Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Overview of Unique Device Identification (UDI) for Australian healthcare

Enhancing patient safety through traceability of medical devices

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Foreword

The Therapeutic Goods Administration (TGA) is advancing toward our goal of supporting patient safety through device traceability. Certain crucial details, currently under consideration by the Australian Government, will be integrated into forthcoming updates of this document. In the interim, we encourage you to explore our UDI Hub for the latest news and updates on implementation timeframes and policy positions.

About Unique Device Identification in Australia | Therapeutic Goods Administration (TGA).

Your interest in reading this document is appreciated, and we trust it serves as a valuable introduction to this impactful work.

Contents

Introduction

As the regulator of therapeutic goods in Australia, the Therapeutic Goods Administration (TGA) is implementing a medical device Unique Device Identification (UDI) system in Australia.

Implementation of UDI in Australia has involved:

- Amendments to the Therapeutic Goods Act 1989 and the Medical Device Regulations 2002
- Establishment of the Australian UDI Database (AusUDID) by the TGA
- Extensive consultation with sponsors and manufacturers of medical devices
- Consultation with the healthcare community about the UDI and its use in the healthcare supply chain
- Working with the Australian Commission for Safety and Quality in Healthcare (ACSQHC) and state-based healthcare pilot sites to inform use and adoption of UDI in healthcare organisations.

The main purpose of UDI is to improve patient safety. When adopted in the supply chain, clinical and other health systems, UDI can enable easier and faster identification of patients implanted with devices of concern (for example a device with a safety incident or recall).

In addition, UDI can support identification and removal of those devices from stocks, storage, and distribution to prevent any further use of devices of that model.

It will also allow patients, consumers, and health professionals to access product information in the Australian UDI Database (AusUDID) about the devices that they use, including any recalls or safety incident related to that device.

UDI could improve device performance assessment by regulatory bodies, clinical quality registries and device manufacturers through accurate product identification that better supports comparative studies.

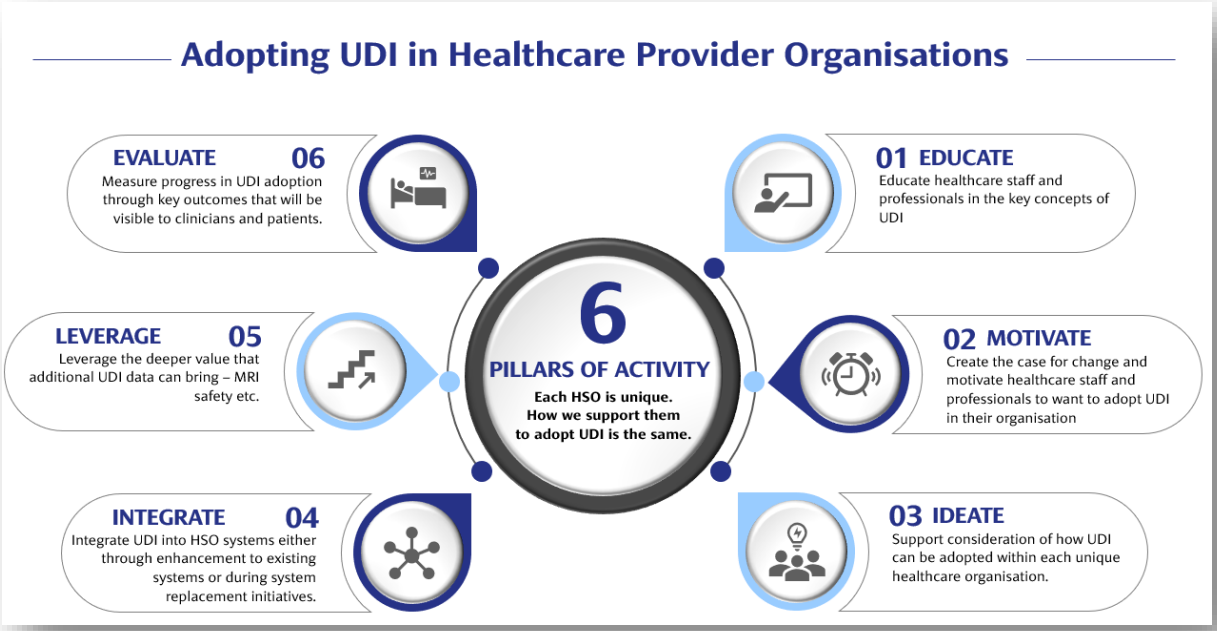
The TGA continues to work with regulators globally to harmonise UDI requirements, and work will continue to share learnings of UDI adoption in healthcare organisations.

Up-to-date information, guidance documents, user guides and other resources are on the TGA website: About Unique Device Identification in Australia | Therapeutic Goods Administration (TGA).

Purpose

This document supports UDI awareness and adoption in Australian healthcare settings. It educates readers in the main concepts of UDI and highlights the benefits of UDI adoption in healthcare provider organisations.

Further documents may be developed to support the activities shown in the diagram below.



Intended audience

This document is for use by staff in healthcare provider organisations including executive level staff, management, clinical governance, health informatics, clinicians, Quality and Risk/Recall Coordinators, biomedical engineering, healthcare professionals, procurement, supply chain, IT, finance, and administration.

Related resources

See Appendix E for a list of resources about UDI in Australia and globally.

See Appendix F for a glossary of UDI-specific terms.

Overview of Unique Device Identification

UDI overview

Unique Device Identification (UDI) is the placement of unique identifiers on medical devices supplied in Australia. The unique identifiers enable the global tracking and tracing of medical devices and in vitro diagnostic (IVD) devices throughout the supply chain and in healthcare systems all the way to the patient record.

A Unique Device Identifier is a series of numeric or alphanumeric characters that is created through a globally accepted standard and applied to a specific model of medical device. It is comprised of both device information and production information.

The major benefit of the UDI system is improved patient safety. UDI also offers:

- Traceability of medical devices to support timely identification of specific medical devices and patients treated with medical devices impacted by recalls, device failures or serious adverse events
- Use of UDI in clinical processes such as theatre set up can ensure recalled or expired products are not used
- Use of UDI in billing processes supports cost management and automation of billing or reimbursement
- Increased transparency through availability of additional medical device information to the public.

Benefits of UDI for healthcare

This diagram is based on: NEST Coordinating Center - A Playbook for Health System Unique Device Identifier Implementation at the Point of Care v1.0, April 17, 2023

Changes occurring

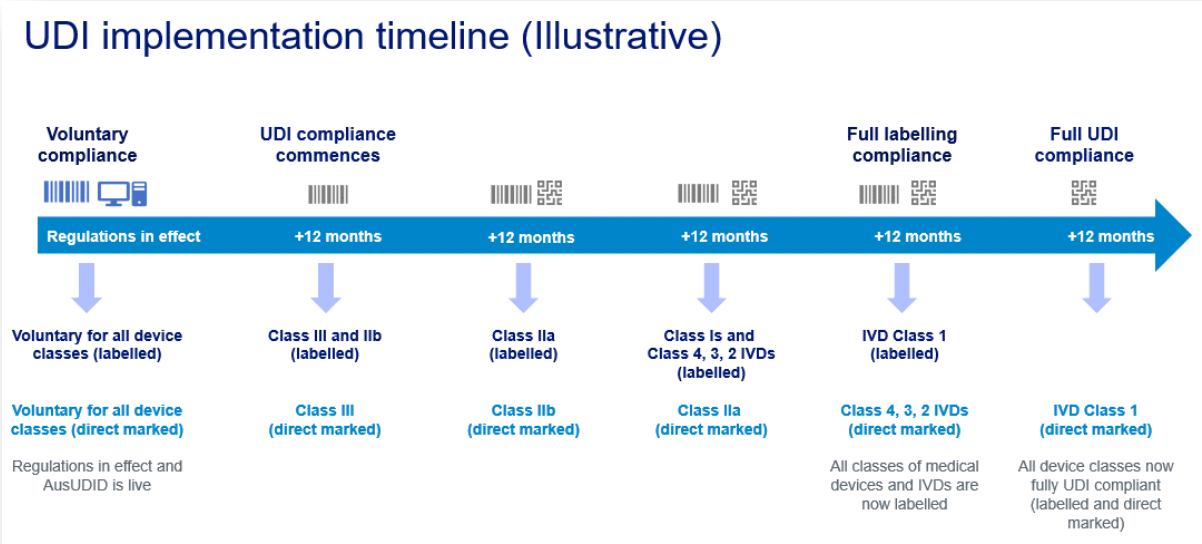
Sponsors of medical devices supplied in Australia are required to undertake 3 main activities for their devices:

1. Allocate a unique identifier that has been allocated by a TGA recognised UDI Issuing Agency
2. Include the UDI on the device label, packaging and in some cases direct marked onto the device
3. Submit UDI and related device information to the Australian UDI database (AusUDID) developed by the TGA.

