Australian Government
Department of Health, Disability and Ageing

Overview of Unique Device Identification for Australian healthcare

Enhancing patient safety through traceability of medical devices

Version 2.0, July 2025

Contents

Introduction

As the regulator of therapeutic goods in Australia, the Therapeutic Goods Administration (TGA) has implemented the Unique Device Identification (UDI) system for medical devices in Australia.

With the introduction of UDI, manufacturers supplying medical devices in Australia will identify their devices through bar coding on all packaging and labelling and submit this data to the TGA. This UDI information can be used in hospital systems and patient records like My Health Record to clearly identify the model of medical device used or implanted. A public database of UDI information, the Australian UDI Database (AusUDID), will allow patients to access the relevant information about their device.

Development of the UDI system involved:

- amendments to the *Therapeutic Goods Act 1989* and the *Therapeutic Goods (Medical Device) Regulations 2002* - Federal Register of Legislation - Therapeutic Goods Legislation Amendment (Australian Unique Device Identification Database and Other Measures) Regulations 2025
- establishment of the AusUDID, to be maintained by the TGA
- 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
- working with 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 devices implanted into patients in the event of an adverse event, safety alert 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 allows patients, consumers, and health professionals to access product information in the AusUDID about the devices that they use.

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

With the UDI system now in place, we will continue to work with global regulators to harmonise UDI requirements, share learnings and promote UDI adoption in healthcare organisations.

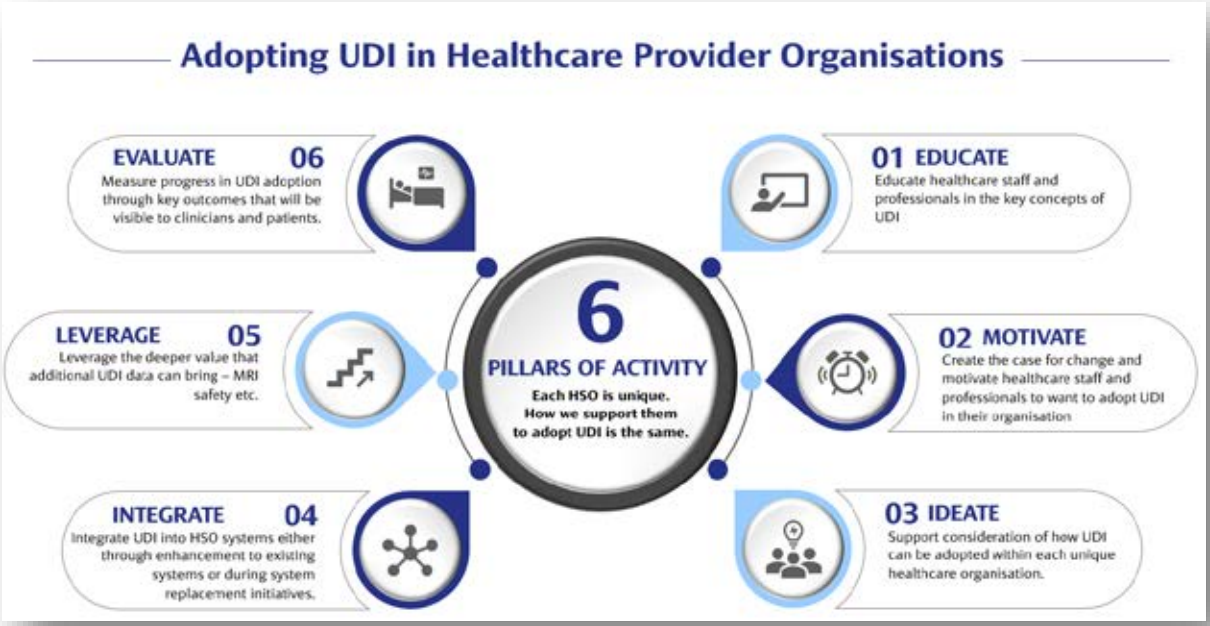
For up-to-date information, guidance documents, user guides and other resources, see: Unique Device Identification (UDI) hub | Therapeutic Goods Administration (TGA).

Purpose

This document is focused on education of healthcare stakeholders and increased awareness and adoption of UDI in Australian healthcare settings. It explains key 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.

Figure 1: Activities for Adopting UDI in Healthcare Provider Organisations



Audience

This document is intended for use by staff in healthcare provider organisations including but not limited to:

- executive level staff
- management
- clinical governance
- health informatics
- clinicians
- Quality and Risk/Recall Coordinators
- biomedical engineering
- healthcare professionals
- procurement
- supply chain
- IT
- finance
- administration.

Document conventions

For this document:

- *we* refers to the Therapeutic Goods Administration (TGA)
- *you* refers to the reader
- *medical devices* refers to both medical devices and in vitro diagnostic (IVD) devices
- *UDI record* refers to a UDI-DI and related data published as a record in the Australian Unique Device Identification Database (AusUDID)
- *devices in scope of UDI requirements* refers to devices that are of a risk classification that must meet UDI requirements and are not otherwise exempt.

Related resources

Several key acronyms and terms are used throughout this document.

Acronym	Description
ARTG	The Australian Register of Therapeutic Goods. Maintained under s. 9A of the *Therapeutic Goods Act 1989* for the purpose of compiling information in relation to, and providing for evaluation of, therapeutic goods for use in humans.
AusUDID	The Australian Unique Device Identification Database, managed by the Therapeutic Goods Administration, stores UDI-DIs and medical device data supplied by sponsors and manufacturers to identify models of device supplied in Australia.
UDI	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 the UDI-DI and UDI-PI. The UDI is applied to the device label and all applicable levels of packaging for the device in both machine and human readable form.
UDI-DI	UDI-Device Identifier 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).*
UDI-PI	UDI-Production Identifier identifies the production specific information such as the production run of the device. This could include a batch number, lot number, expiry date, software version/build number or manufacturing date. The UDI-PI is present on the device but not stored in the AusUDID.

For a full list of definitions of UDI-specific terms and acronyms, see UDI glossary | Therapeutic Goods Administration (TGA).

For broader TGA terms and acronyms, see Acronyms and glossary terms | Therapeutic Goods Administration (TGA).

For a list of resources about UDI in Australia and globally, see Appendix C.

Overview of Unique Device Identification (UDI)

The Australian UDI system is comprised of 2 parts:

- the placement of UDIs on medical devices, and
- supply of the UDI-DI and related device data to the TGA's AusUDID, allowing patients, consumer and healthcare to access this information.

A 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 incorporates both device information and production information about the specific production run of the device.

UDIs enable the global tracking and tracing of medical devices through the supply chain and in healthcare systems to the patient record.

The major benefit of the UDI system is improved patient safety. Additional benefits include:

- 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 public availability of up-to-date medical device information.

Timing

The Australian UDI regulatory framework includes a phased introduction of the UDI requirements, starting with high-risk implantable devices from 1 July 2026 followed by a progressive roll out to other device classes up to 30 June 2030.

The diagram below shows the implementation timeframe for industry compliance.

Figure 2: UDI Industry Compliance Timeframe

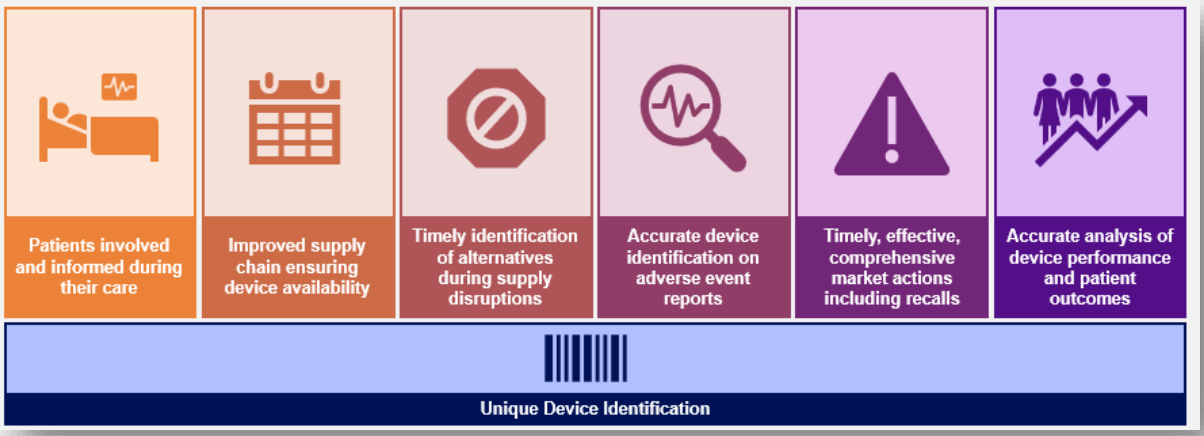
At the time of writing there is no mandatory requirement for healthcare providers to adopt UDI. We are working with the ACSQHC to consider inclusion of UDI in the 3rd edition of the National Safety and Quality Health Service (NSQHS) Standards due for release in 2028-29.

You may already see UDIs on labels in the healthcare setting. This likely indicates that the device labels are UDI compliant in other jurisdictions such as the United States and the European Union. US and EU labels are accepted under the Australian UDI system.

