

# UDI Roadshow

**Sydney and Melbourne  
2025**



**Australian Government**

**Department of Health, Disability and Ageing**  
Therapeutic Goods Administration

**[tga.gov.au](https://www.tga.gov.au)**

# 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 and present.

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

# Objectives

1

To help sponsors **understand and comply with Australian UDI requirements**

2

To support industry compliance by discussing **key readiness activities and upcoming compliance timeframes**

3

To gather feedback to shape TGA's future **communications, support initiatives and system improvements**

# Welcome – Tracey Duffy



The team and approach



The stakeholders and contributors



The international experience



The importance and value



The future





## UDI Foundations

# The key requirements of a UDI system



## Labelling

A unique identifier for each model of device and applicable production information is applied to the device label and all higher levels of packaging.

Global uniqueness is maintained by requiring the UDI-Device Identifier (UDI-DI) to be issued by a recognised Issuing Agency.

Each production run of the device is assigned a UDI-Production Identifier (UDI-PI) in accordance with the Issuing Agency's requirements.



## UDI Database

The UDI Device Identifier (UDI-DI) and related device data is stored in a central UDI database.



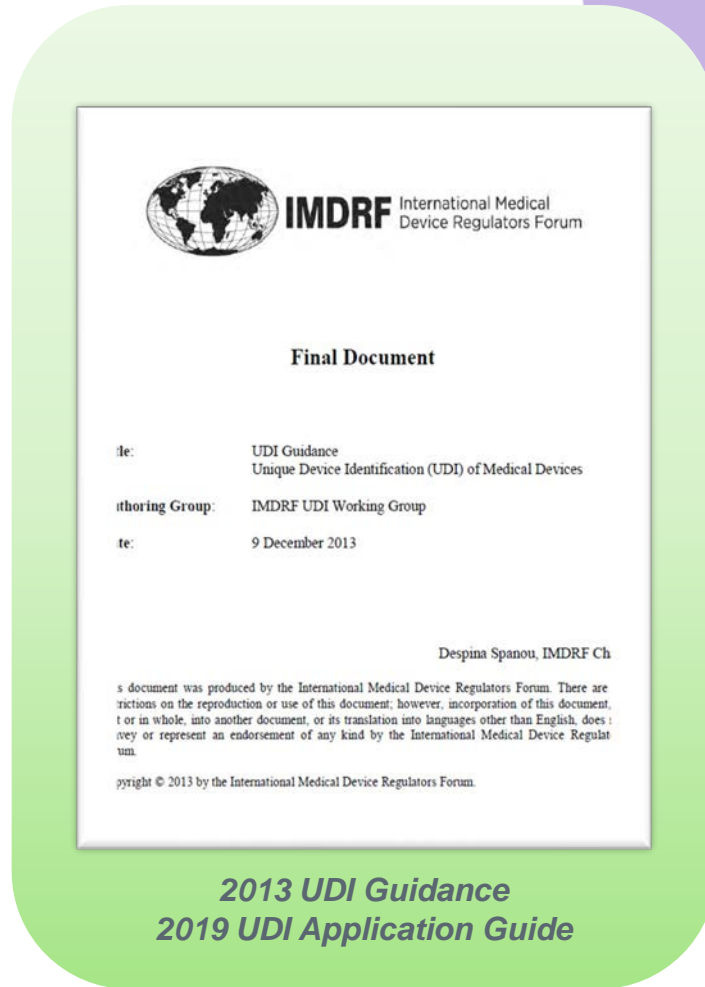
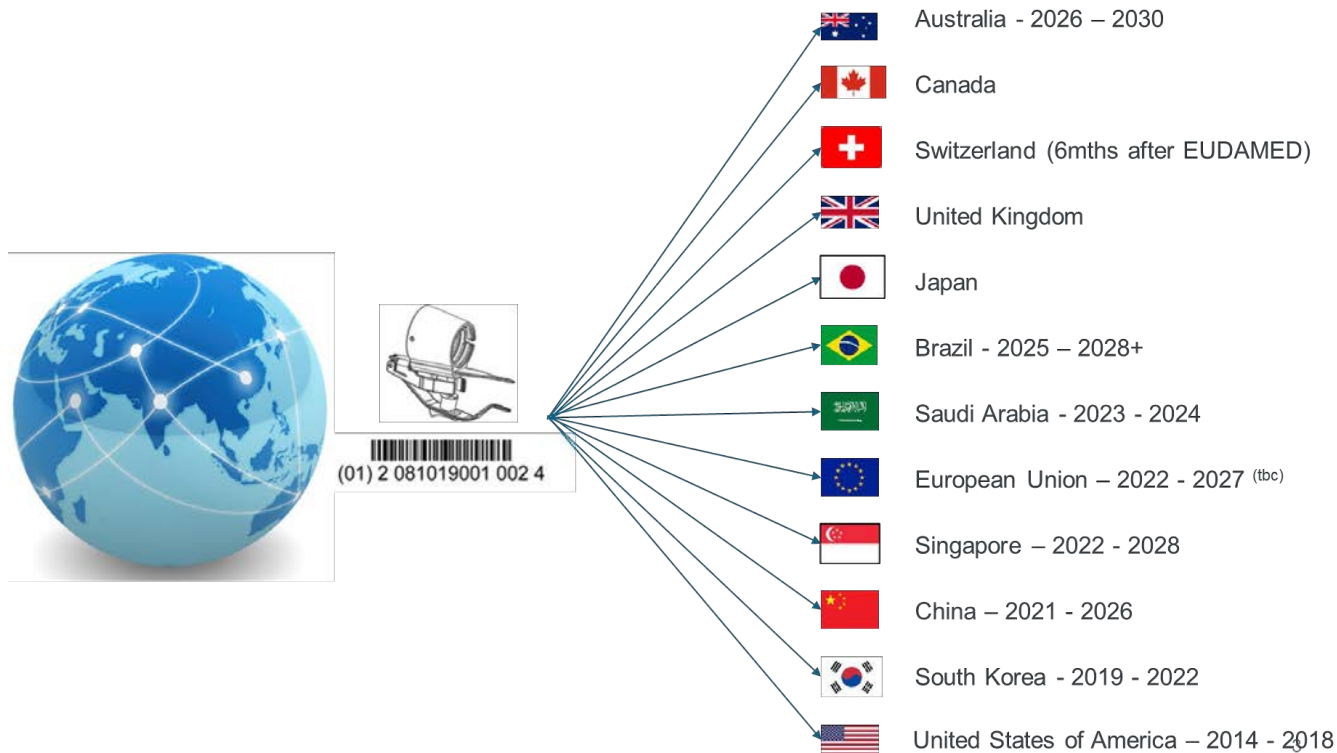
## In Australia