Sponsors also must include UDI in their regulatory activities such as recalls and adverse event reporting.

Implementation timeframe

Australian regulations will be introduced in a phased approach based on the device risk classification. The diagram below shows an indicative implementation timeframe for industry compliance.



Please note: Class I and Class Im will **not** be required to meet UDI requirements. More information on devices required/exempt from UDI requirements is detailed later in this document.

At the time of writing there is no timeline set for adoption in healthcare settings.

You may see UDIs on labels before Australian regulations are in effect, particularly where device labels are already compliant in other jurisdictions such as the United States and the European Union.

For up-to-date implementation information, refer to the TGA website.

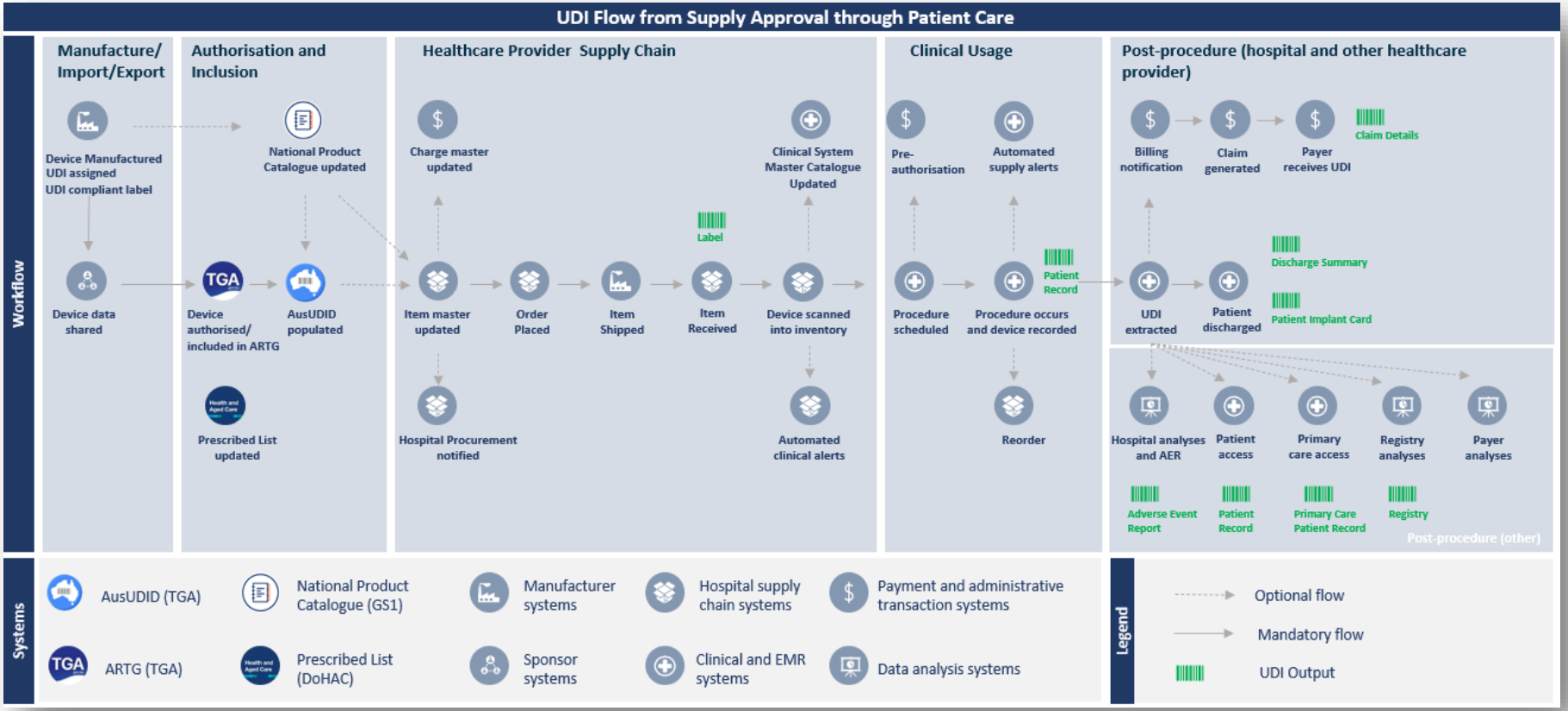
Impact of UDI on healthcare

UDI has the potential to deliver value through the entire device lifecycle from manufacture of the device, supply into healthcare facilities, patient care, adverse event reporting, recalls and in assessment of device performance and efficacy – including by clinical quality registries.

The TGA is working with the Australian Commission for Safety and Quality in Health Care (ACSQHC) to include UDI in the National Safety and Quality Health Service (NSQHS) Standards and/or Guidelines.

This document aims to support the adoption within hospitals and large healthcare providers. During implementation, the TGA will work with stakeholder groups and peak bodies to support drafting of artefacts that support specific groups (such as surgeons and pharmacies) in understanding how introduction of UDI impacts their work.

Adoption of UDI in healthcare may be a complex undertaking and will impact people, processes, and technology. There are many models of care with different processes and workflows. We have abstracted common elements into the diagram below to provide one example of where UDI could possibly assist healthcare processes. This may not resemble the processes followed in your organisation, and adoption of UDI should be approached in a way that best suits your organisation.


UDI Flow from Supply Approval through Patient Care
Workflow
Manufacture/ Import/Export
Authorisation and Inclusion
Healthcare Provider Supply Chain
Clinical Usage
Post-procedure (hospital and other healthcare provider)
Device Manufactured UDI assigned UDI compliant label
Device data shared
National Product Catalogue updated
Device authorised/ included in ARTG
AusUDID populated
Prescribed List updated
Charge master updated
Item master updated
Hospital Procurement notified
Order Placed
Item Shipped
Label
Item Received
Clinical System Master Catalogue Updated
Device scanned into inventory
Automated clinical alerts
Pre-authorisation
Automated supply alerts
Procedure scheduled
Procedure occurs and device recorded
Patient Record
Reorder
Billing notification
Claim generated
Payer receives UDI
Claim Details
UDI extracted
Patient discharged
Discharge Summary
Patient Implant Card
Hospital analyses and AER
Patient access
Primary care access
Registry analyses
Payer analyses
Adverse Event Report
Patient Record
Primary Care Patient Record
Registry
Post-procedure (other)
Systems
AusUDID (TGA)
ARTG (TGA)
National Product Catalogue (GS1)
Prescribed List (DoHAC)
Manufacturer systems
Sponsor systems
Hospital supply chain systems
Clinical and EMR systems
Payment and administrative transaction systems
Data analysis systems
Legend
Optional flow
Mandatory flow
UDI Output

At a more detailed level, Australian healthcare provider organisations vary significantly and will need to formulate their own approach to adopting UDI. This will include consideration of available resources, strategic priorities, system landscape, business needs and future digital roadmap.

There is no mandatory requirement for healthcare providers to adopt UDI. However, the TGA is working with the Australian Commission for Safety and Quality in Health Care (ACSQHC) to include UDI in the National Safety and Quality Health Service (NSQHS) Standards and/or Guidelines.

We encourage you to start preparing for UDI adoption early. Benefits include increased quality care for patients, improved patient safety outcomes, increased supply chain efficiency translating to reduced costs. We encourage you to start preparing for UDI adoption in your healthcare setting, allowing you to improve patient outcomes and the care you provide.