Benefits of UDI for healthcare

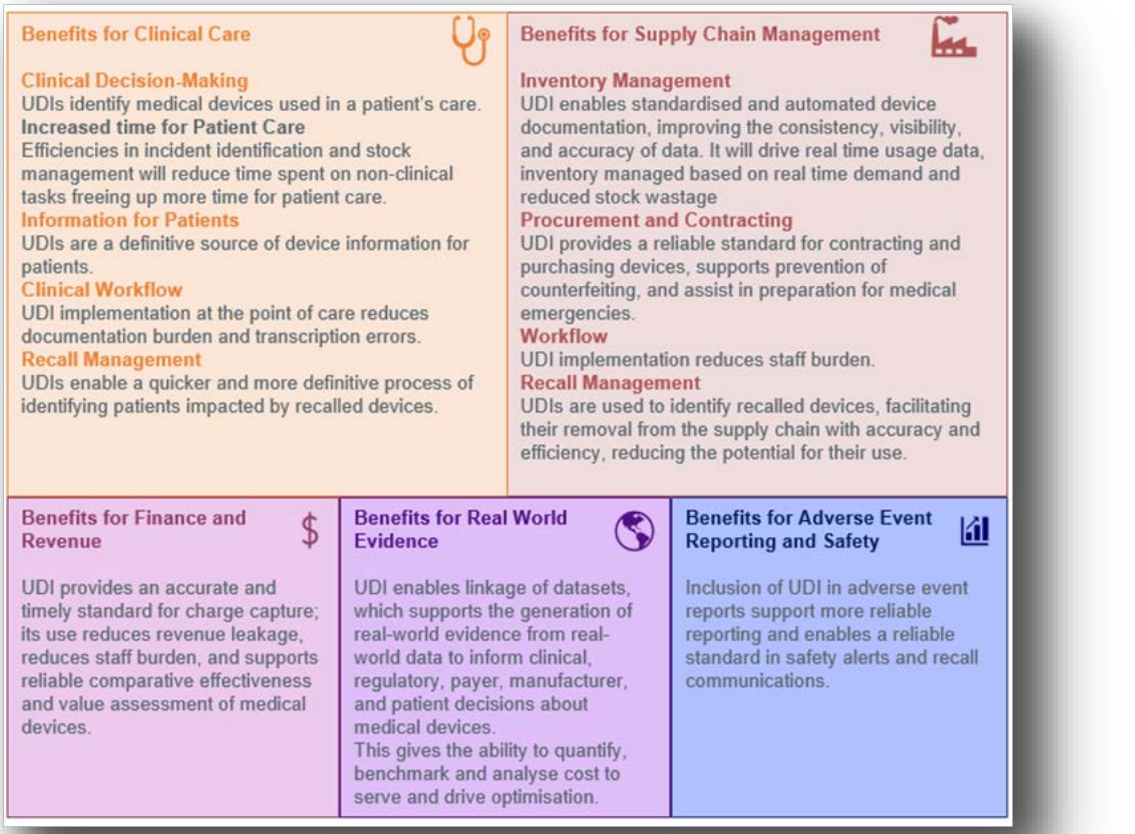
UDI is a cornerstone to several patient safety initiatives; measurable patient safety outcomes will be seen when UDI is adopted within healthcare organisation systems, supply chain processes and relevant clinical quality registries.

Figure 3: UDI underpins several important activities that directly deliver improved patient safety outcomes



Use of UDI in healthcare can result in many benefits for hospitals, clinicians, patients, and payers. These are illustrated in the diagram below.

Figure 4: Benefits of UDI

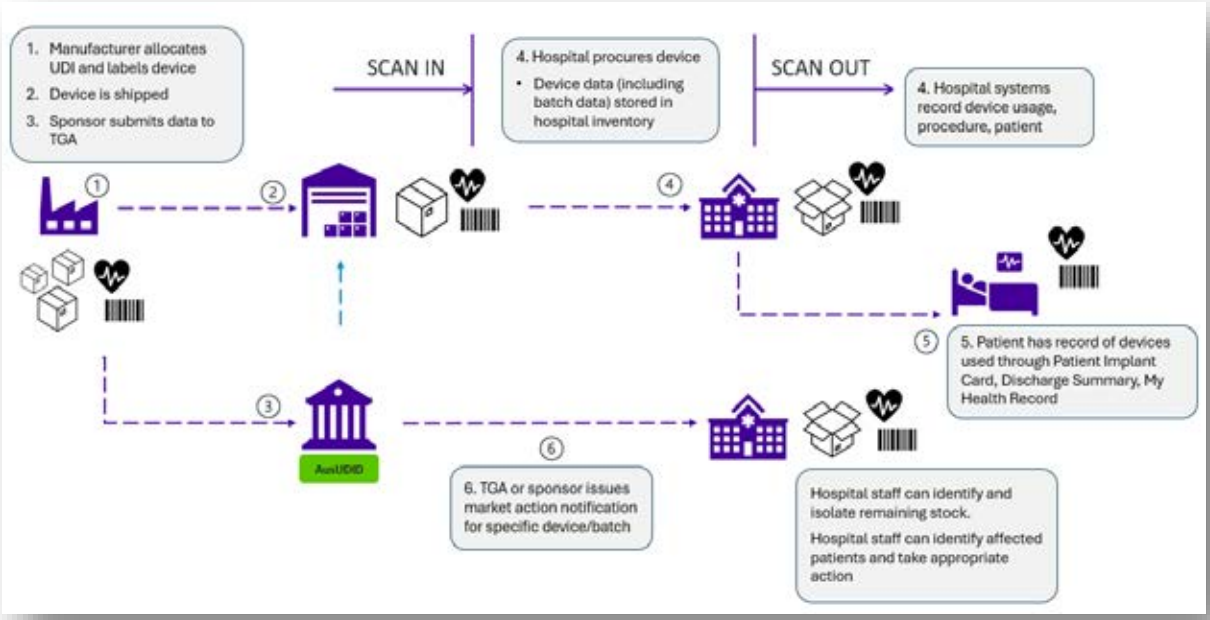


This diagram is based on: *NEST Coordinating Center - A Playbook for Health System Unique Device Identifier Implementation at the Point of Care v1.0, April 17, 2023.*

Impacts of UDI on healthcare

UDI has the potential to deliver value through the entire life of a device. The value starts from device manufacture, supply into healthcare facilities and use in patient care. The UDI continues to be valuable during adverse event reporting, recall management and in assessment of device performance.

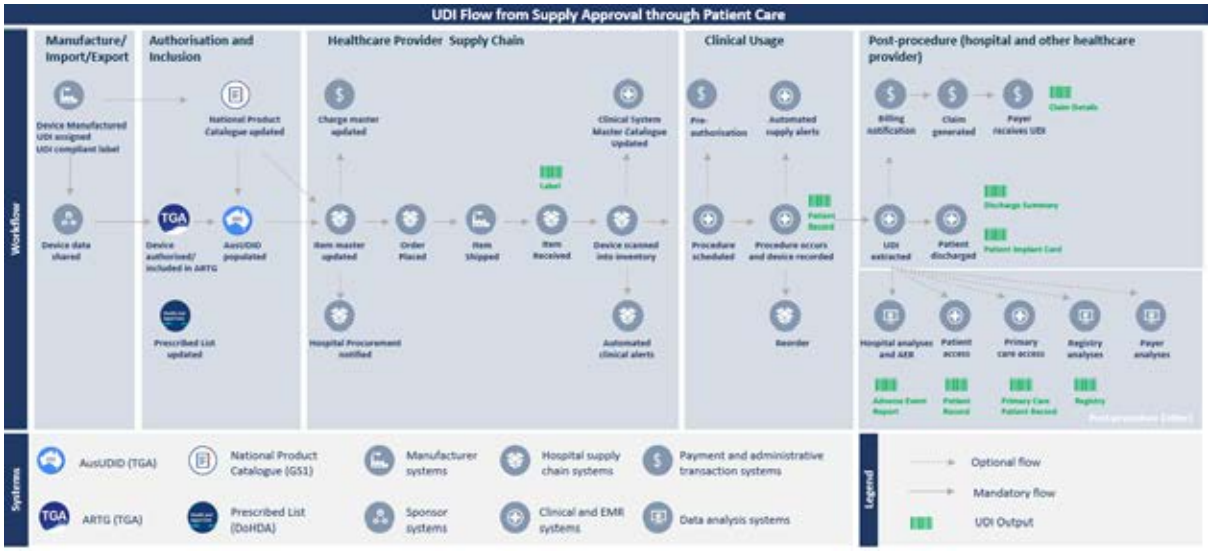
Figure 5: Vision for UDI adoption in Australian healthcare



This document aims to support UDI adoption within hospitals and healthcare providers. We will work with stakeholder groups and peak bodies to support drafting of artefacts that support specific groups (such as surgeons and pharmacies). These artefacts will support understanding of how UDI might impact 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 assist healthcare processes. This may not reflect exactly the processes followed in your organisation, and adoption of UDI should be approached in a way that best suits your organisation.

Figure 6: UDI flow from supply approval through to patient care



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

We encourage you to start preparing for UDI adoption in your healthcare setting. Benefits include increase quality care for patients, improved patient safety outcomes, increased supply chain efficient translating to reduced costs.

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 C). 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 implementation approach** that works for your organisation, remembering that undertaking a proof of concept or following a staged adoption might be more achievable than addressing all systems in one go.

Consider systems that may require updates and conduct a Change Impact Assessment.

Assess each system for UDI readiness including storage of UDI data and upstream/downstream integration.

