword... Filters ARTG ID (Exact) Patient Information Leaflet ▾

URL  Attachment  No Documents

### Add Document

Select a device to add a new Document.

Add a new document to 2 devices

### Replace / Delete Documents

Select a device with the below document to Replace/Delete.

URL  Attachment

Search for URL or Filename

Select to Replace Select to Delete

<input checked="" type="checkbox"/>	Primary DI	Brand	Manufacturer	ARTG ID
<input checked="" type="checkbox"/>	<a href="#">00801741077692</a>	Phasix™ Mesh	Becton Dickinson & Company	<a href="#">225406</a> ↗
<input checked="" type="checkbox"/>	<a href="#">00801741061066</a>	Atlas® Gold	Becton Dickinson & Company	<a href="#">177789</a> ↗



# AusUDID – Add document to many devices at once

Add Supporting Document ✕

On this page you can add a supporting document or URL for multiple devices.  
You can upload supporting documents or URLs that can be accessed by the public, such as Patient Information Leaflets.  
You are responsible for ensuring this data is up to date, including any referenced URLs.  
You can add a PDF document, with maximum file size of 50 MB, or specify the URL relevant to the selected devices.

Document Type \*

Patient Information Leaflet ▾

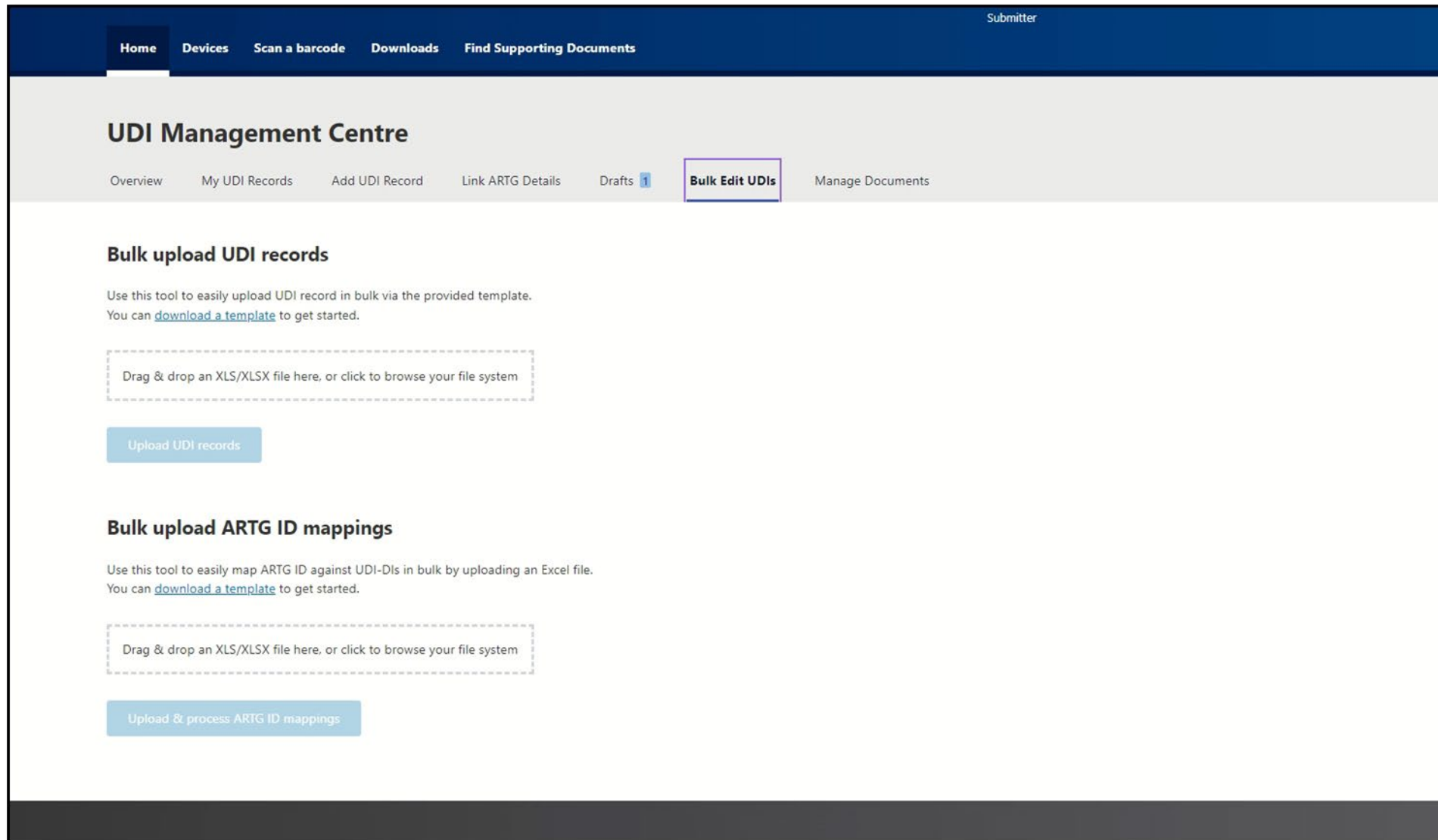
Document Provided As

URL  Attachment

URL \*

[Cancel](#)

# AusUDID – Bulk Upload



The screenshot shows the 'Bulk Edit UDIs' page in the AusUDID system. The page has a dark blue header with navigation links: Home, Devices, Scan a barcode, Downloads, Find Supporting Documents, and Submitter. Below the header is a light grey navigation bar with links: Overview, My UDI Records, Add UDI Record, Link ARTG Details, Drafts (1), Bulk Edit UDIs (highlighted with a purple box), and Manage Documents. The main content area is white and contains two sections: 'Bulk upload UDI records' and 'Bulk upload ARTG ID mappings'. Each section includes a dashed box for file upload and a blue button to initiate the process.

Submitter

Home Devices Scan a barcode Downloads Find Supporting Documents

## UDI Management Centre

Overview My UDI Records Add UDI Record Link ARTG Details Drafts 1 **Bulk Edit UDIs** Manage Documents