The UDI record is linked to the relevant ARTG inclusion(s) 30 days after the device is first supplied into Australia.

# Why is it important - International

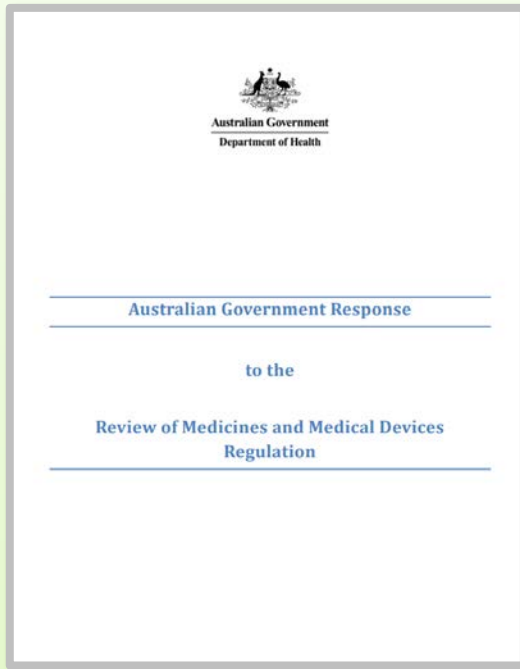
There is global recognition that clearly identifying medical devices is essential to **protect patient safety** and **improve outcomes** across the medical device industry.

Demand for improved traceability of medical devices has seen other regulators implement the UDI system



# Why is it important – Australia

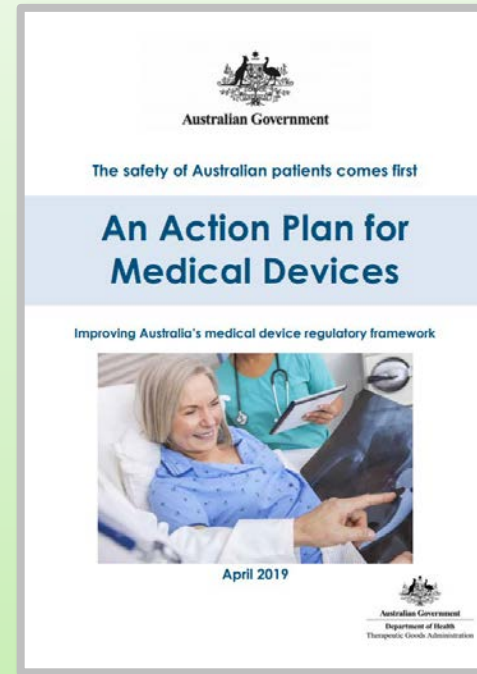
Inability to **effectively** and **efficiently** track and trace medical devices that have been supplied to or implanted into patients has **constrained timely clinical and regulatory action** in medical device safety crises.



**2015**  
*Review of Medicines and Medical  
Devices Regulation*



**2018**  
*Senate Community Affairs  
References Committee Report*



**2019**  
*TGA Action Plan  
for Medical Devices*

# The key features of Australia's UDI system



## UDI REQUIREMENTS

- In the Essential Principles, including requirement to keep data up to date
- No individual UDI related fees, costs are included in annual ARTG charge



## SCOPE

- Medical devices and in vitro diagnostic (IVD) medical devices included on the ARTG
- Existing ARTG exclusions – data to be provided when device is next imported / supplied