Systems most likely impacted by UDI are those that handle product or patient data, such as:

- supply chain management systems including warehouse and inventory
- clinical suite software including theatre management
- electronic health or patient records
- claims, reimbursement and billing
- biomedical asset management systems
- clinical quality registries
- clinical incident and recall management systems.

Consider how UDI implementation can align with digital delivery plans, including using pilots or proof of concepts.

The example below illustrates how UDI can be considered while upgrading scanning technology, that can act as a critical foundation for the full realisation of UDI benefits.

- **Consider a staged implementation that starts small and regularly delivers measurable business outcomes**, helping build support for the change. Consider non-technology outcomes that can be leveraged. For example improved labelling and enhancing manual processes can support UDI understanding and adoption before investment in scanning solutions is required.
- **Promote integration and interoperability** of scanning technology and sharing of UDI across key systems, including barcode scanners, RFID readers and imaging systems to ensure information is current and accurate.

  This can lead to improved patient safety, better coordination of patient care and streamlined workflows including within:

  - Replenishment
  - Procurement
  - Logistics
  - Patient safety
  - Clinical management.

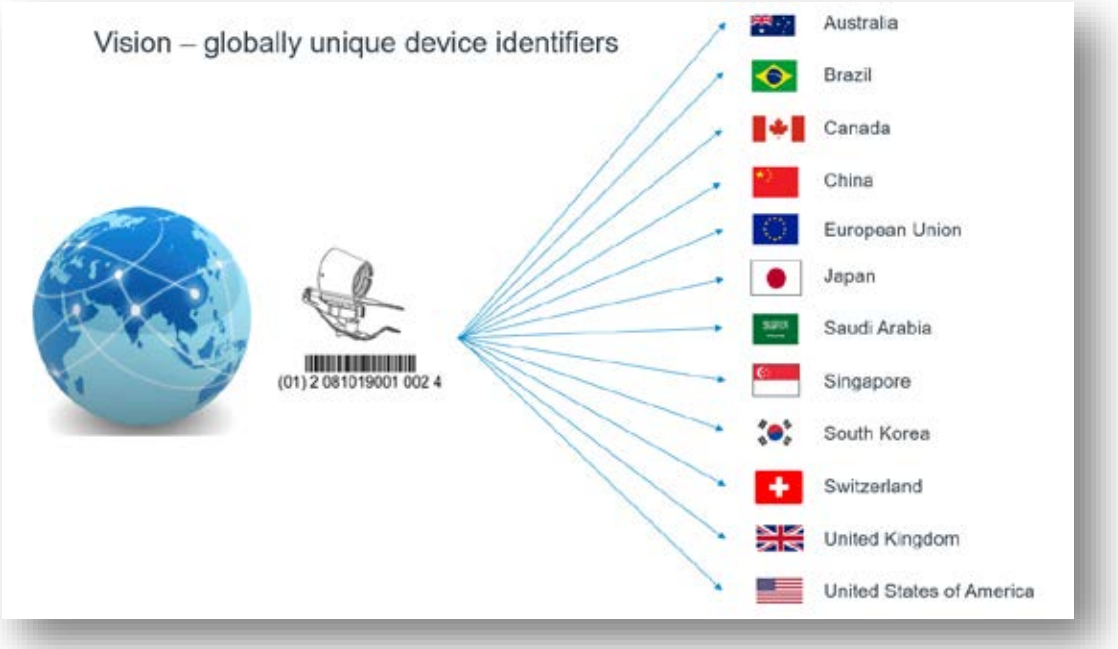
- **Include ongoing physical validation** at key handling milestones. Physical validation of devices helps improve data quality and confirms data flow between systems is correctly showing the location and movement of devices and physical assets.

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.

Figure 7: Global UDI initiatives



We have been working with manufacturers and sponsors of medical devices to develop 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.

Australian Unique Device Identification system

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 3 Issuing Agencies to issue UDIs for medical devices:

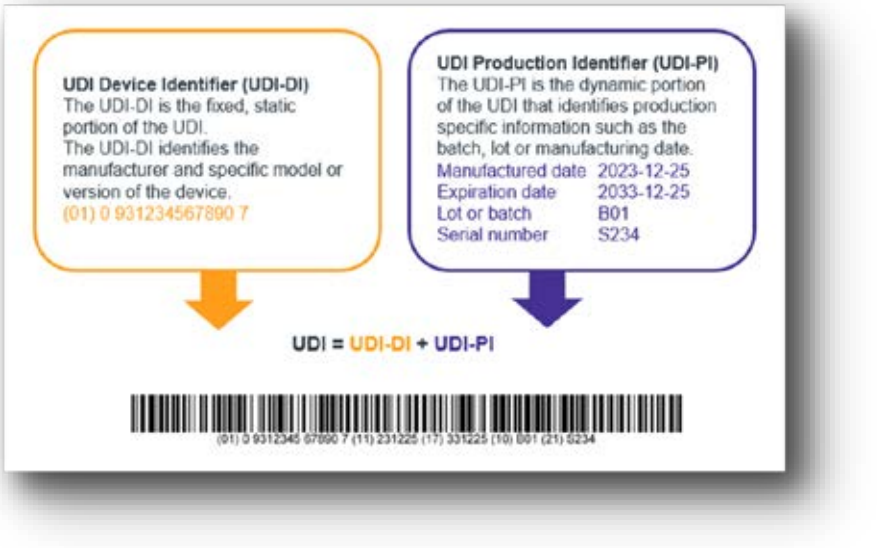
- GS1
- Health Industry Business Communications Council (HIBCC)
- International Council for Commonality in Blood Banking Automation (ICCBBA).

A UDI is made up of 2 parts:

1. UDI-Device Identifier (UDI-DI)
2. UDI-Production Identifier (UDI-PI).

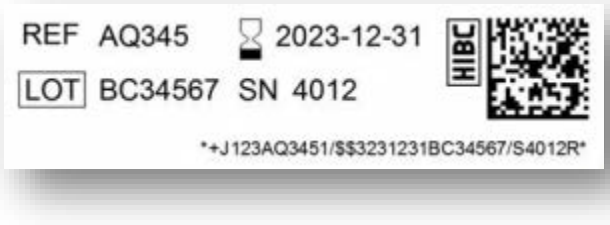
Below is an example of a UDI in a linear barcode (GS1 format).

Figure 8: Example of a UDI – linear barcode



Below is an example of a UDI in a Data Matrix (HIBCC format).

Figure 9: Example of a UDI – Data Matrix



Every device in scope of UDI requirements will have a UDI-DI. 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. This depends on the type of device. A new UDI-DI must be assigned when there is a significant change in the device characteristics such as:

- brand name
- device version or model
- clinical size
- quantity of devices provided in a package
- critical warnings or contraindications.

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.

For UDI examples from the 3 TGA recognised Issuing Agencies, see Appendix A.

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

UDI requirements in Australia

Sponsors and manufacturers of medical devices supplied in Australia are required to undertake 3 main activities for devices they supply in Australia:

1. Get a UDI-DI from a TGA recognised Issuing Agency and allocate a UDI-PI per Issuing Agency standards
2. Include the UDI on the device label, packaging and in some cases permanently marked onto the device itself
3. Submit the UDI-DI and related information to the TGA's AusUDID.

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

Devices to meet UDI requirements

Medical devices and IVDs supplied in Australia that are included in the Australian Register of Therapeutic Goods (ARTG) must meet UDI requirements, unless they are covered by a specific exemption.

Medical device classifications, examples and whether UDI requirements apply 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 whether UDI requirements apply 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

UDI requirements do not apply for:

- medical devices that are Class I non measuring nonsterile
- medical devices that are Class I measuring (Im)
- custom-made medical devices
- patient-matched medical devices with a volume of 5 or less supplied each financial year
- medical devices supplied under Special Access Scheme or Authorised Prescriber Scheme
- Surgical Loan Kits at the kit level

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

Sponsors may choose to comply with UDI requirements for any exempt devices. Note that UDI records for that are exempt from inclusion in the ARTG will not be available in the AusUDID. This is because the AusUDID requires an ARTG ID to be linked to a UDI record for data validation purposes.

Where to find UDIs

Device labels

The UDI must be on the label of a medical device or on the device itself. It must also appear on all applicable higher levels of packaging. This is to ensure that the device can be identified throughout the supply chain.

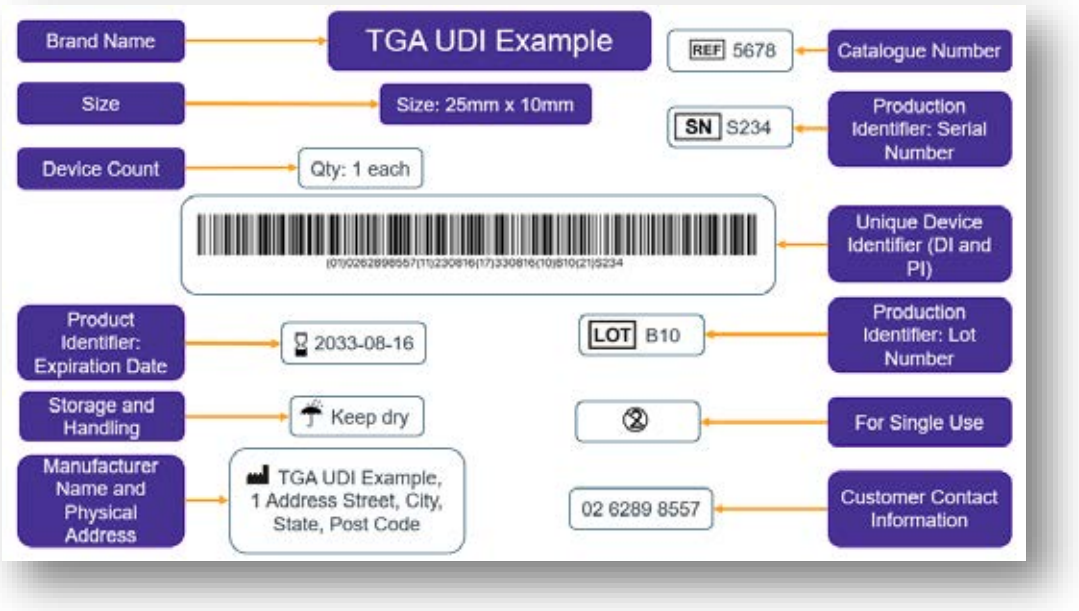
The UDI must be shown in 2 forms:

- human readable form
- machine readable form such as a barcode or QR code.