Considerations for implementing UDI in a healthcare organisation

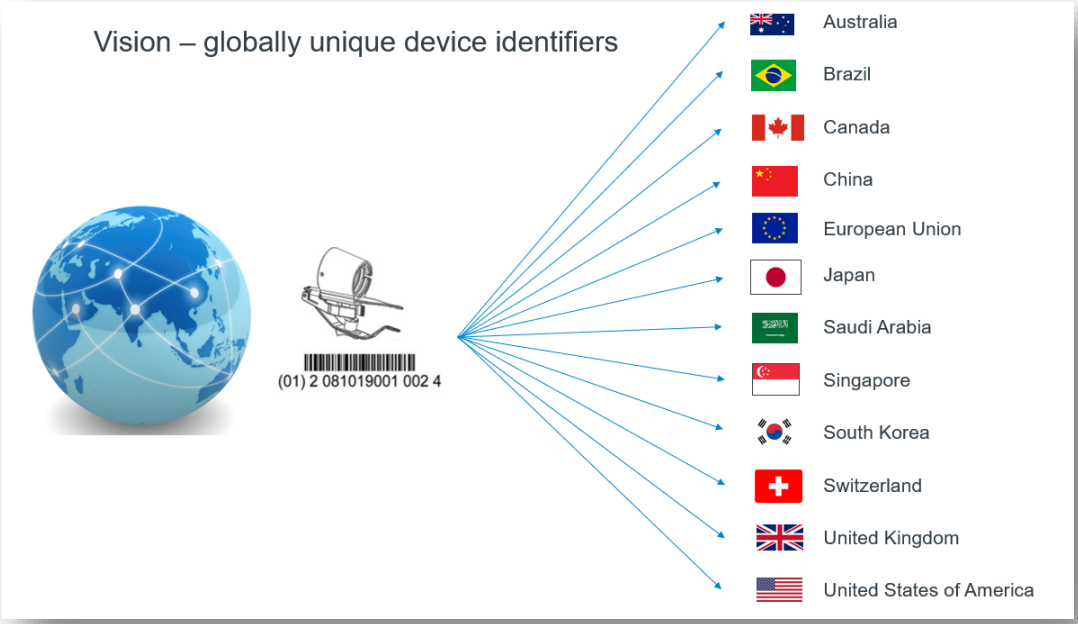
To begin adopting UDI, consider the following high-level steps:

1. Understand the benefits of UDI and **create the case for change**.
2. **Educate your staff** in foundational information such as the information in this document. Leverage what is happening globally - there are many documents and resources that describe UDI use in other countries (refer to Appendix E). Executive-level staff also need this foundational understanding so that UDI implementation is considered in strategic initiatives such as workforce planning and digital reforms/roadmaps.
3. **Define an approach** that works for your organisation, remembering that undertaking a proof of concept or following a staged approach might be more achievable than addressing all systems in one go. Digital reforms/roadmaps offer opportunities to consider UDI requirements in system upgrades or replacements. Systems potentially requiring update include:
    - Supply chain management systems (warehouse and inventory)
    - Clinical suite software (theatre management)
    - Electronic health/patient records
    - Claims, reimbursement, and billing
    - Biomedical asset management systems
    - Clinical quality registries
    - Clinical incident and recall management systems.

    Scanning technology is a critical enabler for the full realisation of UDI benefits. Absence of scanning technology does not preclude staged implementation as there are opportunities to adopt UDI in other ways. For example, clearer labelling will present opportunities for more streamlined and consistent manual processing. Likewise, scanning and systems capability may be present in some healthcare provider organisations but could need upgrade to cater for the complete benefits UDI.
4. Consider **workforce planning and change management** from the outset. Perceptions that UDI implementation will increase workload at point of care may need to be addressed. Processes for management of recall actions require review to modify data management and data capture across supply chain and clinical processes. Some dual processes may be required during UDI transition to cater for devices that are UDI-compliant, alongside those that are not. In addition, education, training and change management activities are required to support consistent and thorough understanding across staff.

Future of Unique Device Identifiers

Countries all over the world have implemented or are implementing UDI regulations. Over time the understanding of UDI will grow, and the quality of UDI data will improve. Patients will become more aware of the availability of this type of data and will expect it to be part of their routine medical care.



The TGA has been working with manufacturers and sponsors of medical devices over many years to create and implement the Australian UDI system. During this time, we have consulted with healthcare providers to better understand how UDI can be adopted by Australian healthcare organisations.

Support

Should you have any questions or require any support please contact the TGA's UDI Support Team: udi@health.gov.au

Australia's Unique Device Identification System

Unique Device Identifier

A UDI is a combination of numbers, symbols and letters given to each model of device to support unambiguous identification of the device. UDIs must be issued through a TGA recognised body called an Issuing Agency who ensures every UDI is globally unique.

The TGA recognises 3Issuing Agencies to issue UDIs for medical devices:

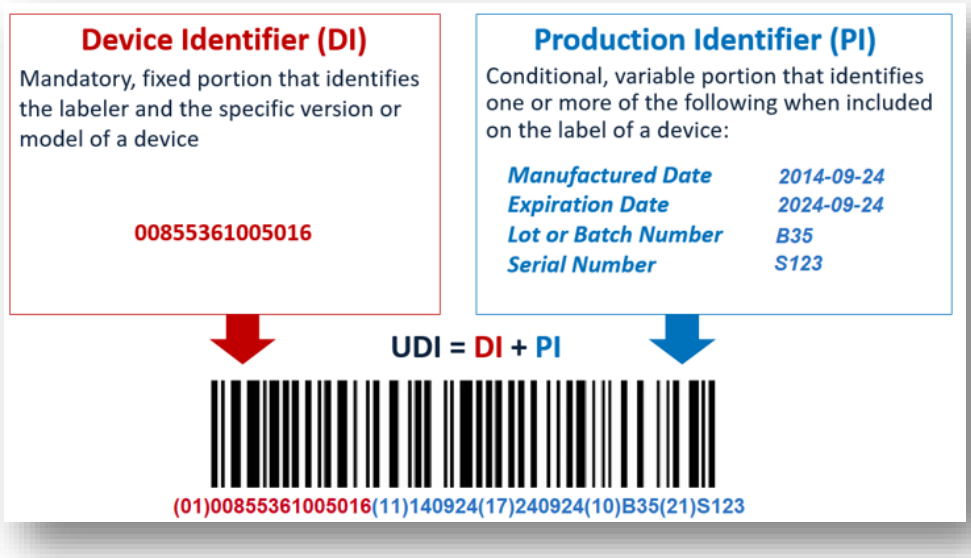
- GS1
- Health Industry Business Communications Council (HIBCC)
- International Council for Commonality in Blood Banking Automation (ICCBBA).

A UDI is made up of 2 parts:

1. **Device Identifier (UDI-DI)** – a fixed, static part which identifies the manufacturer and the specific model or version of the device
2. **Production Identifier (UDI-PI)** – a dynamic part that includes production information such as lot, batch or serial number, expiration date and manufacture date.

Every device will have a UDI-DI, but some devices may not have a UDI-PI, or it will contain only certain components such as the expiration date but not a batch number.

Below is an example of a linear UDI barcode in GS1 format.



Appendix A provides UDI examples from the 3 Issuing Agencies.

Appendix B provides examples of UDI conventions. UDIs must be provided in human readable form and in machine readable form such as a linear bar code or 2D Data Matrix.

The UDI-DI must change when there is a significant change in the device characteristics such as its specifications (new model or version), size, packaging, performance, composition, etc.

Date formats on medical device labels should conform to the international standard format of YYYYMMDD to ensure dates are unambiguous and clearly understood by device users.

Devices to meet UDI requirements

Clarification on devices needing a UDI will continue throughout implementation of UDI both in Australia and globally. Refer to the TGA website for the latest advice About Unique Device Identification in Australia | Therapeutic Goods Administration (TGA)

Medical devices and in vitro diagnostic (IVD) devices supplied in Australia need a UDI, unless they are exempt from UDI requirements.

Device compliance with UDI requirements is set according to the device risk classification. Refer to the TGA website (Medical devices overview | Therapeutic Goods Administration (TGA)) for more information on the classification of medical devices and IVD devices.

Medical device classifications, examples and UDI requirements are shown in the table below.

Class	Risk	Examples	UDI Required
Class I	Low	Face shield, tongue depressor, non-sterile gauze, incontinence pants, otoscope	NO
Class Im	Low-medium	Oral syringe, surgical drill guide, ECG recording paper	NO
Class Is	Low-medium	Surgical gown, sterile glove, medical drape equipment, basic IV set	YES
Class IIa	Low-medium	Digital or infrared thermometer, surgical glove, automated blood pressure cuff, suction tip	YES
Class IIb	Medium-high	Hypodermic needle, surgical laser, lung ventilator, external defibrillator	YES
Class III	High	Aortic heart valve, major joint replacement prostheses, catheter guide wire, hernia mesh, absorbable sutures	YES

IVD classifications, examples and UDI requirements are shown in the table below:

Class	Risk	Examples	UDI Required
Class 1	No public health risk or low personal risk	Microbiological culture media Cleaning solutions Glucose meter	PARTIAL (See below)
Class 2	Low public health risk or moderate personal risk	Pregnancy and fertility self-testing kits Tests to detect rotavirus or adenovirus infections Cholesterol test	YES
Class 3	Moderate public health risk or high personal risk	Sexually transmitted disease test, e.g. herpes, chlamydia, HPV Human genetic test, e.g. Cytomegalovirus, Cystic Fibrosis Cancer diagnostic test Rapid antigen test for SARS-COV-2 virus	YES
Class 4	High public health risk	Blood screening tests for HIV, syphilis Test for Ebola	YES

Class 1 IVDs categorised as follows must comply with the UDI regulations:

- Instrument/analyser IVDs (Global Medical Device Nomenclature (GMDN) Collective Term 943)
- Software IVDs (GMDN Collective Term 944).