	Medical Devices	In Vitro Diagnostic Medical Devices
<b>UDI required</b>	<ul style="list-style-type: none"><li>• Class III</li><li>• Class IIb</li><li>• Class IIa</li><li>• Class I – supplied sterile</li></ul>	<ul style="list-style-type: none"><li>• Class 4</li><li>• Class 3</li><li>• Class 2</li><li>• Class 1 (Software or Instrument/Analyser)</li></ul>
<b>UDI not required</b>	<ul style="list-style-type: none"><li>• Class I – measuring</li><li>• Class I</li><li>• Class 1 IVDs</li><li>• In house IVDs</li><li>• Medical devices or IVD devices intended only for export from Australia</li><li>• Patient-matched medical devices with a volume of 5 or less supplied each financial year</li><li>• Exempt under the Special Access Scheme (SAS) or Authorised Prescribed Scheme (AP)</li></ul>	

# The key features of Australia's UDI system

## LABELLING

- UDI labelling requirements are in addition to current labelling requirements – label to include AIDC and HRI carriers
- UDI to be on the base package and all higher levels of packaging
- Devices reprocessed between use on subsequent patients are direct marked
- Australia accepts devices with UDI compliant labels from US and EU

## UDI ISSUING AGENCIES

- Manufacturers to contact issuing agency if devices do not currently have UDI issued by one of these agencies



**ENDOPATH®**  
**dextrus**  
Finger-Mounted Locking Forceps

REF FMF02 LOT 1Q34  
080100 QTY 4  
(01) 2 081019001 002 4  
(17)080100(10)1Q34

**T.A.G.**  
Manufacturer  
T.A.G. Medical Products  
Kibbutz Gaalon 25130 Israel  
Tel: 972-4-9858400, Fax: 972-4-9858404

CE 0344

**EC REP**  
EU representative  
MEDNET GmbH  
Borkstrasse 10 48163 Muenster, Germany  
Tel: +49 (251) 32266-0  
Fax: +49 (251) 32266-22

**Distributor**  
Ethicon Endo-Surgery Inc  
Cincinnati OH  
45242-2839 USA

Does not contain latex or PVC  
Single patient use only  
STERILE R R<sub>x</sub> Only

REF FMF02

**CompuHyper GlobalMed®**  
Ultra Implantable™  
Fictitious Medical Device  
2.25 mm x 8 mm

CAT 123ABC  
LOT 1234AB

USE BY: 2019-05-15  
MANUFACTURED ON: 2018-10-01

SN 0478EDFG  
QTY: 1 EA

2 SINGLE USE  
DO NOT USE IF PACKAGE IS DAMAGED  
40°C UPPER LIMIT OF TEMPERATURE  
KEEP DRY

**Manufacturer**  
CompuHyper GlobalMed®  
123 Technology Dr  
Somewhere, XX 00000  
800.555.1234 (USA)  
555.555.1234 (All Others)  
www.chgm.com

MedDevFront UK  
Somewhere, XX 00000  
XX12 3XX UK  
www.mdfo.uk

\*X999123ABC0531905151234AB/55678EDFG/16D20151001J\*

PC: T0479 BONE, STRIP Demineralized  
DIN: A9997 14 123456 ♂ B  
SN: 25  
Exp Date: 2016-01-08  
Store at room temperature

=/A9999XYZ100T0479'  
=,000025=A99971412345600=>016008

# The key features of Australia's UDI system



## UDI TRIGGERS

- A new UDI-DI is required because the change in data could lead to misidentification of the medical device and/or ambiguity in its traceability



## INFORMATION

- When available, UDI included on:
  - Patient Implant Cards
  - Adverse Events / Device Incident Reports
  - Market actions, e.g. recalls, alerts, corrections

## Australian Trigger Data Elements

- Labelled as single use
- If the restricted number of reuses changes
- Packaged sterile
- Need for sterilisation before use
- Critical warnings or contraindications:
  - Contains latex
  - MRI safety status \*
- Clinical size (including volume, length, gauge, diameter) \*
- Brand name
- Device version or model (including software add/change of features that result in change to intended purpose / a new major version number)
- Quantity of devices provided in a base package (device count)

# How does Australia compare with other jurisdictions?



- Key differences when compared with the International Medical Device Regulators Forum (IMDRF) UDI Guidance and Application Guide