Australia accepts labels that are UDI-compliant with European Union (EU) and United States (US) regulations, provided the device and its label are also compliant with Australia's medical device regulations.

An example of a UDI compliant label is shown below:

Figure 10: Example of UDI Carrier in a fictitious label



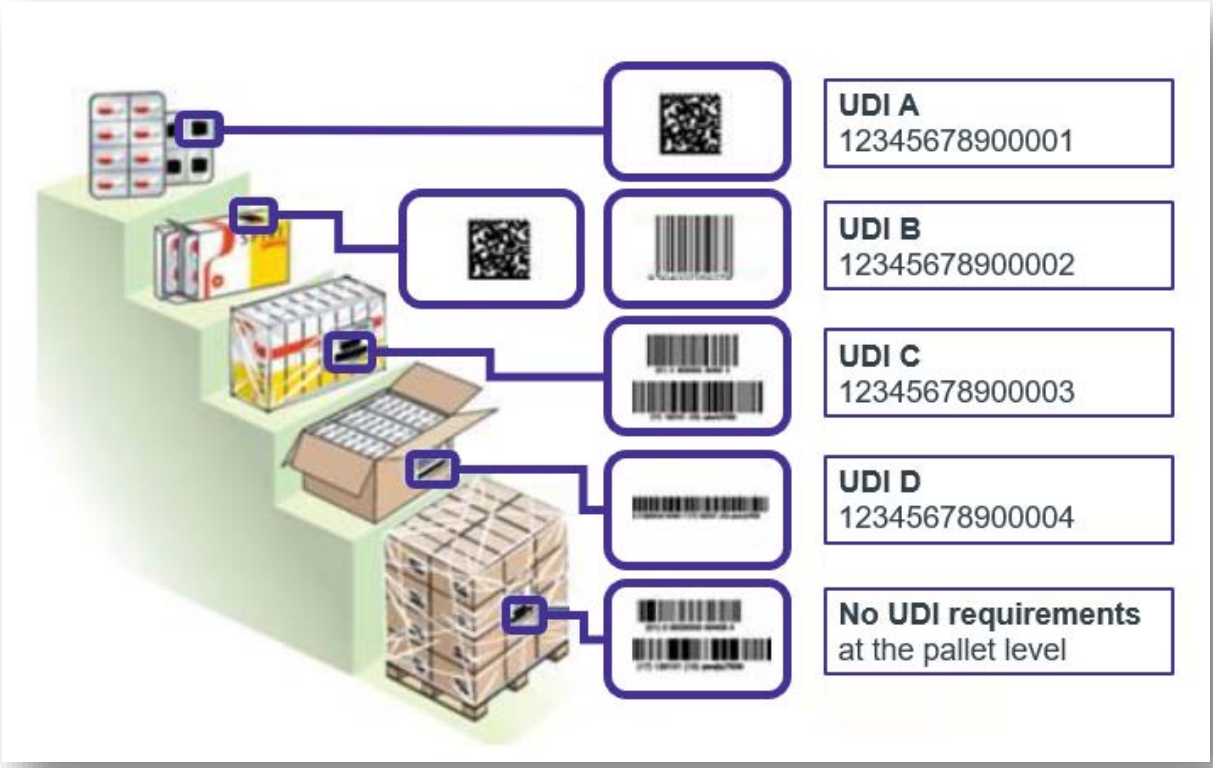
Device packaging

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.

As shown in the diagram below, the UDI can be presented in a range of machine-readable formats including linear and 2D barcodes.

Figure 11: Example of UDI packaging levels



Unit of Use (UoU)

A Unit of Use DI is assigned to an individual medical device when its base package contains more than one unpackaged and unlabelled device. The Unit of Use DI supports healthcare organisations and professionals allocating 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 DI is allocated to the syringes. Note that the Unit of Use DI is the same for each individual device within the tray.

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

Figure 12: Example of device package that requires Unit of Use DI

For examples of Unit of Use and packaging configurations, see Appendix C.

Sam the manufacturer and sponsor

Sam manufacturers a tray of 25 syringes. Sam includes the UDI on the label of the tray; this includes the UDI-DI and UDI-PI.

To allow the individual device to be associated with and tracked to a specific patient, Sam allocates a UoU DI to the tray. The UoU DI is the same for each individual device within the tray. Sam does not need to label the syringes in the tray with the UoU DI, nor does Sam need to label the base package with the UoU DI, as it is a virtual identifier only.

Unit of Use DIs are not required for procedure packs or kits including IVD kits.

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 intended to be reusable and to be reprocessed, the UDI is direct marked indelibly onto the device itself. The following figure illustrates.

Figure 13: Example of a UDI direct marked on a device

Direct marking is not required for:

- 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
- capital equipment.

Note that capital equipment will still bear a UDI, however this is not referred to as Direct Marking.

Mary the sponsor and manufacturer

Mary manufactures a box of 5 scalpels. Mary includes the UDI on the label of the box; this includes the UDI-DI and UDI-PI.

Because Mary's scalpels are reusable, Mary has also directly marked her devices with a Direct Marked DI. Because Mary has directly marked her devices, she does not need to meet UoU requirements.

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

Instructions for Use

The UDI is not required on Instructions for Use documentation, although some manufacturers may choose to include it.

Patient Information Leaflets

The UDI is not required on Patient Information Leaflets (PILs), although some manufacturers may choose to include it. 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

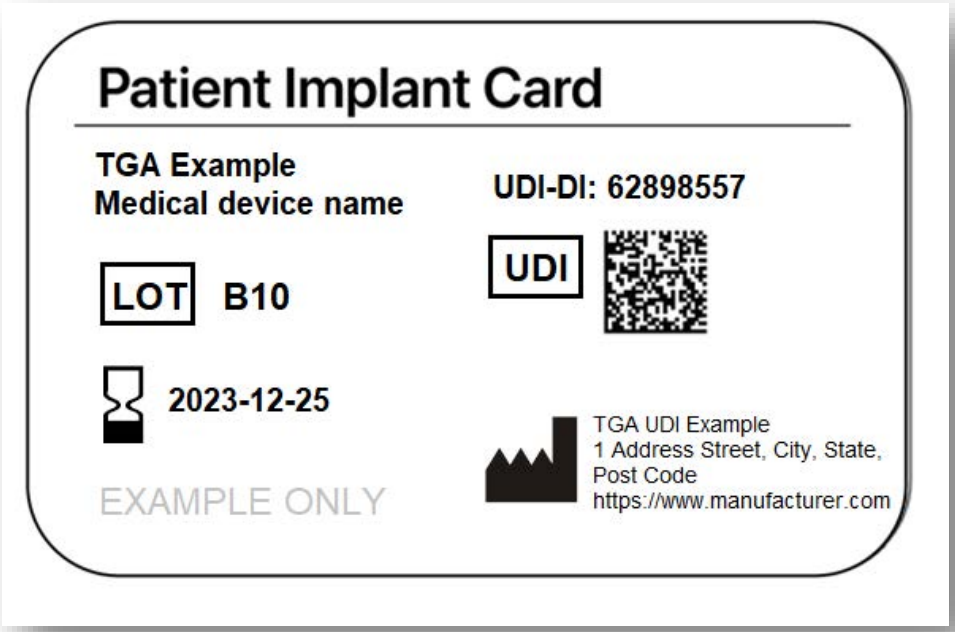
Patient Implant Cards (PICs) must be included within medical device packaging for provision to patients who receive a medical device implantation.

PICs must include 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 below an example of a PIC with a UDI:

Figure 14: Example of a Patient Implant Card with a UDI



Reporting

Where relevant and available, the UDI-DI and UDI-PI will be provided in TGA reporting including:

- market actions including 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 several batches of a device could include the UDI-DI and multiple UDI-PIs.