Devices exempt from meeting UDI requirements

Medical devices exempt from the UDI regulations are those devices classified as:

- Class I – with a measuring function (Class Im)
- Class I.

In vitro diagnostic (IVD) devices exempt from UDI regulations are:

- Class 4 in-house IVDs
- IVDs classified as Class 1, that are not:
    - Instrument/analyser IVDs (GMDN Collective Term 943)
    - Software IVDs (GMDN Collective Term 944).

In addition, medical devices and IVDs that are exempt from inclusion in the Australian Register of Therapeutic Goods (ARTG) under Schedule 4 of the *Therapeutic Goods Regulations 1990* are not required to comply with UDI requirements. For example, medical devices that are:

- Export only
- Custom made
- Patient matched with a volume of 5 or less imported, exported or supplied per financial year
- Exempt under Special Access Scheme (SAS) or Authorised Prescriber Scheme (APS)
- Class 1, 2 and 3 in-house IVDs.

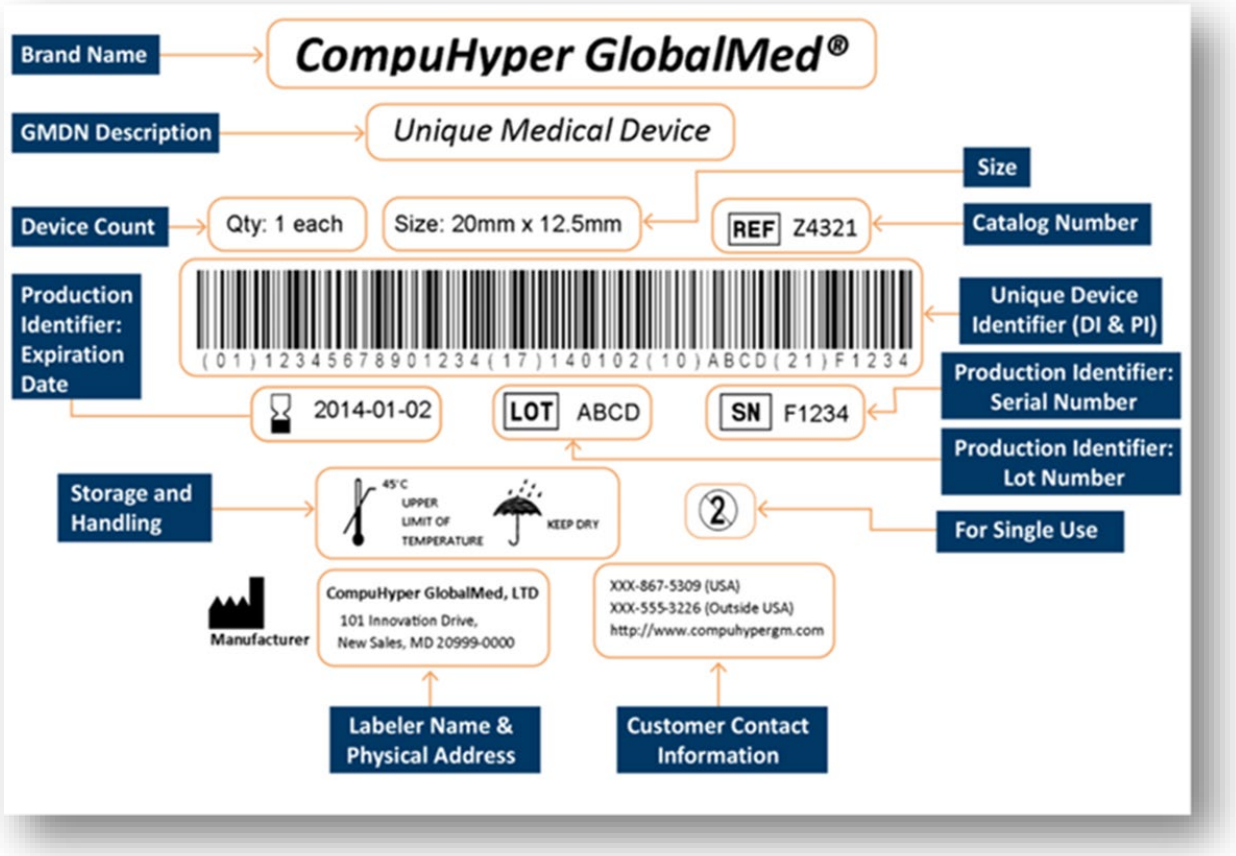
Sponsors may choose to comply with UDI requirements for any exempt devices.

UDI labelling requirements

Device Labels

The UDI must be on the label of a medical device. Australia is accepting labels that are compliant with European Union (EU) and United States (US) UDI Regulations, provided the device and its label are also compliant with Australia's medical device regulations.

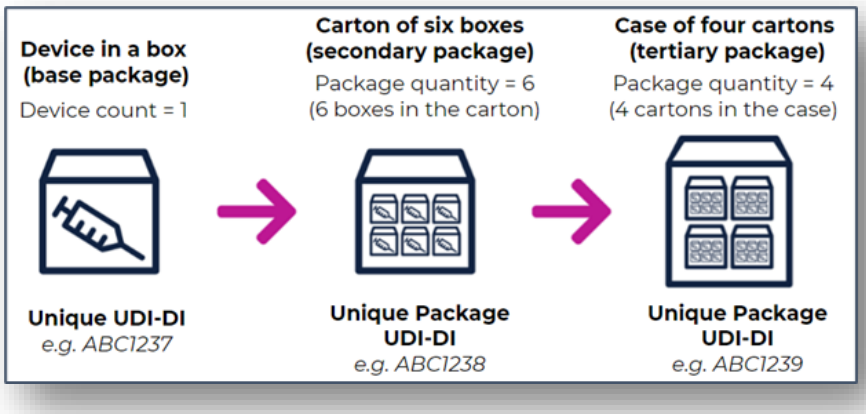
An example of a UDI compliant label from the United States is shown below:



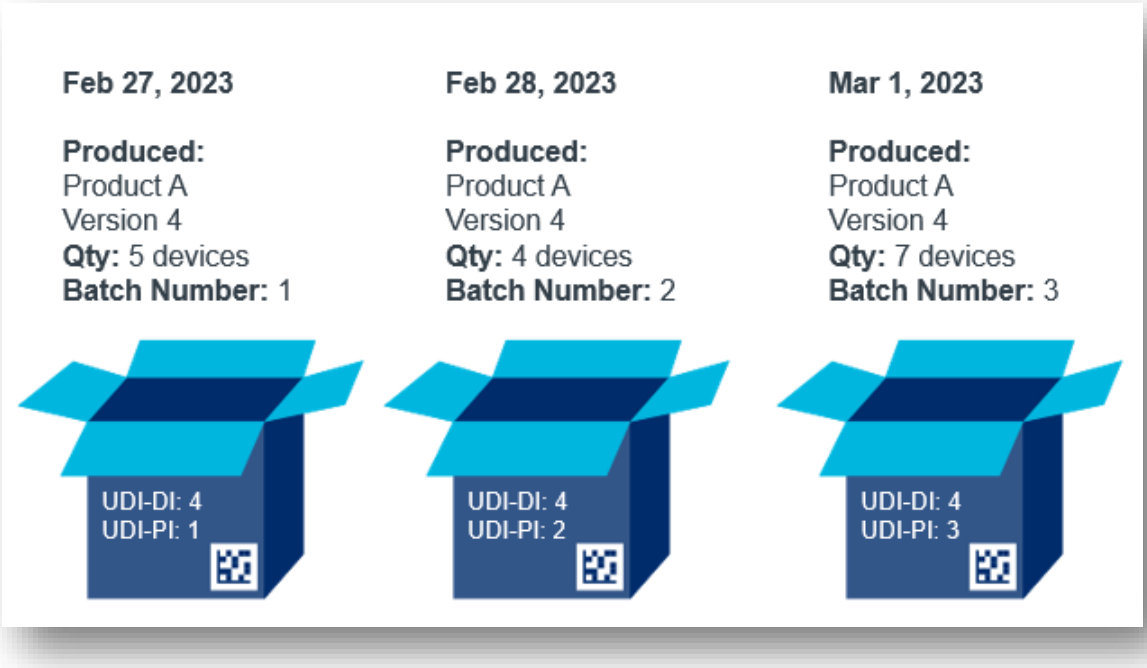
Device packaging

To support identifying medical devices at all points in supply and inventory management systems, a different UDI is required at each level of packaging containing a fixed quantity of medical devices, for example a single device, carton, case. This does not include shipping containers such as pallets.

The UDI-DI must be globally unique at all levels of packaging.