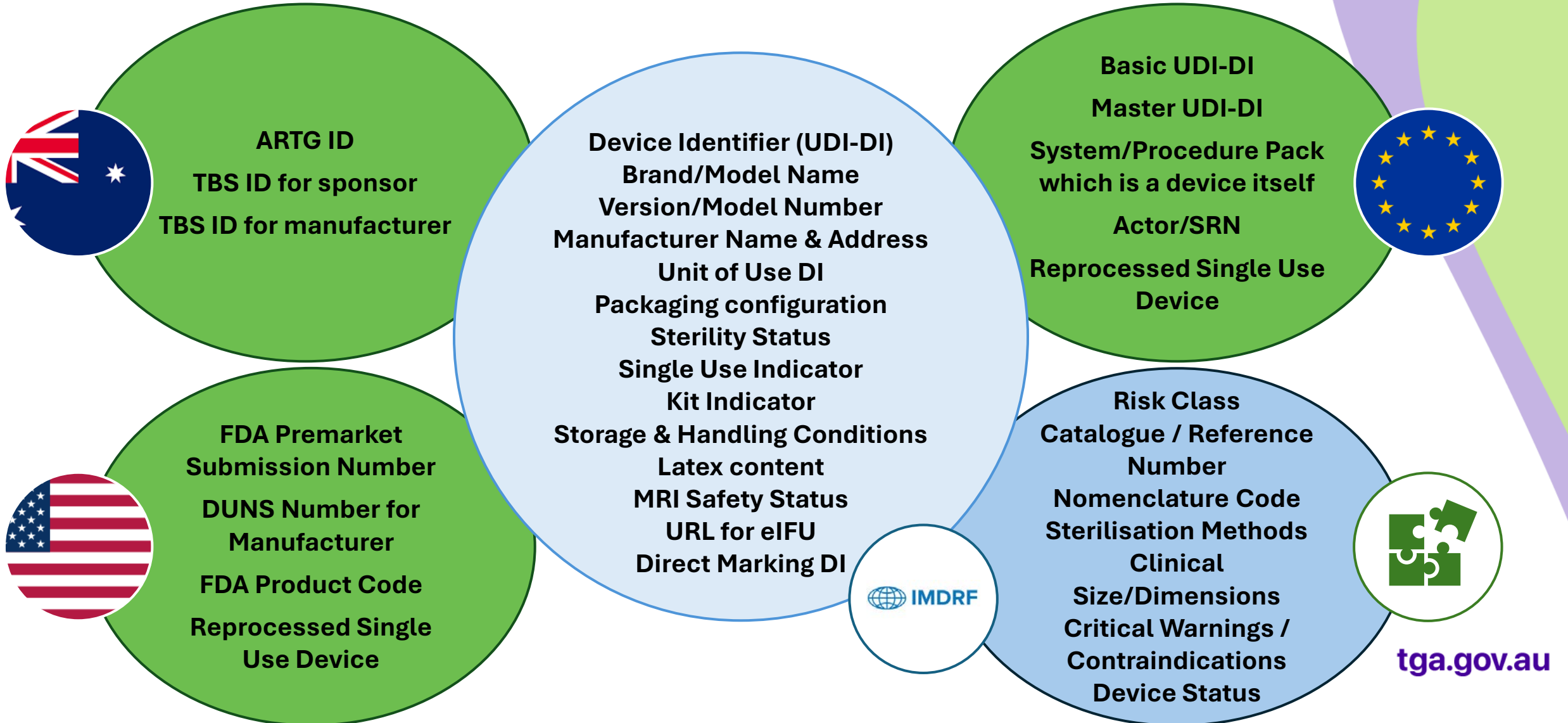
- Small differences in data fields and rules
- Sponsor is responsible for the UDI data; multiple sponsors of the same device (UDI-DI)
- UDI record must be linked to market approval (ARTG inclusion)
- 4 data submission methods: online, Excel spreadsheet, HL7 SPL, NPC
- Submission timeline: within 30 days of supply in Australia
- Australia accepts UDI Carriers that meet the UDI requirements of the US and the EU
- Some Class I devices and Class 1 IVDs are exempt
- Ability to test data before Production submission

- Small differences in data fields and rules
- Labeller (usually manufacturer) is responsible for the UDI data
- UDI record may have link to FDA Premarket Submission Number
- 2 methods for data submission: online, HL7 SPL
- Submission timeline: Before device is placed on US market
- All medical devices and IVDs are in scope
- Can test data before Production submission (HL7 SPL only)

- Substantial number of EU specific data fields and rules
- Manufacturer is responsible for the UDI data
- UDI record requires a Basic UDI-DI
- 2 methods for data submission: online, XML (EUDAMED schema)
- Submission timeline: Before device is placed on EU market
- All medical devices and IVDs are in scope
- 4 Issuing Agencies (Entities)
- Can test data submission before Production

# How does Australia compare with other jurisdictions – Data Elements

Key differences when compared with the International Medical Device Regulators Forum (IMDRF) UDI Guidance and Application Guide



# How does Australia compare with other jurisdictions – Data elements

- Key differences when compared with the International Medical Device Regulators Forum (IMDRF) UDI Guidance and Application Guide



## COMMON DATA ELEMENT

IMDRF Data Element
Device Identifier (UDI-DI)
Brand / Model Name
Version / Model Number
Manufacturer Name & Address
Sterility Status
Single Use Indicator
Kit Indicator
Storage / Handling Conditions
Latex Content
MRI Safety Status
Unit of Use DI
URL for e-IFU
Packaging Configuration

## COMMON DATA ELEMENT WITH SOME VARIANTS

IMDRF Data Element	Comment
Catalogue / Reference Number	Australia can have multiple catalogue numbers
Risk Class	Australia – derived from ARTG
Nomenclature Code	GMDN or EMDN
Sterilisation Methods	Different options / methods across countries
Clinical Size / Dimensions	Different units across countries (e.g. mm vs inch)
Critical Warnings / Contraindications	Some differences on what data provided due to regulatory changes
Device Status	Will depend on ARTG status in Australia

# How does Australia compare with other jurisdictions – Data elements



- Each jurisdiction has a range of data elements that are unique to their regulatory environment



## AusUDID

ARTG ID
TBS ID for Sponsor and Manufacturer
Nomenclature: GMDN (from the ARTG)
Device Status (linked to ARTG status)