### Bulk upload UDI records

Use this tool to easily upload UDI record in bulk via the provided template. You can [download a template](#) to get started.

Drag & drop an XLS/XLSX file here, or click to browse your file system

Upload UDI records

### Bulk upload ARTG ID mappings

Use this tool to easily map ARTG ID against UDI-DIs in bulk by uploading an Excel file. You can [download a template](#) to get started.

Drag & drop an XLS/XLSX file here, or click to browse your file system

Upload & process ARTG ID mappings



# AusUDID – Public: Find Supporting Documents

Home Devices Scan a barcode Downloads Find Supporting Documents

Search: mesh Filters: Patient Information Leaflet

Primary DI	Brand	Manufacturer	ARTG ID
00801741077692	Phasix™ Mesh	Becton Dickinson & Company	225406


Page 1 of 1 pages Showing 20 items per page

1 total matching items found

# AusUDID – Public: Find Supporting Documents

[Home](#) [Devices](#) [Scan a barcode](#) [Downloads](#) [Find Supporting Documents](#)


[Home](#) > [All devices](#)

Brand Name **Phasix™ Mesh** Model or Version **1190400** Manufacturer **Becton Dickinson & Company** 

## Supporting Documents

[Edit Device](#)

On this page you can find supporting documents for medical devices, if provided by the Sponsor. Sponsors may choose not to upload their documents or URLs. Sponsors are responsible for ensuring this data is up to date, including any referenced URLs.

Filters:  

Date	Type	Sponsor	ARTG	Document
6 June 2023	Patient Information Leaflet	Becton Dickinson Pty Ltd	225406	<a href="#">View</a>

### Download Device Record

[XML](#) [JSON](#)

### Device Overview

- Device Identifiers
- Device Information
- Clinical Characteristics
- Manufacturer Details
- ARTG Details
- Global Medical Device Nomenclature
- Packaging
- Production Information
- Supporting Documents
- History
- Device Actions



# AusUDID – Public: Download Data

Home Devices Scan a barcode Downloads ×

## Download the Aus UDI Database


On this page you can download the full Australian UDI Database, previous versions, and daily/weekly/monthly updates so you can keep up with changes to all devices.