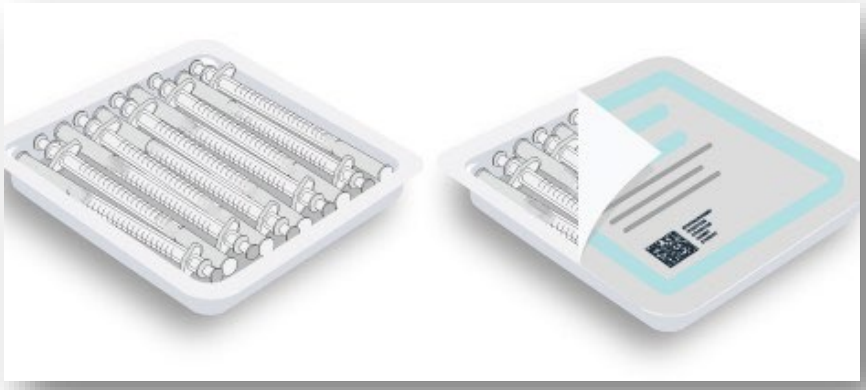


The diagram below shows three packages with three different production batches, for a particular model of device. It shows how the same UDI-DI would apply to each package with a different UDI-PI for each batch.



A Unit of Use UDI-DI is assigned to an individual medical device when its base package contains multiple models of the same device which are unpackaged and unlabelled. The Unit of Use UDI-DI supports healthcare organisations and professionals allocate a single device to a patient.

For example, the diagram below which shows a tray of 25 syringes. In this scenario the tray packaging would show the UDI-DI of the tray, a separate Unit of Use UDI-DI is allocated to each individual syringe. The Unit of Use UDI-DI is the same for each individual device within the tray.

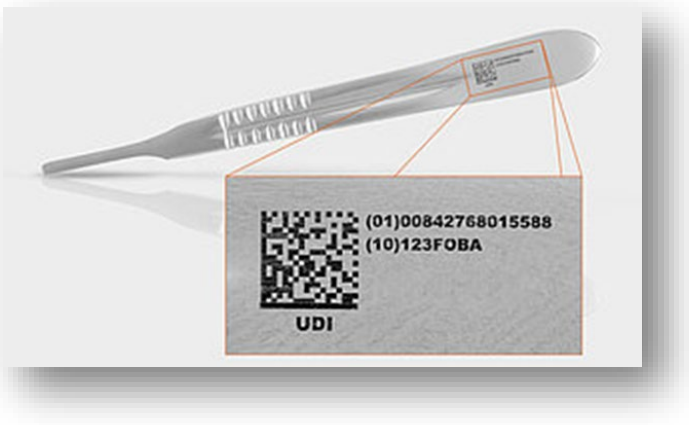


The Unit of Use UDI-DI is referred to as a virtual UDI as it is recorded in the AusUDID under the base package UDI-DI, but not labelled on the individual devices or their base package.

See Appendix C for examples of Unit of Use and packaging configurations.

Direct marked on the device

Health service organisations disinfect and sterilise reusable medical devices prior to and between patient uses. This will result in devices being separated from their packaging. Therefore, when a device is to be reprocessed and used on subsequent patients, the UDI is direct marked indelibly onto the device itself. The following figure illustrates.



Direct marking is not required for:

- Devices reprocessed between uses on the same patient
- Implantable devices
- If any type of direct marking would interfere with the safety or performance or effectiveness of the device
- If it is not technologically feasible to directly mark the device.

Devices that are manufactured and labelled before their direct marking compliance dates will be exempt from direct marking requirements for the lifetime of the device.

Instructions for use

UDIs are not required on instructions for use documentation, although some manufacturers may choose to do so.

Patient Information Leaflets

UDIs are not required on Patient Information Leaflets (PILs), although some manufacturers may choose to do so. PILs can be hard copy or electronic. They may be available through a website or optionally be made available through the AusUDID.

Patient Implant Cards

Patient Implant Cards (PICs) should be included within medical device packaging for provision to patients who receive a medical device implantation.

PICs require the following information:

- Name of the device
- Model of the device
- Batch code, lot number or serial number of the device
- Manufacturer’s name, address, and website
- The full UDI (UDI-DI and UDI-PI) in machine-readable form
- UDI-DI in human-readable form.

See Appendix D for an example of a Patient Implant Card.

Reporting

Where relevant and available, the UDI-DI and UDI-PI are to be provided to supplement existing requirements when reporting to the TGA. This includes for:

- Recalls
- Adverse event reports.

Given the phased approach to UDI implementation it will take several years for the UDI to become available for inclusion in reporting. Once UDI information is available, components of the UDI will be used (along with other product identifiers) per the following examples:

- Example 1: A recall notice for a model of device could include the UDI-DI
- Example 2: A recall notice for a single batch of a model of device could include the UDI-DI and UDI-PI
- Example 3: A recall notice for a number of batches of a device could include the UDI-DI and multiple UDI-PIs.

Reports for UDI exempt devices will continue as per current practice and should include any applicable information.

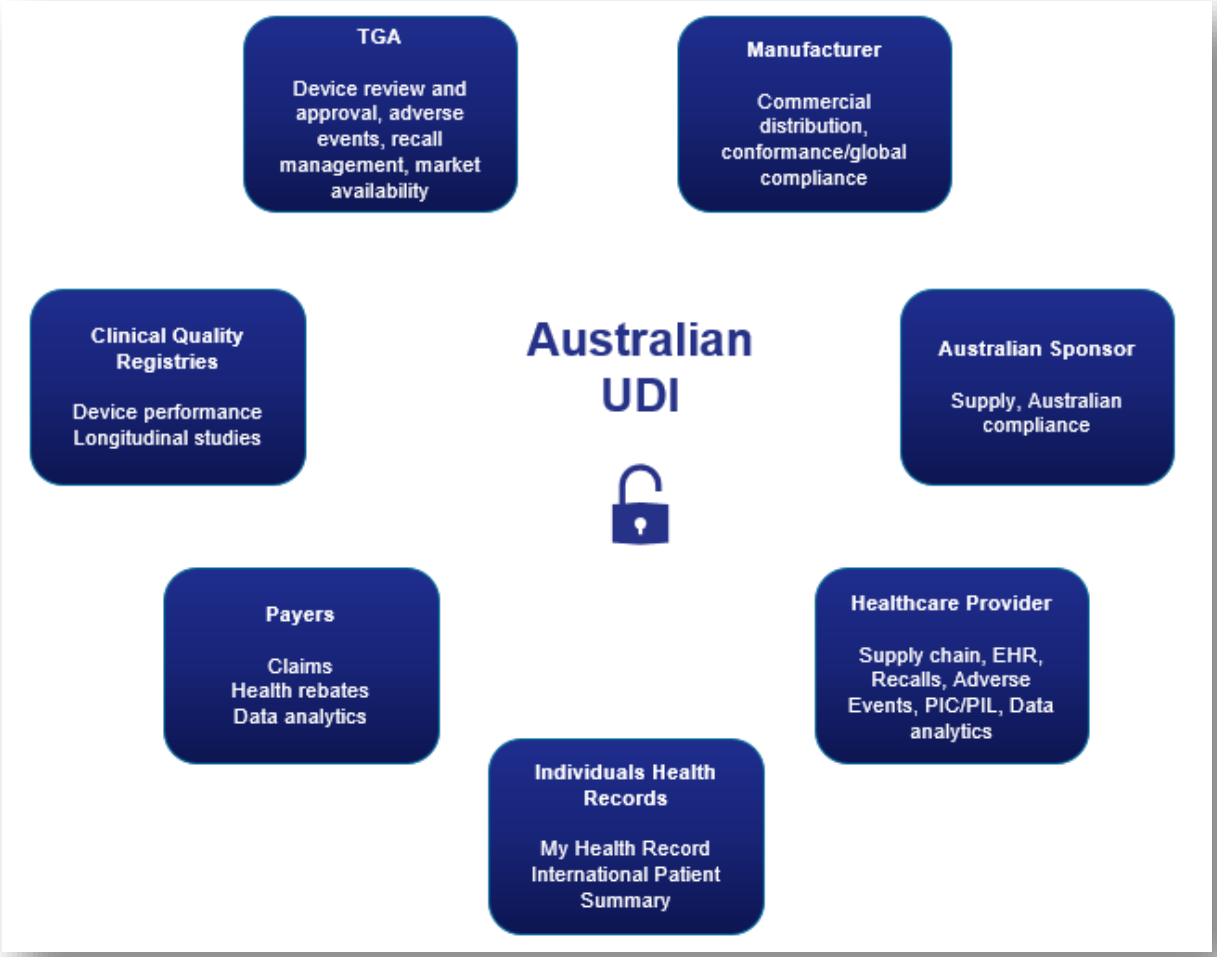
Benefits of UDI

Use of UDI in healthcare can result in many benefits for hospitals, clinicians, patients, and insurers including:

- Standardised device recording in patient care
- Easier identification during patient care:
  - Before a revision procedure or other surgery
  - Before scheduling an MRI
  - In an emergency
- Increased accuracy and efficiency in executing a recall or safety action:
  - Easier identification and removal of recalled products in inventory
  - Prevention of use of recalled or expired products during patient care
  - Easier identification of patients affected by a recalled device
- Improved understanding of the safety and performance of medical devices:
  - Improved support for comparative studies on product, treatment outcomes and patient care
  - Provision of accurate product data to registries to support research and monitoring activities
- The ability for patients and consumers to find device information
- The ability for patients to share information on their devices with health practitioners.