## GUDID

FDA Premarket Submission Number
DUNS Number for Manufacturer
Nomenclature – GMDN
FDA Product Code
Reprocessed Single Use Device
Additional Critical Warnings / Contraindications
Device Status



## EUDAMED

Basic UDI-DI
Master UDI-DI
Actor / SRN
Reprocessed Single Use Device
System/Procedure Pack which is a device in itself
Additional Critical Warnings / Contraindications
Device Status

# When will sponsors need to be compliant?



## WHAT IS COMPLIANCE

- 3 key requirements:
  - Have UDI assigned and the device label includes UDI in both AIDC and HRI form
  - Direct marking of the device, if applicable
  - UDI and related data about the device is submitted to the AusUDID and linked to applicable ARTG inclusion(s)
- Sponsors unable to meet the UDI requirements by the compliance dates are to request Consent to import or supply a medical device that does not comply with one or more Essential Principles

## A PHASED INTRODUCTION

- Compliance is phased by device risk class over 4 years, starting with high-risk devices



# When will sponsors need to be compliant?



## WHEN WILL UDI REQUIREMENTS APPLY

- Devices manufactured and labelled on or after the compliance date must meet the UDI requirements
- Data is to be in the AusUDID for these devices within 30 days after the device is imported / supplied into Australia

Requirement	Medical devices				In vitro diagnostic medical devices			
	Class III	Class IIb	Class IIa	Class Is	Class 4	Class 3	Class 2	Class 1
UDI on the label	1 July 2026		1 July 2027	1 July 2028	1 July 2028		1 July 2029	
Data submitted	1 July 2026		1 July 2027	1 July 2028	1 July 2028		1 July 2029	
Direct Marked	1 Jan 2028	1 Jan 2029			1 July 2029		1 July 2030	

# When will sponsors need to be compliant?



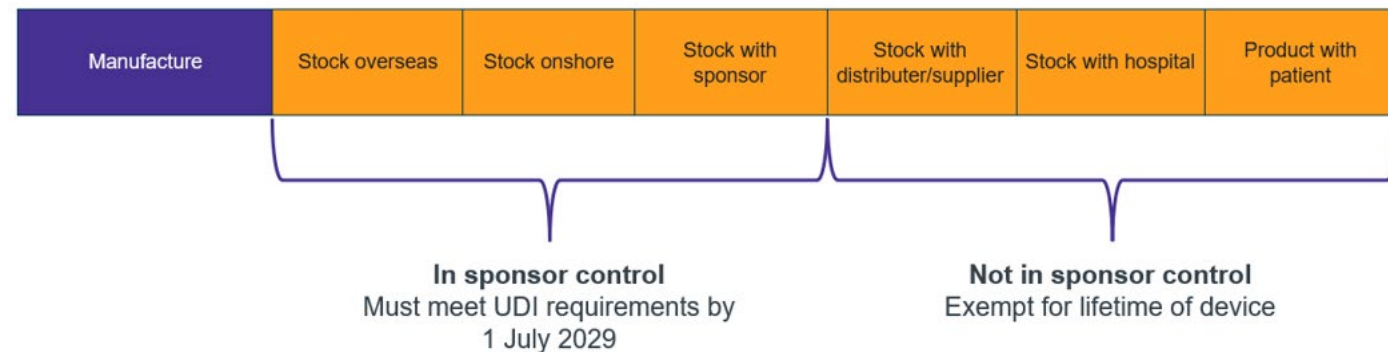
## DEVICES TRANSITIONING FROM MDD / IVDD TO MDR / IVDR HAVE EXTRA TIME

- The EU extensions mean some legacy devices cannot be UDI compliant until after December 2028 (medical devices) and December 2029 (IVDs)
- Devices supplied under an MDD or IVDD certificate have extra time to be UDI compliant
- Once compliant under MDR or IVDR, must meet Australian UDI requirements

Requirement	Class III	Class IIb implantable	Class IIb non-implantable	Class IIa	Class Is	Class 4	Class 3	Class 2	Class 1
UDI on the label	1 Jan 2028		1 Jan 2029			1 July 2028	1 Jan 2029	1 Jan 2030	
Data submitted	1 Jan 2028		1 Jan 2029			1 July 2029		1 July 2030	
Direct Marked	1 Jan 2028	Not applicable	1 Jan 2029			1 July 2029		1 July 2030	

## EXISTING DEVICES

- Class III and IIb devices manufactured and labelled before 1 July 2026 and are still in the sponsor's control must be relabelled and have data in the AusUDID by 1 July 2029
- All other devices manufactured and labelled prior to their UDI compliance date are exempt for the lifetime of the device



## Practical examples

1

**Existing ARTG inclusion** for a Class III medical device approved for supply using an **EU MDD** certificate

2

**New application** submitted before 1 July 2027 for a Class IIa medical device using an **MDSAP** certificate

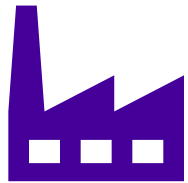
3

**New application** submitted after 1 July 2026 for a Class IIb medical device. The evidence provided is a US FDA certificate