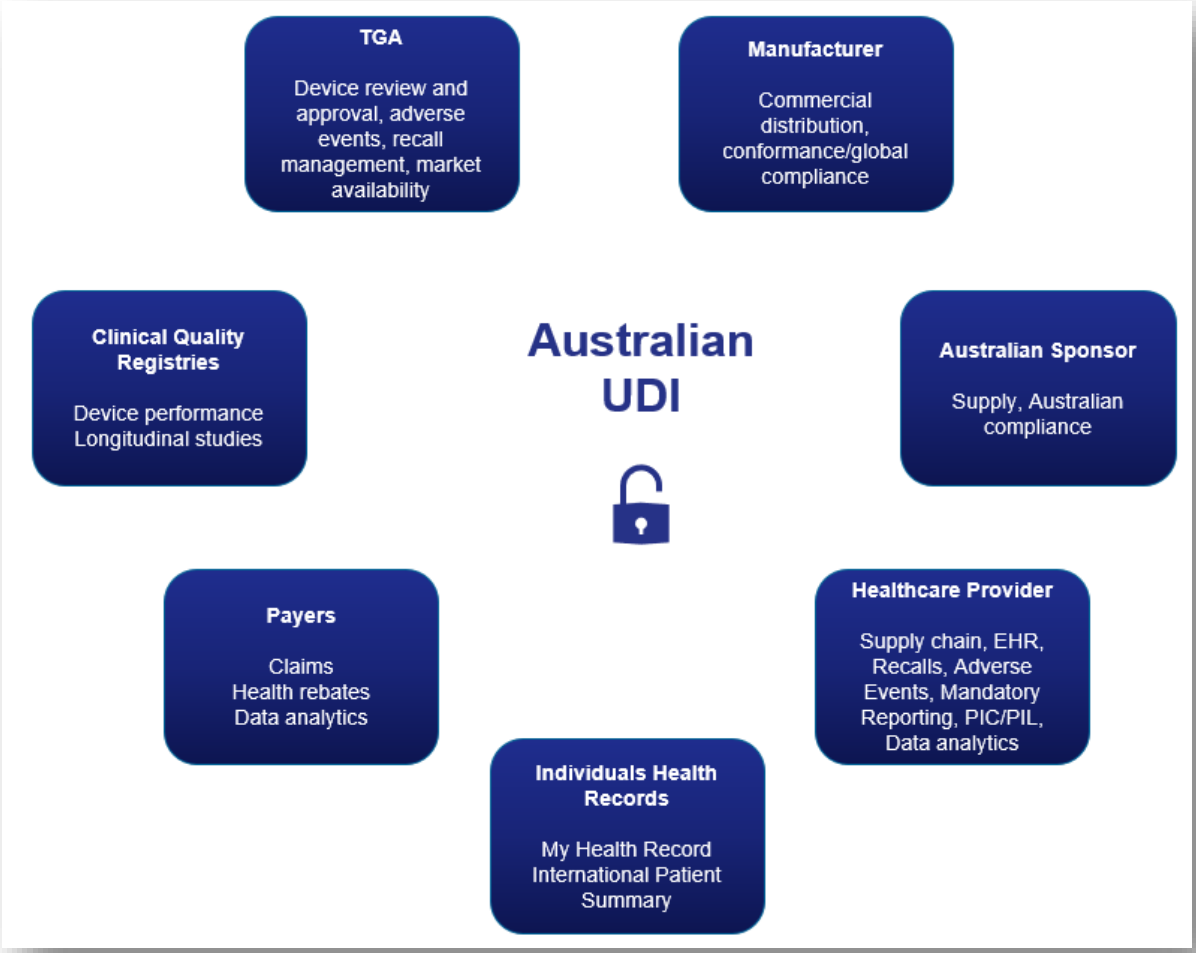
Reports for UDI exempt devices will continue as per current practice and should include any applicable information.

The UDI has been included as an optional field in the recently introduced mandatory reporting dataset.

Using Unique Device Identifiers

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.

Figure 15: Stakeholders of the Australian UDI system



UDI versus existing identifiers in healthcare

Several identifiers are already 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 in the UDI 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 or manufacturing date).

UDIs address these shortcomings and complement other identifiers used in healthcare.

UDI and Global Trade Item Numbers (GTIN)

Some (within supply chain in particular) refer to GTINs. A GTIN is the Global Trade Item Number (GTIN) used by GS1 to identify all types of products, including devices.

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.

A GTIN issued by GS1 is shown below with the GTIN highlighted in green.

Figure 16: Example of a GTIN issued by GS1

UDI and United Nations Standard Products and Services Code (UNSPSC)

UNSPSC is a hierarchical coding system used to classify products and services (including medical devices) for procurement, supply chain management, and financial reporting. It does not support the identification and tracking of individual models of device.

UDI and UNSPSC can be used together to provide information about a medical device. UDI provides granular identification for an individual batch of a device. UNSPSC offers broader classification of a product to support business functions such as inventory categorisation and asset management.

For example, a hospital may use the UDI to track production information about a device whilst it will use the UNSPSC code to classify the device for inventory and purchasing purposes.

Although hospitals may require provision of a UNSPSC, this is not a regulatory requirement under existing Medical Device Regulations.

UDI and Prescribed List Billing Codes

The Prescribed List (previously known as the Prostheses List) specifies the minimum benefits that private health insurers must pay for a listed item (device or product).

The Prescribed List allocates a Billing Code to each item; this is independent of the UDI. In future the Prescribed List may include the UDI which will assist with the identification and allocation of medical devices to the Prescribed List.

Requirements for specific types of devices

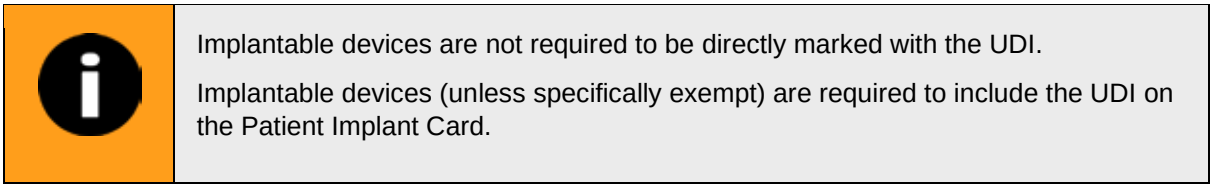
Some types of devices have specific UDI requirements related to how they are typically used and who uses them. These are outlined further in the sections below.

Implantable devices

Due to the high risks associated with implantable devices, the UDI for an implantable device should be identifiable before implantation. This can minimise the risks of misidentification of the implanted device. With this UDI stored in the hospital's clinical records, it can help hospitals be faster to identify patients with a specific implant.

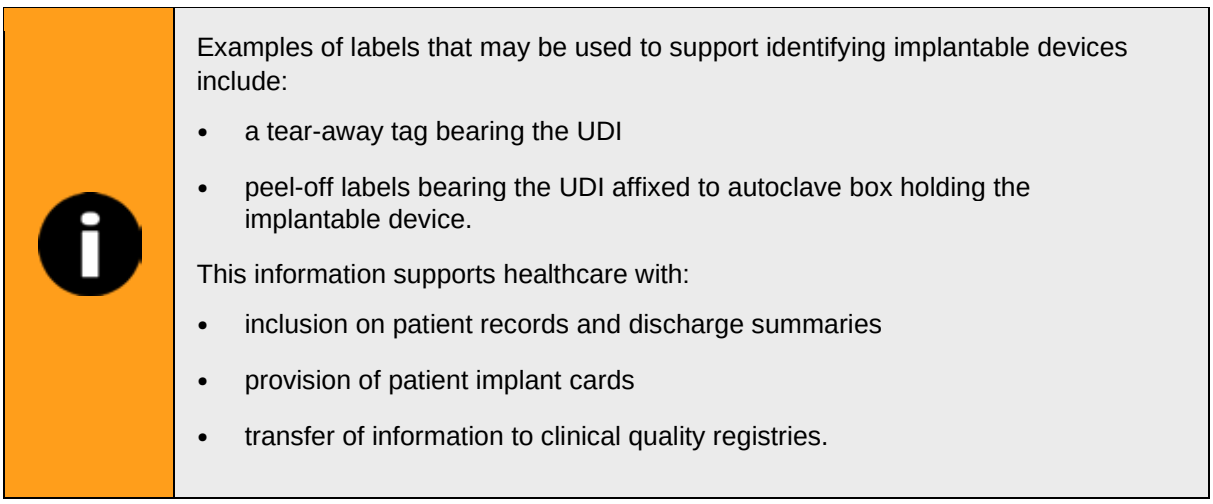
The following UDI requirements apply for implantable devices:

- 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 an active implantable device must include the serial number. For any other implantable device, the UDI-PI must include the serial or the lot number.



Implantable devices are not required to be directly marked with the UDI.

Implantable devices (unless specifically exempt) are required to include the UDI on the Patient Implant Card.



Examples of labels that may be used to support identifying implantable devices include:

- a tear-away tag bearing the UDI
- peel-off labels bearing the UDI affixed to autoclave box holding the implantable device.

This information supports healthcare with:

- inclusion on patient records and discharge summaries
- provision of patient implant cards
- transfer of information to clinical quality registries.

Single use devices

A device used on an individual patient during a single procedure and then **discarded** is considered a single use device. These must meet UDI requirements where the device is in scope of devices required to meet UDI requirements.

Where a single use device is packaged and sold individually, the UDI will be shown on the individual device packaging.

Where a single use device is packaged with other similar devices, the UDI will be shown on the base level packaging.

When the end user (for example, healthcare provider) is not expected to have access to the base level packaging, the UDI is to be provided on the individual device packaging.

Josh the manufacturer

Josh manufactures a surgical drill bit that will be using during a single procedure with an individual patient and then discarded. The drill bits can be purchased in a box of 10 with each drill bit contained in individual packaging.

Josh's drill bits are single use; they are intended to remain packaged until use.

Josh is not required to apply a UDI to each individual package within the box as they cannot be purchased individually.