### Full database downloads

These links will download full copies of the Australian UDI Database in JSON format.

[Latest version \(taken on Jun 6, 2023 12:00 AM\) >](#)

[Previous version \(taken on Jun 5, 2023 12:00 AM\) >](#)




### Periodic updates

Links will be provided to download differential updates for each day, week and month in JSON format.


[Daily Update \(period ending Jun 4, 2023\) >](#)

[Weekly Update \(period ending Jun 3, 2023\) >](#)

[Monthly Update \(period ending May 31, 2023\) >](#)



# AusUDID – Public: View all published devices

Home	Devices	Scan a barcode	Downloads		
<input type="text" value="Search all devices by keyword..."/>		<a href="#">Browse by GMDN</a>			
Brand	Model	Manufacturer	GMDN term	ARTG ID	Primary DI
<input type="checkbox"/> SmartSync	24970A	Medtronic Inc	Cardiac pulse generator programmer	313620	00763000203979
<input type="checkbox"/> MDT Guidewire	GWBC30	Medtronic Corevalve LLC	Cardiac/peripheral vascular guidewire, single-use	274174	00643169357051
<input type="checkbox"/> Phasix™ Mesh	1190400	Becton Dickinson & Company	Extra-gynaecological surgical mesh, composite-polymer	225406	00801741077692
<input type="checkbox"/> Atlas® Gold	ATG120264	Becton Dickinson & Company	Peripheral angioplasty balloon catheter, basic	177789	00801741061066
<input type="checkbox"/> Jamshidi	EJC6011	Bard Peripheral Vascular Inc Trading as CR Bard Inc	Bone marrow biopsy needle, single-use	403962	10885403464072



# AusUDID – Public view and Download

The screenshot shows the AusUDID public interface. At the top, there is a navigation bar with the TGA logo, the text 'Department of Health and Aged Care Therapeutic Goods Administration', and a search bar labeled 'Search the device database'. A yellow banner below the search bar indicates 'PRE-PRODUCTION ENVIRONMENT'. The main navigation menu includes 'Home', 'Devices', 'Scan a barcode', and 'Downloads'. The main content area features the title 'Australian Unique Device Identification Database' and a search instruction: 'Enter any ARTG identifier, device identifier, brand name, device name or Global Medical Device Nomenclature (GMDN) term in the search box below to instantly find all matching devices.' Below this is a search input field with the placeholder 'Search devices by keyword...' and a 'Search' button. A link below the search box reads 'Not sure on keywords? Try browsing by Global Medical Device Nomenclature (GMDN) >'. A blue notification bar contains the text 'Please contact the UDI support team if you have any questions'. The main content is split into two columns: 'Welcome to the Australian Unique Device Identification Database (AusUDID)' and 'Support'. The 'Welcome' section contains several paragraphs of introductory text and links to 'See the UDI Hub' and 'Search for a device or scan a barcode'. The 'Support' section lists contact information: 'Phone: 02 6289 8557' and 'Email: udi@health.gov.au'. A red 'Give Feedback' button is located in the bottom right corner.

GA AusUDID TGA AusUDID Sign... Sign in to your acco...

Department of Health and Aged Care  
Therapeutic Goods Administration

Search the device database  
PRE-PRODUCTION ENVIRONMENT

Home Devices Scan a barcode Downloads

## Australian Unique Device Identification Database

Enter any ARTG identifier, device identifier, brand name, device name or Global Medical Device Nomenclature (GMDN) term in the search box below to instantly find all matching devices.

Search devices by keyword... Search

[Not sure on keywords? Try browsing by Global Medical Device Nomenclature \(GMDN\) >](#)

Please contact the UDI support team if you have any questions

### Welcome to the Australian Unique Device Identification Database (AusUDID)

The AusUDID contains key device identification information submitted to the Therapeutic Goods Administration (TGA) about medical devices that have Unique Device Identifiers (UDI).