Unique Device Identifier uses

UDI provides a key to device information throughout the life of a medical device. The diagram below shows the main stakeholders who can use the UDI system.



UDI versus existing identifiers in healthcare

Several identifiers are used in healthcare, these include:

- **Serial number** – when a device has a serial number it will be included in the Product Identifier (UDI-PI) part of the UDI.
- **Model number, version number, catalogue number** – these identifiers (where applicable) are still on the device labels and will be included in the AusUDID device record.

No other identifiers give healthcare providers and their staff the ability to clearly identify a model of medical device or its production information (e.g. batch number of manufacturing date). UDIs address these shortcomings and complements other identifiers used in healthcare.

UDI and Global Trade Item Numbers (GTIN)

A GTIN represents the device identifier portion of a UDI, this is further explained below.

A GTIN is issued by GS1 to identify products in the supply chain (sample GTIN highlighted in green frame below).

A UDI has 2 parts:

1. The device identifier (UDI-DI) specific to a version of model of device
2. The production identifier (UDI-PI) which includes production data relating to the device such as manufacture date, expiration date, lot number, batch number, serial number.

With GS1 being one of 3 Issuing Agencies recognised to allocate UDIs in Australia, GS1 will issue GTINs as the device identifier (UDI-DI) portion of the UDI. The production identification (UDI-PI) part of the UDI is appended to the GTIN in accordance with GS1 standards to form the full UDI.

Special cases

Clarification on some types of devices will occur throughout implementation of UDI both in Australia and globally. Please refer to the UDI Hub on the TGA website for the latest advice About Unique Device Identification in Australia | Therapeutic Goods Administration (TGA).

Current positions on a range of specific device types are below.

Implantable devices

Due to the high risks associated with implantable devices, the UDI for an implantable device should be identifiable prior to implantation, to minimise the risks of misidentification of the implanted device. Therefore, the following applies for implantable devices:

- The full UDI in both human and machine-readable formats must be provided with implantable devices, for checking prior to surgery and for capture at the point of implantation
- Base packs of smaller implantable devices (lowest level of packaging) need to be identifiable and marked with a full UDI (UDI-DI and UDI-PI) in both human and machine-readable formats
- The UDI-PI of a Class III implantable device must include the serial number. For any other implantable device, the UDI-PI must include the serial or lot number.

The UDI is not required to be directly marked on implantable devices.

Software

Medical devices and IVDs that are software or incorporate software, will be required to meet UDI requirements unless they are exempt.

Software specific UDI labelling and data provision requirements are determined on factors such as the type of software, whether it is a physical product, packaged or unpackaged.

Systems or procedure packs

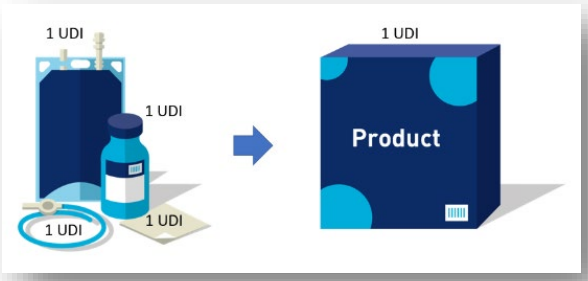
A system or procedure pack (SOPP) must be assigned a UDI if it contains one or more medical device classified as Class I – supplied sterile, Class IIa, Class IIb, or Class III.

Systems or procedure packs that contain only medical devices that are Class I – with a measuring function or Class I, do not require a UDI on the pack. However, the assembler or manufacturer of the SOPP may voluntarily choose to apply a UDI.

Any SOPP component that is a medical device classified as Class I – supplied sterile, Class IIa, Class IIb, or Class III, must include a UDI on the individual device, unless the medical device is:

- Not commercially available on its own
- An individual single-use disposable device where the uses are generally known to the persons using them and are not intended for individual use outside the context of the system or procedure pack, e.g. an unpackaged sterile syringe in a sterile pack cannot be used for another procedure once removed from the pack
- Exempt from UDI requirements.

The diagram below illustrates (source GS1):



Medical device components that are commercially supplied individually, must be included in the Australian Register of Therapeutic Goods (ARTG), and comply with UDI requirements.

Surgical loan kits

Surgical loan kits (SLK) are exempt from requiring a UDI at the kit-level as they are specialist logistics units, not co-packaged medical devices.

Any surgical loan kit component that is a medical device requires a UDI if that device is classified as Class I – supplied sterile, Class IIb, Class IIa, or Class III, unless they are:

- Not commercially available on their own
- Otherwise exempt from UDI requirements.

The full UDI (UDI-DI and UDI-PI) for each medical device component in a SLK must be easily accessible at the point of care to allow the linking of the medical devices to their implantation or use on patients.

The TGA acknowledges there are global challenges to assigning UDI identification to devices in surgical loan kits, as typical UDI labelling methods are often not feasible. As such, the method of providing the UDI is not prescribed by the TGA. The Australian implementation aims to be consistent with the flexibility provided by other international regulators, including allowing provision methods such as stickers, tags, inventory sheets and data carrier strips. The TGA continues to work with manufacturers, sponsors, and the healthcare sector to define the suitable labelling methods for surgical loan kits.

The Australian UDI Database

The TGA developed the Australian UDI Database (AusUDID) to store Australian UDI data. It contains all information essential to identify models of medical device approved for supply in Australia, including a history of changes for each model of device.

The AusUDID will be publicly available at no cost. Users can search, view, and download device information such as Patient Information Leaflets and electronic Instructions For Use where available.

The AusUDID does not contain patient information.

Searching for device information

The AusUDID supports searching for a device in many ways including:

- Brand name
- Model name
- Manufacturer name
- ARTG ID
- GMDN term
- UDI
- Scanning the barcode on the device label/packaging using a mobile phone or other device with a camera.

Downloading device data

AusUDID data is available for download for an individual record, the full database, or for a set of search results. Device data can be downloaded in a range of formats.

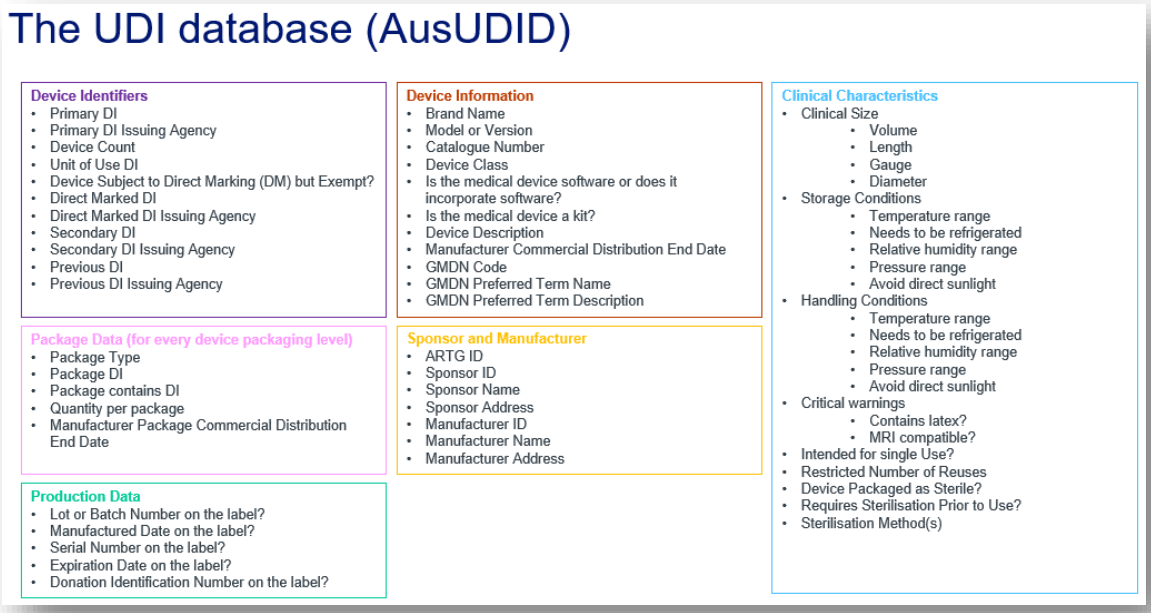
UDI record data elements

The diagram below shows the data elements that included for each UDI record, many of these will be freely accessible to the healthcare sector and the public.