Josh is required to apply the UDI to the box of 10. Josh also allocates a UoU DI, as this is a virtual identifier it does not need to be shown on the box.

Reusable Medical Devices

Reusable Medical Devices (RMD) are intended to:

- be used more than once
- undergo high-level disinfection or sterilisation before each use.

Reusable devices must be direct marked so that the UDI is:

- readable after each reprocessing
- able to withstand usage and reprocessing for the lifetime of the device.

Tash the manufacturer

Tash manufactures reusable scalpels. Because Tash's devices are intended to be reusable and reprocessed, Tash must directly mark her scalpels with the UDI.

Tash also manufactures single use syringes. As the syringes are not reusable, Tash is not required to directly mark her syringes with the UDI.

Capital equipment

Capital equipment must be labelled with a UDI, but it is not required to be directly marked. This includes:

- MRI machines

- IV pumps
- IVD bench top instruments.

Catherine the manufacturer

Catherine manufactures MRI machines. As Catherine's MRI machines are capital equipment, Catherine does not need to directly mark these devices. However, her MRI machines are in scope of UDI requirements and therefore must be labelled with a UDI.

Catherine chooses to apply a metal plate to the MRI machine that bears the UDI, making her MRI machine UDI labelled and UDI compliant.

Personalised medical devices (PMDs)

Medical devices that are designed and manufactured, or adapted or modified, to meet the needs of an individual are personalised medical devices (PMD).

3 specific terms are used by the TGA to describe personalised medical devices:

- **patient-matched** medical devices
- **adaptable** medical devices
- **custom-made** medical devices.

UDI requirements for each of these types of PMD vary, with each described separately below.

Patient-matched medical devices (PMMDs)

UDI requirements apply to patient-matched medical devices (PMMDs) if:

- they are included in the ARTG
- more than 5 are manufactured per financial year, and
- the PMMD is in scope of devices required to meet UDI requirements.

Adaptable medical devices

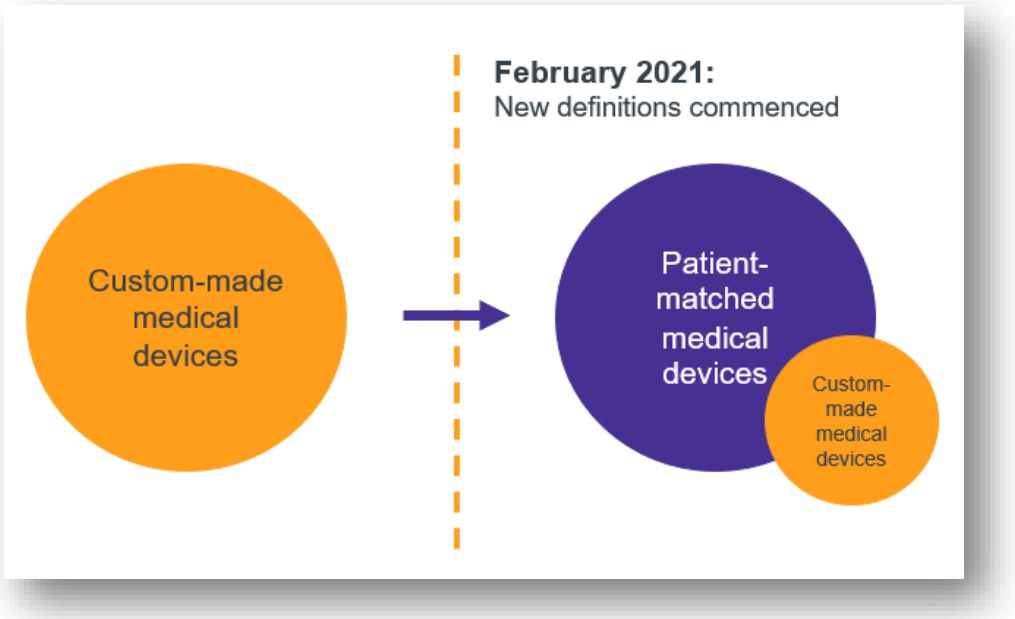
Adaptable medical devices are devices that are mass-produced and intended to be assembled or adapted after supply. Adaptable medical devices must meet UDI requirements, where they are in scope of devices required to meet UDI requirements.

Custom-made medical devices

Custom-made medical devices are exempt from meeting UDI requirements.

Note that most of the devices that were previously supplied under the custom-made medical device exemption now meet the definition of PMMD. You must meet UDI requirements for PMMDs, unless otherwise exempt.

Figure 17: Illustration of relationship between custom-made medical devices and patient-matched medical devices after new definitions commenced



Dental

Implantable dental devices

Dental practitioners acting as sponsors must meet UDI requirements for implantable dental devices.

Implantable dental devices require ARTG inclusion and are subject to UDI requirements when made using materials included in the ARTG. Examples include:

- dental implants and implant abutments
- implant abutments with special attachments
- temporary anchorage devices (TADS), such as mini screws.

Dental devices attached to implant abutments or fixed to TADS are exempt from ARTG inclusion and UDI requirements when made using ARTG included materials. Examples include:

- crowns
- bridges
- fixed or removable non-implant orthodontic appliances.

Software

Medical devices and IVDs that are software or incorporate software must meet UDI requirements.

A new UDI-DI is required for major software revisions that affects performance, effectiveness, safety or the intended use of the software. A new UDI-PI is allocated for minor software revisions such as bug fixes, usability enhancements or operating efficiency.

The UDI may be found on:

- the medium itself (for example, the CD)
- the packaging
- an electronic display such as a startup screen or About screen.

If the UDI is originally supplied on packaging and later requires a new UDI-DI, this can be provided through the electronic display.

Surgical Loan Kits (SLKs)

Surgical loan kits (SLKs) are supplied on loan to Australian hospitals for use in a particular surgical procedure and generally comprise collections of reusable surgical instruments. They may also include implantable medical devices and other medical devices. All goods in a SLK are medical devices and each medical device in the SLK must be included in the ARTG.

Surgical loan kits (SLK) are exempt from requiring a UDI at the kit-level. This includes the item used for transporting the kit (tray, tub or case).

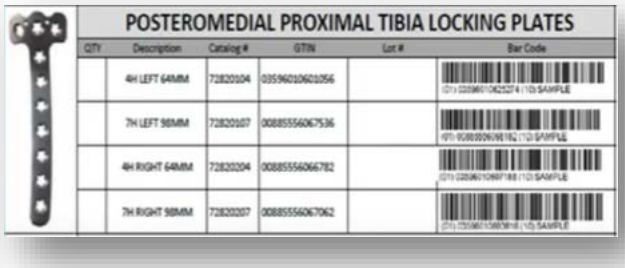
Any surgical loan kit component that is a medical device requires a UDI if that device is classified as Class I – supplied sterile, Class IIb, Class IIa, or Class III, unless they are:

- Not sold separately
- 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.

In acknowledgment that there are global challenges with UDI identification for devices in surgical loan kits, 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.

Figure 18: Examples of methods for identifying small implantable devices



Meg the manufacturer

Meg supplies a SLK to a hospital. All the components of Meg's SLK are medical devices that are in scope of UDI requirements.

Meg does not need to apply a UDI to the SLK, as it is considered a logistics unit. However, Meg does need to meet UDI requirements for components of her SLK.

Meg chooses to provide the UDI for the components that must meet UDI requirements via an inventory sheet. Meg must ensure that the inventory sheet that bears the UDI is easily accessible by healthcare practitioners at point of care.

System or Procedure Packs (SOPPs)

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.

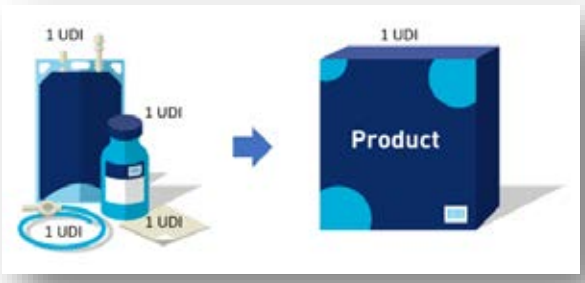
System or procedure packs (SOPP) require a UDI on the pack if they contain one or more medical devices classified as Class I – supplied sterile, Class IIa, Class IIb, or Class III.

Medical devices within the SOPP that are classified as Class I – supplied sterile, Class IIa, Class IIb, or Class III, must include a UDI on the individual device, unless it is:

- not sold separately
- 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):

Figure 19: Example of UDI applied to components of a SOPP as well as the SOPP at the pack level



Systems that are medical devices

A System is 2 or more goods that the manufacturer intends to be connected, used together or combined to achieve a specific medical purpose. The goods may be packaged together or packaged separately.

A System is **not**:

- a single item
- a collection of miscellaneous items that the manufacturer does not intend to be used together for a specific medical purpose
- bulk packs of one or more items
- a procedure pack (though a procedure pack can include a system in it).

Examples of Systems that are medical devices include:

- knee-joint replacement System
- orthopaedic drill System
- a patient-monitoring System with a monitor, power cable, and backup power supply
- a blood-glucose monitoring kit with a blood-glucose meter, test strips, controls, lancets, and a lancing device.

Configurable systems

Some systems can be configured; in these cases a UDI is allocated to the entire system (referred to as the System UDI for ease of reference). Each configuration will be identified using a specific UDI-DI. Later change of a component or accessory does not change the UDI-PI of the system.