*Are there other scenarios you would like us to discuss?*

# Where to go for more information

## Your manufacturer



## Your Issuing Agency



## UDI Support team

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

## UDI Hub



[Unique Device Identification \(UDI\) hub |  
www.tga.gov.au](http://www.tga.gov.au)

[tga.gov.au](http://tga.gov.au)



## The Australian UDI Database – AusUDID

# The Australian UDI Database – AusUDID



## What it is

- To enhance patient safety by supporting the use of UDI for accurate device identification and traceability
- To provide a publicly accessible, centralised repository of information relating to medical devices approved for supply in Australia



## What it is not

- A replacement of the ARTG
- A supply chain or inventory management system

*The AusUDID supports the recording of data about the device as it progresses through its lifecycle*



# AusUDID – Major stakeholders

The AusUDID has been designed to support the needs of different stakeholders



Sponsors and  
Manufacturers

- Manage device identifiers and data for devices supplied in Australia
- Link devices to the applicable approval to supply (ARTG Inclusion(s))
- Record history of changes to device data
- Support audit decisions



TGA

- Support and inform regulatory approvals and actions
- Support post market monitoring of device issues and usage in Australia



Healthcare

- Enable accurate data on devices used in healthcare and linking to patients and clinical procedures
- Support procurement and inventory management, patient records, adverse event reporting, recall management and billing/reimbursement



Consumers

- Support informed healthcare journey with confident identification of devices, better links to the approval to supply, adverse events and other market actions, and broader view of device use and performance

# The AusUDID - Key concepts (1)



## Requirements

- Data within 30 days of supply
- All in scope devices
- Existing devices
- Updated when information changes
- Supports Class I and Class 1 devices (if sponsor wishes)



## Users able to maintain data

- Manufacturers
- Sponsors
- Agents
- Third-party data providers (HL7 SPL only)



## Record states

- Draft
- Published
- Publicly available

Manufacture /  
Import / Export

Authorisation and  
Inclusion

Circulation

End of Life

## The AusUDID - Key concepts (2)



### Corrections & Grace Period

- Supports corrections of genuine data entry errors for Trigger fields
- Grace Period – a period after the UDI record is first published; fix all UDI data without triggering the requirements for a new UDI-DI
- Correction – fix UDI Trigger data; select a Correction and provide a reason



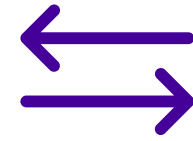
### Multiple Sponsors

- Possible for 2 or more sponsors to supply a device with the same UDI-DI
- To reduce confusion for the end user – same record in the AusUDID
- Changes to device data requires a correction including a reason

**This device is associated with multiple sponsors.**

**D** Changes to device fields will require a correction.

**T** Changes to trigger fields will require a correction.



### History of changes

- A history of changes will be maintained and can be accessed by all users

Manufacture /  
Import / Export

Authorisation and  
Inclusion

Circulation

End of Life

# Maintaining AusUDID data

- Data must be kept current for the life of the device
- When changes occur, relevant AusUDID data must be updated within 30 days of device supply
- A history of changes will be maintained and can be accessed by all users
- Updates can be made through all data submission methods except the Bulk Upload
  - If you created a record through one submission method, you can update it via another

**History**

Change date	Record version number	Version status	Downloads
18 September 2025, 11:07:58 by R-Biopharm Pty Ltd	6	<b>CORRECTION</b>	↓ <a href="#">XML</a> <a href="#">JSON</a>
18 September 2025, 11:03:52 by NPC Technical Test Supplier 2	5	<b>CORRECTION</b>	↓ <a href="#">XML</a> <a href="#">JSON</a>
18 September 2025, 11:02:04 by NPC Technical Test Supplier 2	4	<b>UPDATE</b>	↓ <a href="#">XML</a> <a href="#">JSON</a>
18 September 2025, 10:58:28 by R-Biopharm Pty Ltd	3	<b>CORRECTION</b>	↓ <a href="#">XML</a> <a href="#">JSON</a>
18 September 2025, 09:56:41 by R-Biopharm Pty Ltd	2	<b>UPDATE</b>	↓ <a href="#">XML</a> <a href="#">JSON</a>
18 September 2025, 09:54:44 by R-Biopharm Pty Ltd	1	<b>CREATE</b>	↓ <a href="#">XML</a> <a href="#">JSON</a>

Manufacture /  
Import / Export

Authorisation and  
Inclusion

Circulation

End of Life

## Changing critical device information (Triggers)

- When a Trigger data element changes, a new model of device / UDI record is required
- You must:
  - Get a new UDI-DI from your Issuing Agency
  - Relabel your devices with the new UDI-DI
  - Create a new record in the AusUDID and link it to the correct ARTG inclusion(s)
- If the change is to correct a genuine error for a Trigger data element, you can use a Correction

### Provide your device information

Add details to clearly describe and identify your device. These details help others to find your UDI record within the Australian UDI Database.