Not all data elements are required to be supplied to the AusUDID. Device sponsors may choose only to provide mandatory data elements.

Rules regarding which fields are mandatory and optional are detailed in the Australian UDI Data Dictionary which can be found here on the TGA website.

NOTE: The AusUDID stores UDI-DI and associated medical device data. The AusUDID does not store UDI-PI data.



Changes to certain data fields will result in a new UDI-DI and therefore a new record in the AusUDID. These are referred to as Trigger Fields.

Changes that are clinically relevant	• **Labelled as single use**
	• **Number of reuses**
	• **Packaged sterile**
	• **Need for sterilisation before use**
	• **Critical warnings or contraindications:**
	  ○ **Contains latex**
	  ○ **MRI safety status**
	• **Clinical size (including volume, length, gauge, diameter)**
	• **Software add/change features that result in change to intended purpose (new major version).**

Changes that are not clinically relevant	• Brand name • Device version or model • Quantity of devices provided in a package (device count).

When a new UDI-DI is required, the manufacturer must change the affected device labels to incorporate the new UDI-DI and updated data must be supplied to the AusUDID. Data must be submitted to the AusUDID before the newly labelled device is supplied in Australia.

AusUDID user guides for healthcare providers

The AusUDID Healthcare User Guide supports understanding of the features of AusUDID relevant to healthcare organisations and practitioners. The user guide includes:

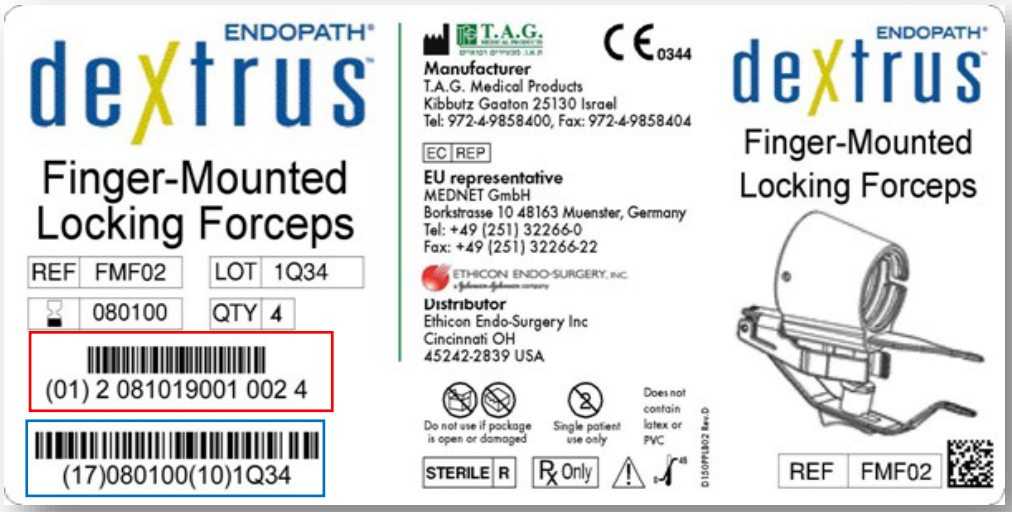
- Accessing the AusUDID
- Navigating the AusUDID
- Searching the AusUDID
- Downloading AusUDID data.

Appendix A: Examples of Unique Device Identifiers

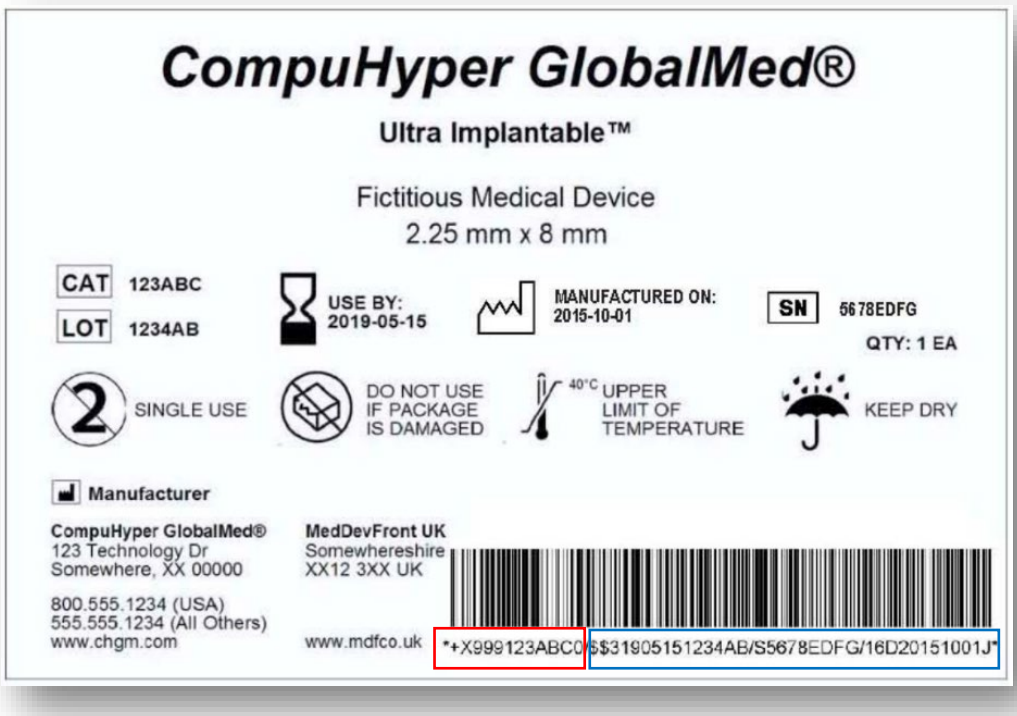
Below are examples of labels from each of the 3 Issuing Agencies. The 2 parts of the UDI have been framed in each diagram:

- The device identifier (UDI-DI) is framed in red
- The production identifier (UDI-PI) is framed in blue.

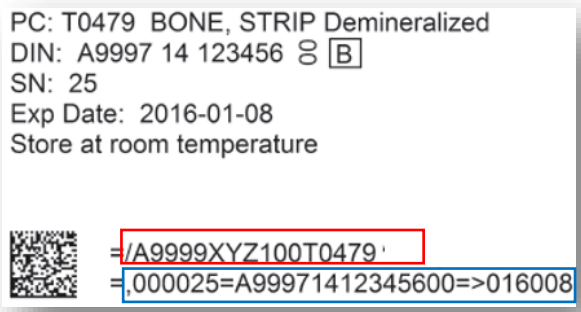
GS1



HIBCC



ICCBBA


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

Appendix B: Additional examples of UDI conventions

Concatenated data – a single linear barcode that includes UDI-DI and UDI-PI

GS1-128 concatenated with DI and PI's (Expiration Date + Lot/Batch Number)

Non-concatenated data – two separate barcodes, one represents UDI-DI and the second represents the UDI-PI

GS1-128 non-concatenated (shared in 2 parts)

a) DI only

b) PI's (Expiration Date + Lot/Batch Number)

2D barcode – combines UDI-DI and PI into a single 2D barcode

GS1 Data Matrix with DI and PI's (Expiration Date + Lot/Batch Number + Serial Number)

(01)09506000117843
(17)201231
(10)1234AB
(21)5678CD

Appendix C: Examples of Unit of Use and packaging configurations

Single Item
(Unmarked)

Tray of 25
(Full UDI Marked)

Case of 1000
(Full UDI Marked)

Unit of Measure (Package Level)	Device Identifier (DI)	Qty	Units of lower Package Level	Contains DI Package
Single Item	UoU DI (Unmarked)	1	-	-
Tray (Lowest Package Level with DI)	Lowest Package Level DI (Full UDI Marked)	25	-	No
Case	Case level DI (Full UDI Marked)	1000	40	Tray

Each (Blister)
(Unmarked)