Manufacturers will place the System UDI on the assembly that most likely does not get exchanged in its lifetime. They will also provide separate UDIs for each component where:

- it is a medical device
- it is included on the ARTG, and
- it is in scope of devices required to meet UDI requirements.

Example: Upgrade to system which impacts safety or performance

Claire the manufacturer

MRI system

Claire manufactures an MRI System, 'Model A', that she manufactures and distributes to customers. She develops new features and functionality for that MRI system which her original approved specifications do not cover. This could be hardware, software or a combination of both. The new features change the safety profile, the performance of the system or the intended uses. Claire determines this results in a new model, 'Model B', of the device. If Claire decides to modify the device as a new installation, she must give the modified device a new System UDI-DI. Alternatively, she may provide an upgrade kit as a medical device with a separate UDI-DI. This with the original System UDI-DI is used for the identification of the changed device.

Example: Component change which impacts safety or performance

Alice the manufacturer

X-ray system

Alice manufactures an X-ray System with a 50 kV generator. She changes the 50kV generator to a 100 kV generator. Alice's original configuration(s) do not specify these generator options, and her change alters the performance of the System. Alice determines this is a new version or model of the System. If Alice decides to modify this device as a new installation, she must give a new System UDI-DI to the modified device. Alternatively, Alice may provide an upgrade kit as a medical device with a separate UDI-DI. This with the original System UDI-DI is used for the identification of the changed device.

Example: New diagnostic feature, not previously approved, added to device

Bella the manufacturer

Cardiac ultrasound system

Bella manufacturers a cardiac ultrasound System. She introduces a new diagnostic algorithm on the cardiac ultrasound system allowing new data calculations and imaging options. The algorithm introduces new indications for use and changes the performance of the System. Bella determines that this change results in a new model or version of the system according to her documented procedures for assessing device changes. If Bella decides to modify this device as a new installation, she must give the modified device a new System UDI-DI. Alternatively, Bella may provide an upgrade kit as a medical device with a separate UDI-DI. This with the original System UDI-DI is used for the identification of the changed device.

A new UDI-DI is not required where a changed device does not require the device to be specifically identified from the original device.

Example: System component changed of an installed device; no change in safety or performance

Indigo the manufacturer

CT system

Indigo manufactures a CT System. One of Indigo's installed CT Systems has an X-ray tube which has reached the end of its life. Indigo replaces this tube with a newer model tube without other changes to the device or its labelling. Indigo determines that this is not a new version or model of the system, according to the documented and approved description of the configuration. For example, the safety profile, the performance of the System and the intended use are unchanged. As there is no significant change to the safety, performance or the intended purpose, the System UDI-DI remains unchanged.

Example: A customer-selectable option changed for an installed device

	**Olivia the manufacturer** **CT system** Olivia manufactures a CT System that has an approved medical device ARTG inclusion, which includes several diagnostic algorithms. When a customer orders the device, they can choose which algorithms they would like activated based on their business model. A customer with an installed System purchases another diagnostic algorithm which was approved for the System because of their changing business needs. The extra algorithm may be installed or activated and does not lead to a new model or version of the System. In this circumstance, the System UDI-DI remains unchanged.

Example: Addition of an accessory for an installed device

	**Matilda the manufacturer** **System used with accessories** Matilda manufactures a System that customers can use with accessories. Customers adding or using accessories with the System is covered by what is originally specified for the defined groups of configurations. A customer adding or using an accessory with the System does not lead to a new model or version of the System. In this circumstance, the System UDI-DI remains unchanged.

Medical device accessories

Accessories are specifically intended to be used with a device. They allow or help the device to be used, in the way the manufacturer intended. UDI requirements apply where the accessory:

- is considered a medical device in its own right
- is commercially available
- has its own ARTG inclusion, and
- is in scope of devices required to meet UDI requirements.

UDI requirements do not apply if the accessory:

- is supplied as part of a convenience, medical procedure, IVD kit or system that is a medical device that has its own UDI
- is exempt from inclusion in the ARTG, or
- is otherwise exempt from UDI requirements.

Replacement parts

Replacement consumable items that a manufacturer supplies separately to the original device are considered accessories.

Spare parts

Though spare parts do not have a formal definition in Australian legislation, the term is taken to mean replacement components. These are not considered an accessory for a device, as they would not normally be supplied separately for use with the device.

UDI requirements apply to spare parts where the part:

- is considered a medical device in its own right
- is sold separately
- has its own ARTG inclusion, and
- is in scope of devices required to meet UDI requirements.

Devices principally sold in retail

Devices principally sold in retail have reduced labelling requirements for the UDI-PI. This is due to the end users of these devices (patients and carers) relying on human readable labelling to understand batch, expiry information.

It is also possible during times of supply disruptions or shortages that these devices could be redirected for use in a healthcare setting. It should be noted that in this scenario UDI-PI may not be accessible in a machine readable form.

Aidan the manufacturer and sponsor

Aidan manufactures and supplies devices to both retail premises and hospitals. Aidan supplies most of the devices to retail premises. Because of this, Aidan can label his devices with the reduced UDI requirements. Aidan labels his devices with the full UDI in non-HRI form, and the UDI-DI in machine readable form.

If Aidan begins to supply the device predominantly in hospitals or healthcare settings, Aidan will need to change his labelling to be fully UDI compliant prior to supply in these settings.

Aidan may choose to use fully UDI compliant labelling for devices he sells principally in retail, so that any changes to where he supplies his device will not impact his ability to supply the device.

The Australian UDI Database

The Australian Register of Therapeutic Goods (ARTG)

The Australian Register of Therapeutic Goods (ARTG) is the TGA's public repository of therapeutic goods that can be legally supplied in Australia. An entry in the ARTG includes information such as:

- sponsor
- manufacturer
- Global Medical Device Nomenclature (GMDN) classification code
- risk classification

- functional description
- intended purpose.

The ARTG provides approval for legal supply of goods as a 'kind of medical device'. Devices are taken to be of the same kind where they have the following characteristics:

- the same sponsor
- the same manufacturer
- the same risk classification
- the same GMDN code.

AusUDID

We established the AusUDID to store information about medical devices supplied for use in Australia. The AusUDID links to the ARTG, providing more granular data about devices approved for supply under a particular ARTG approval.

The AusUDID contains 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 retains historical information to support adverse event reporting and market actions.

The AusUDID is 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.

You can access the AusUDID here: https://ausudid.tga.gov.au/

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-DI.

Downloading device data

You can download AusUDID data in a range of formats.

Downloads can be performed for:

- individual UDI records
- the full database
- a set of search results.

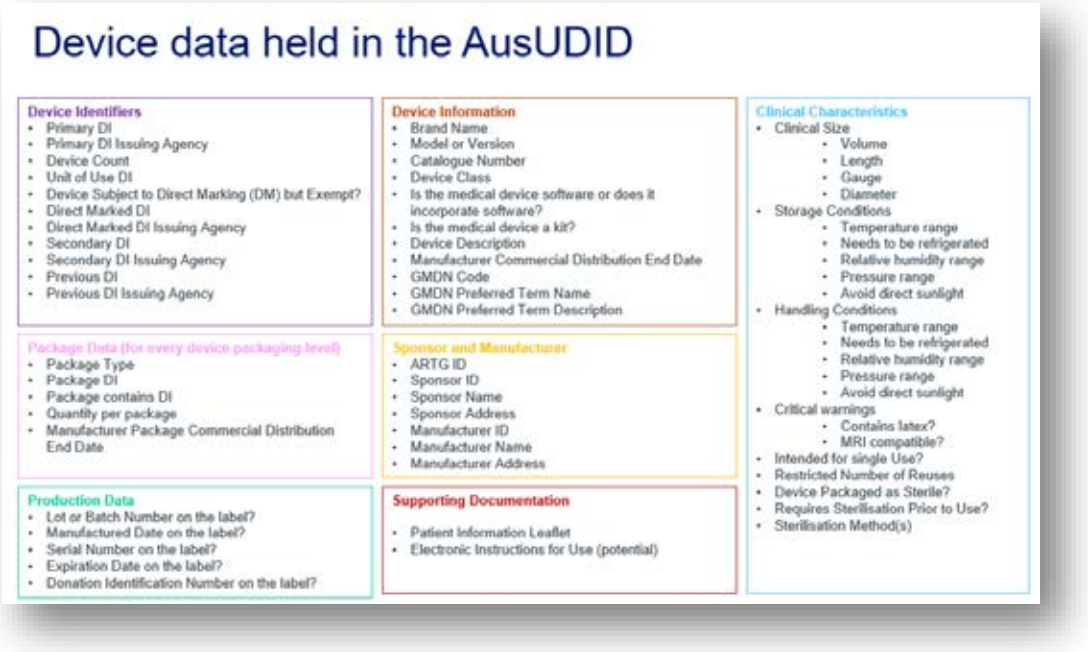
UDI record data elements

The diagram below shows the data elements that are included for each UDI record.

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.

Figure 20: AusUDID data elements



The AusUDID stores UDI-DI and related data.

The AusUDID does not store UDI-PI data.

UDI Triggers

Changes to certain characteristics of a device represent a new model of device. These are referred to as UDI Triggers. Changes to a UDI Trigger require allocation of a new UDI-DI and submission of data for that model of device as a new UDI record in the AusUDID.

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.

When a new UDI-DI is required, the manufacturer must change the affected device labels to reflect the new UDI-DI and updated data must be supplied to the AusUDID. Data must be submitted to the AusUDID within 30 days of the newly labelled device being supplied in Australia.