Brand name (maximum 80 characters) (mandatory)

Test Mesh II

Model or version (maximum 80 characters) (mandatory)

TM2010

### AusUDID Trigger Data Elements

- Labelled as single use
- If the restricted number of reuses changes
- Packaged sterile
- Need for sterilisation before use
- Critical warnings or contraindications:
  - Contains latex
  - MRI safety status \*
- Clinical size (including volume, length, gauge, diameter) \*
- Brand name
- Device version or model (including software add/change of features that result in change to intended purpose / a new major version number)
- Quantity of devices provided in a base package (device count)

## Changing critical device information (Triggers)

- Creating a new record in the AusUDID and linking it to the correct ARTG inclusion(s)

<input type="checkbox"/>	Brand name	Model or version	Manufacturer	ARTG ID	Primary DI
<input type="checkbox"/>	SurgiLance Safety Lancets	SLN100	MediPurpose Pte Ltd	<b>MediPurpose Australia Pty Ltd</b> 332600	38886354701038
<input type="checkbox"/>	SurgiLance Safety Lancets	SLN100S	MediPurpose Pte Ltd	<b>MediPurpose Australia Pty Ltd</b> 332600	38886354702189
<input type="checkbox"/>	SurgiLance Safety Lancets	SLN302	MediPurpose Pte Ltd	<b>MediPurpose Australia Pty Ltd</b> 332600	38886354701861



When entering the new record in the AusUDID, ensure it is easy for end users to distinguish between the records when searching. Do this by putting a meaningful value in the Model or version field.

## End of device life.....

- **UDI records remain in the database indefinitely** to support adverse event reporting and market actions
- **AusUDID Commercial distribution end date** should be updated when the device is no longer in supply. This will then set the status of the device to “no longer in commercial distribution”
- **If the ARTG is no longer active**, it is still visible against the UDI record

**Package Identifier**  
PACKM04112401

**Package Type**  
box

**Distribution Status**  
ARTG 16106  
Not in Commercial Distribution since 2 February 2023

[WRAP](#) [UNWRAP](#) [EDIT](#)

Contains 4 of ↴

**THIS DEVICE**  
#BULKPM04112401  
[WRAP](#)

**Is this device included in the ARTG?**

✓ **Included**  
This device is currently included in the **Australian Register of Therapeutic Goods (ARTG)** under:

- [ARTG identifier 190901](#) Scalpels r Us Pty Ltd

**No longer included**  
This device was previously included in the ARTG under:

- ARTG identifier 122122 Big Deal Devices



## Best Practices – Data quality

### Consequences of poor quality data:

- **Patient harm:** misdiagnoses, incorrect treatments, use of incorrect or recalled devices
- **Inefficient operations:** problems with purchasing and stock management in healthcare
- **Increased risk:** inability to identify and respond to trends in device performance
- **Reduced trust:** eroded confidence in the healthcare system and regulatory outcomes

### High quality data is:

- **Accurate**
- **Complete**
- **Consistent**
- **Timely**
- **Relevant**

<input type="checkbox"/>	Brand name	Model or version
<input type="checkbox"/>	MY BLOOD PRESSURE MONITOR AUTO UPPER ARM - DELUXE	DBP-6191
<input type="checkbox"/>	MY BLOOD PRESSURE MONITOR AUTO UPPER ARM - SMART PRO	DBP-6282B
<input type="checkbox"/>	MY BLOOD PRESSURE MONITOR AUTO UPPER ARM - VITAL PLUS	DBP-13D1

# Best Practices – Device discoverability

## Consequences of poor discoverability:

- **Reduced trust:** damaged reputation, loss of customer trust
- **Inefficient operations:** wasted time and resources, lost revenue due to inhibited procurement practices
- **Increased risk:** impaired decision making, flawed insights

<input type="checkbox"/>	Brand name	Model or version	Manufacturer	ARTG ID	Primary DI
<input type="checkbox"/>	AlignRT Plus	AlignRT Plus	Vision RT Ltd	Vision RT Australia Pty Ltd 453246	05056190500337
<input type="checkbox"/>	AlignRT Plus	AlignRT Plus	Vision RT Ltd	Vision RT Australia Pty Ltd 453246	05056190500443
<input type="checkbox"/>	AlignRT Plus	AlignRT Plus	Vision RT Ltd	Vision RT Australia Pty Ltd 453246	05056190500610
<input type="checkbox"/>	AlignRT Plus	AlignRT Plus	Vision RT Ltd	Vision RT Australia Pty Ltd 453246	05056190500023
<input type="checkbox"/>	AlignRT Plus	AlignRT Plus	Vision RT Ltd	Vision RT Australia Pty Ltd 453246	05056190500580
<input type="checkbox"/>	AlignRT Plus	AlignRT Plus	Vision RT Ltd	Vision RT Australia Pty Ltd 453246	05056190500177

## Discoverable data is:

- **Distinguishable**
- **Consistent**
- **Accessible**
- **Available**

## Best Practices – A few things you can do for high quality and discoverable data

- **Device description:** despite being optional this is critical for discoverability and to distinguish between similar devices.
- **Brand name:** should match what is on the packaging/label
- **Model or version:** critical for discoverability and to distinguish between similar devices. If your device does not have one, consider using the Catalogue number
- **Catalogue number:** important existing identifier that is relied on by healthcare organisations
- **Clinical size(s):** length, width, inches/cms