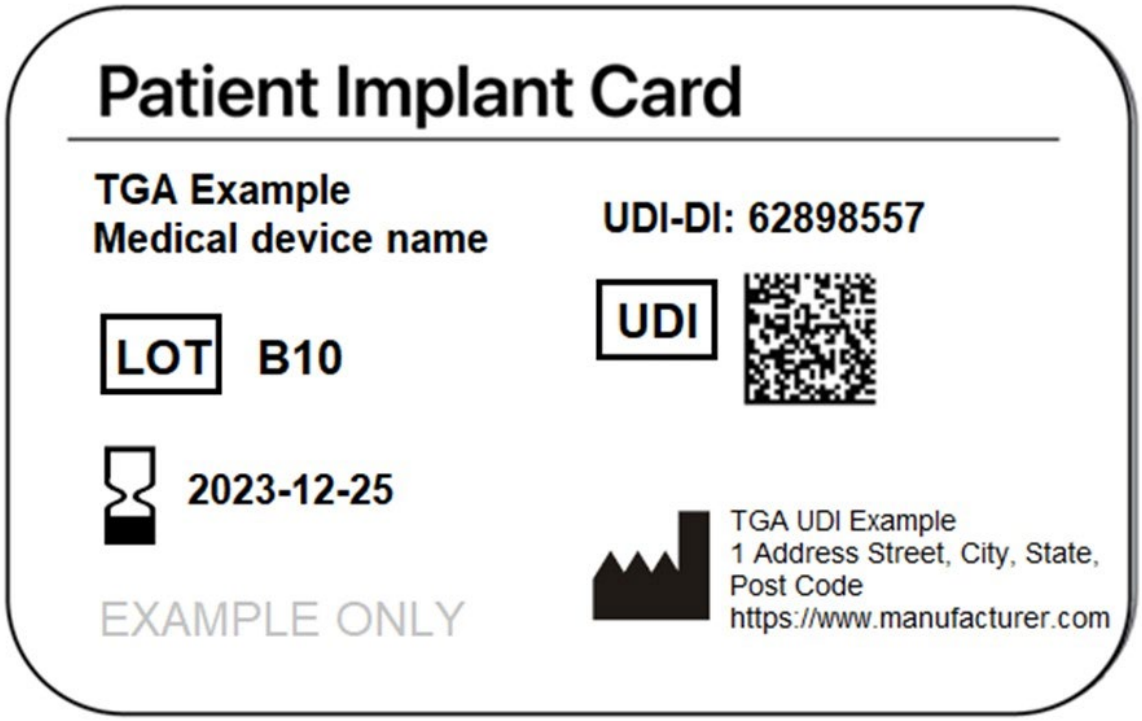
Box of 50
(Full UDI Marked)

Case of 1000
(Full UDI Marked)

Unit of Measure (Package Level)	Device Identifier (DI)	Qty	Units of lower Package Level	Contains DI Package
Each (Lowest Package Level with no DI)	UoU DI (Unmarked)	1	-	-
Box	Box Level DI (Full UDI Marked)	50	50	Blister
Case	Case Level DI (Full UDI Marked)	1000	20	Box

Image sourced from IMDRF Unique Device Identification system Application Guide, 21 March 2019: https://www.imdrf.org/sites/default/files/docs/imdrf/final/technical/imdrf-tech-190321-udi-sag.pdf

Appendix D: Example of Patient Implant Card



Appendix E: Further UDI resources

Many resources are available that provide further information about UDI implementation and adoption, the table below provides a small subset of these.

Title	Link	Comments
TGA – UDI Hub	About Unique Device Identification in Australia | Therapeutic Goods Administration (TGA)	Up-to-date information on the Australian implementation of UDI including guidance documents, user guides and frequently asked questions.
International Medical Device Regulators Forum	https://www.imdrf.org/ IMDRF UDI Guidance (IMDRF/UDIWG/N7FINAL:2013) IMDRF UDI Application Guide (IMDRF/UDIWG/N48FINAL:2019)	IMDRF is a voluntary group of medical device regulators from around the world working together to define a harmonised approach to UDI. Their documents are written to assist all stakeholders, including healthcare supply chain and clinical care systems, to gain a better understanding of their role and impact on the UDI system.
NEST CC UDI Playbook	https://nestcc.org/nestcc-udi-playbook/	A US-based playbook to support Unique Device Identifier implementation at the Point of Care, much of this information is applicable to Australian healthcare organisations
Scan4Safety	https://scan4safety.nhs.uk/	The Scan4Safety program has been implemented in the UK to address digital technology in healthcare as well as using these solutions to address patient safety challenges. Whilst there are some differences between the UK and Australian implementation, there are many lessons we can learn and resources we can leverage from the Scan4Safety program.

Appendix F: UDI glossary

This table provides a glossary of terms and acronyms used in a Unique Device Identification (UDI) context. You can also refer to the TGA Acronyms and glossary terms | Therapeutic Goods Administration (TGA), for broader TGA terms and acronyms.

Term	Acronym	Definition
Automatic Identification and Data Capture	AIDC	Automatic Identification and Data Capture (AIDC) is a method of conveying the UDI into an electronic patient record or other computer system without human involvement.
Australian Unique Device Identification Database	AusUDID	The Australian Unique Device Identification Database (AusUDID), managed by the Therapeutic Goods Administration, contains medical device data supplied by sponsors and manufacturers to identify models of device supplied in Australia.
Device Identifier	UDI-DI	Identifies the model of medical device. The UDI-DI is used as the "access key" to information stored in the AusUDID and will be used for device related information such as adverse events and recalls. *Examples of the UDI-DI include a GS1 GTIN (Global Trade Item Number), a HIBC-UPN (Universal Product Number), or an ICCBBA ISBT 128-PPIC (Processor Product Identification Code).*
Device Classification		A device classification is given to medical devices and therapeutic goods upon application to list on the Australian Register of Therapeutic Goods (ARTG), as per the Australian regulatory framework. See Classification of medical devices | Therapeutic Goods Administration (TGA).
Direct Marked		The UDI Device Identifier (UDI-DI) portion of the UDI that is permanently marked directly onto the device itself if the device is intended to be used more than once on different patients and is intended to be reprocessed between uses.
Human Readable Interpretation	HRI	Human Readable Interpretation (HRI) is characters that can be read by people, e.g. letters and numbers, as opposed to symbol characters within barcode symbols, which are read by machines.
Issuing Agency	IA	A TGA recognised organisation that issues Unique Device Identifiers to manufacturers or sponsors. Currently these are GS1, ICCBBA and HIBCC.
Primary DI		The Primary Device Identifier (Primary DI) is the DI portion of the UDI placed on the lowest package level of a device that is required to meet UDI label requirements. If the device is not packaged, the UDI may be on the device itself, thereby satisfying both the UDI label and the direct marking requirement if the UDI is intended to be permanent. The Primary DI is the main (primary) lookup for a medical device and meets the requirements to uniquely identify a device through its distribution and use.
Production Identifier	UDI-PI	Identifies the production specific information such as the production run of the device. This could include a batch number, lot number or expiry date. The UDI-PI is present on the device but not stored in the Australian UDI Database (AusUDID).
Software as a Medical Device	SaMD	Software as a Medical Device (SaMD) refers to software that can function on, for example, a laptop computer, smartphone, or tablet, and has an intended purpose consistent with the definition of a medical device. This could be any kind of software including, but not limited to, computer programs and applications, mobile applications, software as a service (cloud based), websites, and

Term	Acronym	Definition
		browser delivered products. For more information, see How the TGA regulates software-based medical devices.
Serial Number		The number that allows for the identification of a device, indicating its position within a series. This number is required to be part of the UDI when included on the label to provide the means to track the device back to its manufacturing source or otherwise allow the history of the device manufacturing, packaging, labelling, distribution, and use to be determined.
System or Procedure Packs	SOPPs	System or Procedure Packs (SOPPs) are medical devices intended to be used in a medical or surgical procedure, containing a combination of 2 or more goods where at least one of the goods is a medical device or in vitro diagnostic device, and all goods are packaged together or are to be interconnected or combined for use.
Unique Device Identifier	UDI	A Unique Device Identifier (UDI) is a series of numeric or alphanumeric characters that is created through a globally accepted standard and applied to a specific model of medical device. It is comprised of both device information and production information and is applied to the device label and all levels of packaging for the device in both machine readable and human readable forms.
UDI Carrier		The physical representation of the UDI on the device label, or in some cases on the device itself, in both a machine readable and human readable form.
UDI System		The UDI system encompasses both the UDI labelling on medical devices as well as the provision of UDI and associated medical device data to a UDI database.
UDI Trigger		Changes to certain UDI data elements require a new UDI-DI to be allocated as they represent a change to the medical device that could lead to misidentification of the medical device or ambiguity in its traceability. These data elements are called UDI Triggers.
Unit of Use UDI-DI		Unit of Use UDI Device Identifier (Unit of Use UDI-DI) is an identifier assigned to an individual medical device when its base package contains multiple unpackaged and unlabelled devices. A Unit of Use UDI-DI is used to allocate the use of a single device to a patient. The Unit of Use UDI-DI is available in the UDI database, it is not visible on device packaging.

Version history

Version	Description of change	Author	Effective date
V1.0	Original document release	Devices Reforms Taskforce	April 2024

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
Web: tga.gov.au

Reference/Publication #