Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

# Complying with the Unique Device Identification requirements for medical devices

## Understand the regulatory requirements for supplying UDI compliant medical devices in Australia

Version 2.0, February 2026

# Contents

# Purpose

We developed this guidance to help sponsors and manufacturers understand and comply with Australia's Unique Device Identification (UDI) requirements. It provides examples and practical instructions for implementing UDI.

While this document may reference the UDI implementations of other countries, it does not provide a comparison of Australia's UDI rules, requirements and data elements with other jurisdictions.

## Structure of this guidance

- Introduction: Explains the purpose of UDI, how it fits into the Essential Principles, and how Australia aligns with global UDI frameworks.
- Scope of UDI requirements: Helps you determine whether your device is in scope or exempt from UDI requirements.
- Understanding UDI and identifiers: Defines each type of identifier required under the UDI framework.
- Getting a UDI: Outlines how to obtain a UDI and present it through a UDI Carrier.
- UDI labelling and packaging: Details requirements for placing the UDI Carrier on labels, packaging levels, and direct marking. Explains Unit of Use purpose and requirements.
- Managing UDI Triggers : Explains which device changes require a new UDI and how to manage updates to UDI records.
- UDI for specific device types: Covers device-specific requirements for devices such as implants, medical device software, retail devices and personalised medical devices.
- The Australian UDI Database (AusUDID): Describes how to submit UDI records, manage data elements, and maintain compliance.
- UDI and other TGA processes or activities: Explains UDI's role in market actions, recalls, adverse events, Patient Implant Cards, and other regulatory requirements. Describes how audits will be managed. Includes information on demonstrating compliance with UDI-related Essential Principles.
- Summary of roles and obligations: Summarises sponsor and manufacturer obligations for UDI compliance.
- Resources: Lists additional resources for meeting UDI requirements.
- Appendices: Provides additional examples of topics covered in this guidance.

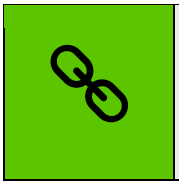
This guidance does **not** include UDI compliance dates. For guidance on UDI compliance dates including transition arrangements, see: *Complying with the Unique Device Identification timeframes for medical devices*.

## Terminology used in this guidance

This guidance uses certain terminology consistently:

- **we** refers to the Therapeutic Goods Administration (TGA)

- **you** refers to sponsors or manufacturers of medical devices or in vitro diagnostic (IVD) medical devices
- **medical devices** includes both medical devices and IVDs
- **UDI record** means a UDI-Device Identifier (UDI-DI) and related data published in the AusUDID
- **devices in scope of UDI requirements** are those that must meet UDI requirements based on their risk classification, for example Class III medical devices
- **devices not in scope of UDI requirements** are those that are not required to meet UDI requirements based on their risk classification, for example Class I non-measuring non-sterile medical devices
- **as a manufacturer** refers to organisations with the role of the manufacturer. Organisations in this role have obligations under UDI requirements that differ from those of the sponsor
- **as a sponsor** refers to organisations with the role of the sponsor; Organisations in this role have obligations under UDI requirements that differ from those of the manufacturer.



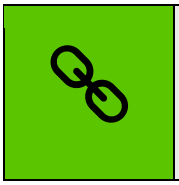
For a full list of acronyms, terms and descriptions, see UDI acronyms and glossary | Therapeutic Goods Administration (TGA).

## Symbols used in this guidance

This guidance uses symbols to show the type of content in a callout box:

The **information** symbol indicates additional details that support understanding.

The **exclamation mark** indicates important information.



The **link** symbol indicates links to extra resources.

## Legislation

Please refer to the official version of legislation Federal Register of Legislation - Therapeutic Goods Legislation Amendment (Australian Unique Device Identification Database and Other Measures) Regulations 2025.

Legislative instruments are amended from time to time and may occasionally be replaced or new instruments made.

# Introduction

The Australian Government introduced the Australian UDI system to strengthen patient safety and improve medical device traceability. This system is part of broader medical device reforms outlined in An Action Plan for Medical Devices.

The UDI system supports the identification of medical devices and other medical device reforms. It is designed to improve the effectiveness of the regulatory framework, including management of post-market safety-related activities such as recalls.

The inability to effectively and efficiently track and trace medical devices that have been supplied to or implanted into patients has constrained timely clinical and regulatory action in a number of medical device safety crises. This includes hip implants, urogynaecological mesh and breast implants.

When adopted across the supply chain, clinical and other health systems, UDI can enable easier and faster identification of medical devices. This supports:

- removal of those medical devices from storage and distribution to prevent further use
- faster identification of medical devices implanted into patients in the event of an adverse event, safety advisory or recall.

The Australian UDI Database (AusUDID) gives patients, consumers and health professionals consistent, easy access to information about the medical devices they use.

By introducing UDI, Australia joins a globally harmonised approach that enables more accurate identification of medical devices.

Please note that the Australian UDI system and the AusUDID are not designed to track inventory information for medical devices, such as stock levels. While UDI can support supply chain processes, this is only a secondary benefit, not the primary purpose of UDI regulations in Australia.

UDI requirements do **not** replace or override any existing requirements or obligations of sponsors or manufacturers of medical devices supplied in Australia. UDI requirements apply **in addition** to existing regulatory requirements.

## Global alignment

We have aligned the Australian UDI requirements with global UDI requirements where possible. This includes:

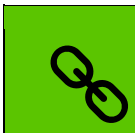
- accepting UDI Carriers compliant with European Union (EU) and United States (US) regulations
- aligning with the International Medical Device Regulators Forum (IMDRF) UDI Guidance IMDRF/UDI WG/N7FINAL:2013 and IMDRF UDI System Application Guide
- recognising internationally accepted Issuing Agencies
- minimising Australian only requirements, whilst maintaining robust regulation.