Component	Source	Example
Major Noun	TRW: Category / Subcategory	DRESSING
Minor Noun	TRW: Category / Subcategory	FILM
Minor Noun	TRW: Category / Subcategory	TRANSPARENT
Key Property: Form	TRW: Category / Subcategory	SHEET
Key Property: Adhesiveness	TRW: Key Properties	ADHESIVE
Key Property: Measurements	TRW: Measurements	20cm x 30cm
Latex Status*	TRW: Latex Status	LATEX-FREE
Disposable / Single Use*	TRW: Disposable / Single Use	
Sterile*	TRW: Sterile Status	STERILE
(Brand Name)	TRW: Brand Name	(TEGADERM)
Item/Manufacturer Part Number	TRW: Item Number	1629
<b>DRESSING FILM TRANSPARENT SHEET ADHESIVE 20cm x 30cm LATEX-FREE STERILE (TEGADERM) 1629</b>		

**Construct meaningful, unique and unambiguous product descriptions that are useful for the majority of end users:  
DRESSING FILM TRANSPARENT SHEET ADHESIVE 20cm x 30cm**

**The remaining data helps healthcare accurately identify the device**



## Getting Ready

# Preparing for UDI



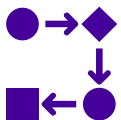
International experiences indicate organisations require 6 – 18 months to be fully ready



Identify which devices must comply and when  
Assess if your current labelling and packaging needs to change



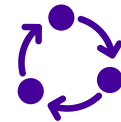
Review your current agreements and define the responsibilities of the manufacturer and sponsor



Confirm internal procedures for assigning, managing and maintaining UDIs and related data



Ensure your UDI data is accurate, complete and aligned with Australia's regulatory requirements



Validate your systems and processes for submitting AusUDID data – use Pre-Production



Submit valid UDI records to the AusUDID Production  
Start ongoing maintenance processes

# Learnings from other implementations - Expected challenges



Based on experiences in Australia and overseas, sponsors may encounter a range of challenges

## Multiple UDIs

- Multiple UDI-DIs for the same device

## Data challenges

- Data quality and discoverability
- Different data and rules between jurisdictions

## Different Triggers

- Issuing Agency rules
- Trigger variations across jurisdictions

## Different standards on the label

- Different IA standards
- Non standardisation of UDI Carrier

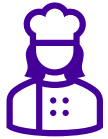
## Nomenclatures

- GMDN and EMDN

## UDI Exceptions

- Exceptions vary across jurisdictions

# Learnings from other implementations



## INGREDIENTS FOR SUCCESS

### Organisational alignment

- Ensure executive management support for UDI implementation
- Educate all involved in UDI requirements
- Align your organisation on the system(s) of record
- Upgrade business IT system(s)

### A dedicated project

- Undertake the work as a dedicated project and allocate people and financials to the work
- A UDI Project Management Office may ensure consistency
- Regardless of whether a project, secure resources (money and people) in your forecasts

### Resource based on four activities

- Rule interpretation and application
- Attribute and IT analysis
- Project overview and governance
- Business implementation management

### Policies, procedures and training

- The breadth of your existing product range
- New product data collection
- End of device life processes
- Attribute understanding and ownership

### Post Launch

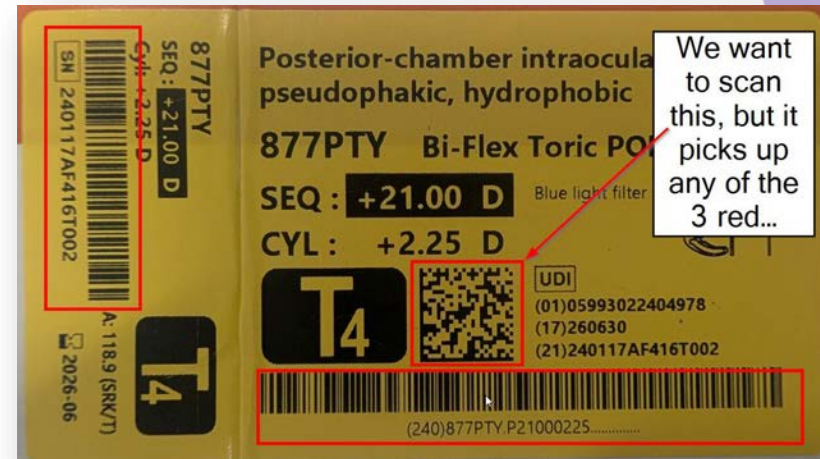
- Undertake post-launch audits of the business to ensure appropriate implementation and refine as required
- Maintain the UDI data held in the UDI databases

# Labelling considerations



## HEALTHCARE CHALLENGES WHEN SCANNING BARCODES

- Ink quality and colour affect barcode readability
- Printing directly on corrugated box hard to read and scan
- Printing on shiny surfaces is hard to scan
- Printing on shipping labels can be prone to fading and smudging
- Multiple barcodes on pack
- Stacked barcodes require two scans
- Two barcode types with the same information - healthcare don't know what's in them so scan twice



### You can help by working with your manufacturer to:

- Support a single scan and consolidate barcodes, whenever possible
- Use the ISO UDI symbol to clearly identify the UDI barcode if stacked or more than 1 barcode is used
- Perform internal barcode quality assurance through barcode validation and verification



**Australian Government**

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**Department of Health, Disability and Ageing**  
Therapeutic Goods Administration