Multiple sponsors of the same device

Where the same device is supplied in Australia by more than one sponsor, there will be a single UDI record in the AusUDID. Each sponsor will link their ARTG record to the UDI record to reflect their approval to supply that device.

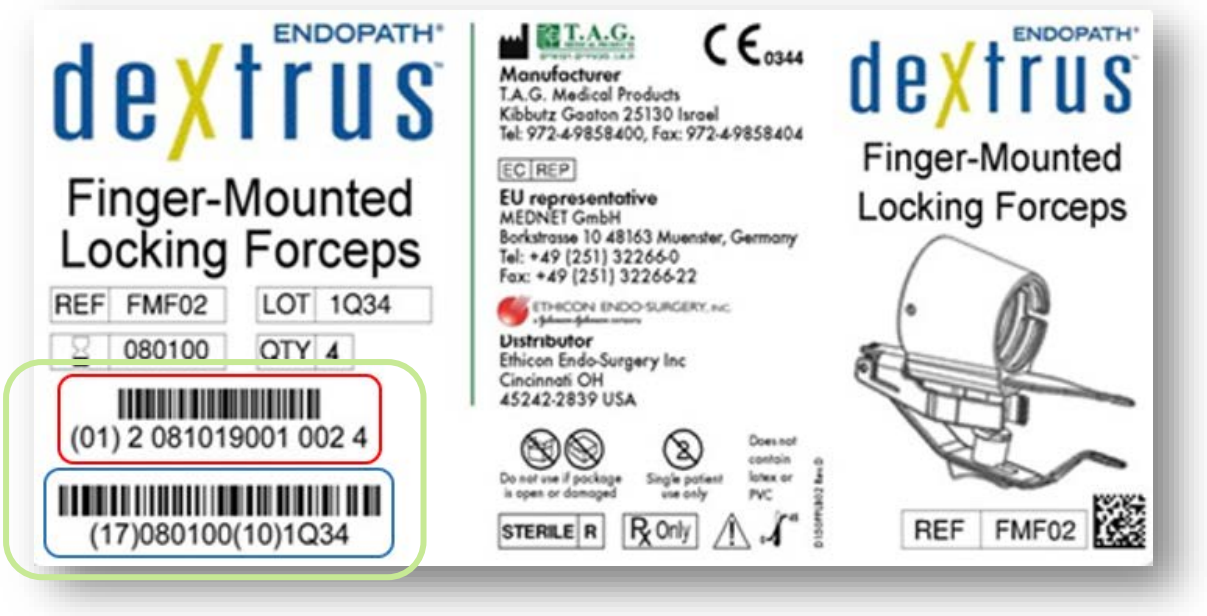
Appendix A: Examples of Unique Device Identifiers

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

- the UDI Carrier is framed in **green**
- the UDI-Device Identifier (UDI-DI) in both AIDC and HRI formats is framed in **red**
- the UDI-Production Identifier (UDI-PI) is framed in **blue**.

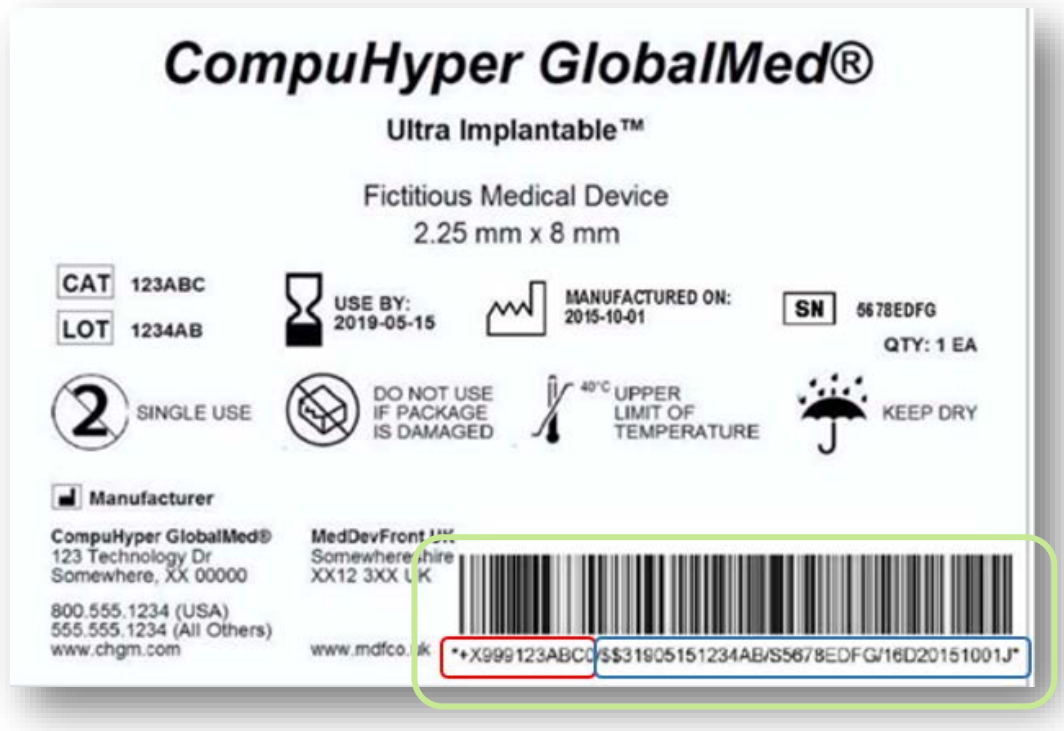
GS1 UDI example

Figure 21: Example of a GS1 label with UDI



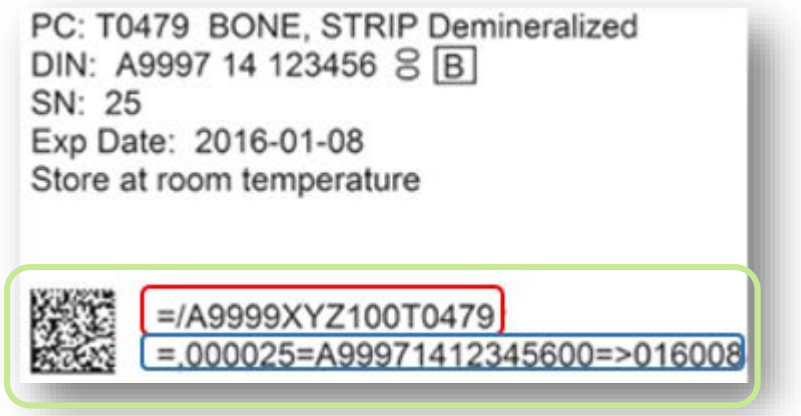
HIBCC UDI example

Figure 22: Example of a HIBCC label with UDI



ICCBBA UDI example

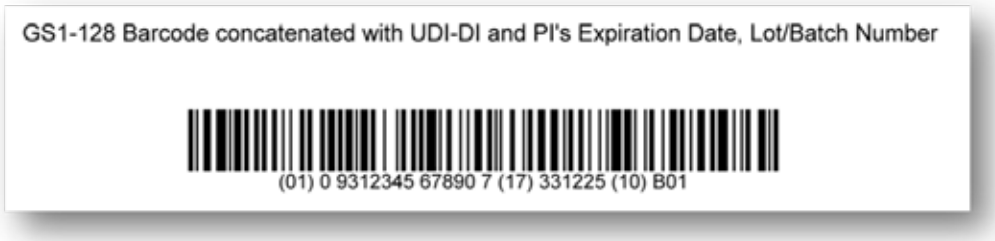
Figure 23: Example of an ICCBBA label with UDI



Appendix B: Additional examples of UDI conventions

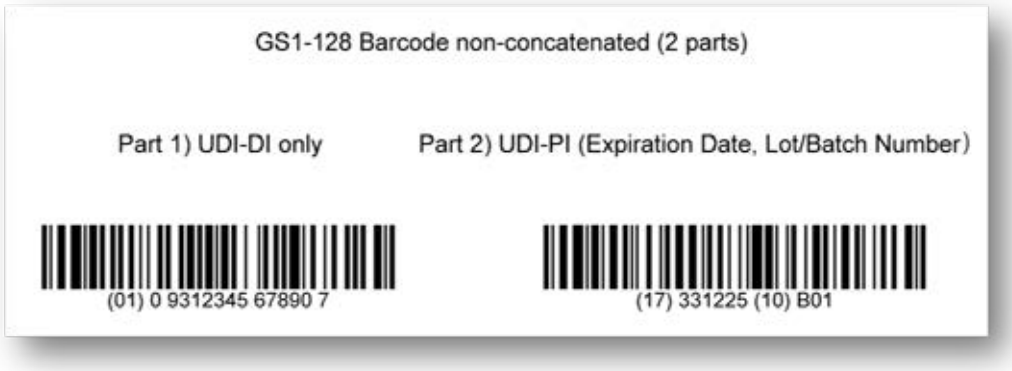
Concatenated data

Figure 24: A single linear barcode that includes UDI-DI and UDI-PI



Non-concatenated data

Figure 25: 2 separate barcodes, one represents UDI-DI and the second represents the UDI-PI



2D barcode

Figure 26: Combines UDI-DI and PI into a single 2D barcode

Appendix C: 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.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Devices Reforms Taskforce	April 2024
V2.0	Document refreshed to reflect UDI regulations introduced in March 2025.	Devices Reforms Taskforce	July 2025

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Reference/Publication #