The TGA is establishing the UDI system to identify medical devices in Australia, from manufacturing through to distribution and patient use.

You can use AusUDID to search for specific medical devices or download the entire database.

Medical devices will be progressively added to AusUDID. You can [see the timeline](#) for when devices will be added.

[See the UDI Hub](#) for more information.

[Search for a device](#) or [scan a barcode](#) to get started.

### Support

Phone: [02 6289 8557](tel:0262898557)  
Email: [udi@health.gov.au](mailto:udi@health.gov.au)

Give Feedback



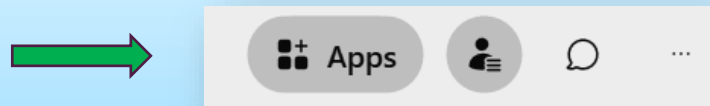
# Agenda

Australian UDI project update  
Face-to-face workshop summary  
AusUDID Pre-Production demonstration  
**Questions and Answers (Gary)**



# SLIDO is now open for questions

## Slido App



- Click on Apps+ icon
- Select “Slido”
- Open “Q&A” tab to ask questions
- Live Poll (use survey tab when prompted)

OR

## Slido QR

Scan the QR code to access separately from your mobile device



# Unique Device Identification Webinar 17

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AusUDID Pre-Production demonstration



**Gary Pascoe**  
UDI Product Manager  
TGA



**Bruce Thomson**  
UDI Business  
Analyst TGA



# Contact us

**UDI Support Team**

[UDI@health.gov.au](mailto:UDI@health.gov.au)

Phone: 02 6289 8557

(+61 2 6289 8557 International)



# Survey - Poll

## How did we go?

We'll be back with you in **1 minute**.

1. Please open SLIDO *(located from your APPS icon)*
2. Open the POLL tab
3. Complete short survey
4. We'll then commence Q&A

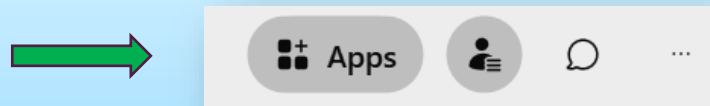


**Anonymous or Open responses welcome**



# SLIDO is now open for questions

## Slido App



- Click on Apps+ icon
- Select “Slido”
- Open “Q&A” tab to ask questions
- Live Poll (use survey tab when prompted)

OR

## Slido QR

Scan the QR  
code to access  
separately from  
your mobile  
device



# Website and link references

UDI Hub

<https://www.tga.gov.au/how-we-regulate/manufacturing/manufacture-medical-device/unique-device-identification-udi-system>

Third UDI consultation paper

<https://www.tga.gov.au/resources/consultation/consultation-detailed-considerations-implementing-proposed-australian-medical-device-udi-regulatory-framework>

\*Closed on 11<sup>th</sup> October

Third UDI consultation paper –  
published responses

[https://consultations.tga.gov.au/tga/udi-consultation-paper-3/consultation/published\\_select\\_respondent](https://consultations.tga.gov.au/tga/udi-consultation-paper-3/consultation/published_select_respondent)

Previous Webinars

<https://www.tga.gov.au/how-we-regulate/manufacturing/manufacture-medical-device/unique-device-identification-udi-system/unique-device-identification-system-communications-and-stakeholder-engagement>

TGA UDI News and Updates

<https://www.tga.gov.au/how-we-regulate/manufacturing/manufacture-medical-device/unique-device-identification-udi-hub/unique-device-identification-udi-news-and-updates>

# Questions



**Gary Pascoe**  
UDI Product Manager  
TGA



**Bruce Thomson**  
UDI Business  
Analyst TGA



Q&A



# More information



TGA website <https://www.tga.gov.au>



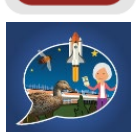
TGA Facebook <https://www.facebook.com/TGAgovau/>



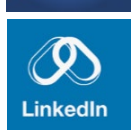
TGA Twitter <https://twitter.com/TGAgovau>



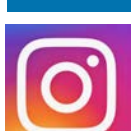
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