## UDI in the Essential Principles

The Essential Principles (EPs) in Schedule 1 of the *Therapeutic Goods (Medical Devices) Regulations 2002* include the UDI requirements.

The table below shows each Essential Principle that relates to UDI and where in this guidance you can find details on the requirements.

| Essential Principle | Location in this guidance |
|---|---|
| 13.5 UDI medical devices—UDI device identifier and UDI production identifier | UDI Carrier |
| 13.6 UDI medical devices—medical device packaging identifier | Packaging levels |
| 13A.2 Patient implant cards etc. for implantable devices | Patient Implant Cards |
| 13C.1 Identifiers relating to UDI medical devices | Understanding UDI and identifiers<br>Getting a UDI<br>TGA recognised Issuing Agencies |
| 13C.2 Inclusion of identifiers in the Australian Unique Device Identification Database | The Australian UDI Database (AusUDID)<br>UDI records |
| 13C.3 Inclusion of other information in the Australian Unique Device Identification Database | *Australian UDI Data Dictionary* |
| 13C.4 Information in the Australian Unique Device Identification Database to be accurate and up to date | AusUDID data elements and rules<br>Data entry rules<br>Correcting and updating UDI records |
| 13C.5 UDI device identifier and UDI production identifier to be directly marked on UDI medical device | Direct marking<br>Reusable devices |



We have also updated the *Essential Principles Checklist* to reflect these changes.

For information on demonstrating compliance for UDI-related Essential Principles, see Demonstrating compliance with UDI-related Essential Principles.

## Non-compliance

As UDI requirements form part of the Essential Principles, we may take regulatory action if you do not comply, including:

- suspension or cancellation of your devices from the Australian Register of Therapeutic Goods (ARTG)
- applying civil penalties as outlined in Part 4-11, Division 1 of the Act
- issuing infringement notices.

See the TGA website for compliance actions and outcomes.

## Consent to Supply (CTS) for noncompliant medical devices

If you cannot meet UDI requirements by the UDI compliance date, you may choose to submit an application for consent to supply.

You must lodge the application well in advance of the UDI compliance date with supporting documentation. We must consider and decide on the application before you supply the non-compliant device.

Please note that a CTS application is considered by the delegate on a case-by-case basis and granted in exceptional circumstances for limited periods of time.

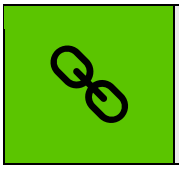
Where we grant CTS for a device, your ongoing regulatory responsibilities remain. These responsibilities include the requirement to undertake recalls, other market actions and reporting of adverse events. You can learn more on our website about your post-market responsibilities for medical devices.

For more information on CTS for UDI, see: Consent to Supply (CTS) process for UDI.

# Scope of UDI requirements

Medical devices and IVDs supplied in Australia and included in the ARTG must meet UDI requirements, unless otherwise exempt.

The scope of devices subject to UDI requirements is based on device risk classification.



To help you determine if UDI requirements apply to your device, see: Does UDI apply to my device | Therapeutic Goods Administration (TGA).

## Medical devices in scope of UDI requirements

The table below shows which medical device risk classifications must meet UDI requirements. These devices must comply with all UDI requirements, unless specifically exempt.

| Device risk classification | UDI required? |
|---|---|
| Class I | **No** |
| Class Im (measuring) | **No** |
| Class Is (supplied sterile) | **Yes** |
| Class IIa | **Yes** |
| Class IIb | **Yes** |
| Class III | **Yes** |

As a manufacturer, you may allocate and apply UDI(s) to Class I and Class Im medical devices. If you do, we recommend meeting all UDI requirements to reduce confusion for end users such as healthcare professionals.

As a sponsor, you may submit and maintain UDI records for Class I and Class Im medical devices. If you do, data must pass AusUDID validation checks.

**Note**: Your UDI record must be linked to at least one ARTG inclusion for its data to appear in the AusUDID and meet your compliance obligations.

# In vitro diagnostic (IVD) devices in scope of UDI requirements

The table below shows which IVD device risk classifications must meet UDI requirements. These devices must comply with all UDI requirements, unless specifically exempt.

| IVD classification | UDI required? |
|---|---|
| Class 1 | **Partial*** |
| Class 2 | **Yes** |
| Class 3 | **Yes** |
| Class 4 | **Yes** |

*Class 1 IVDs that are instruments or software must meet UDI requirements. These typically fall under these Global Medical Device Nomenclature Collective Terms:

- instrument/analyser IVDs (GMDN Code CT943)
- software IVDs (GMDN Code CT944).

IVDs that are also software may have further requirements. See medical device and IVD software.

As a manufacturer, you may allocate and apply UDI(s) to exempt IVDs. If you do, we recommend meeting all UDI requirements to avoid confusion for end users, such as healthcare professionals.

As a sponsor, you may submit and maintain UDI records for exempt IVDs. If you do, data must pass AusUDID validation checks.

**Note**: Your UDI record must be linked to at least one ARTG inclusion for its data to appear in the AusUDID and meet your compliance obligations.

# Devices exempt from UDI requirements

You are not required to meet UDI requirements for:

- devices exempt from ARTG inclusion
- Class I non-measuring non-sterile medical devices
- Class I measuring (Im) medical devices
- in house IVDs
- custom-made medical devices
- patient-matched medical devices with a volume of 5 or less supplied each financial year
- medical devices exempt under Special Access Scheme (SAS) or Authorised Prescriber (AP) Scheme
- Surgical Loan Kits (SLKs) at **kit level**.

Although exempt, you may choose to meet UDI requirements for these devices.

To submit UDI records to the AusUDID, you must link an ARTG ID and provide all mandatory data. Devices exempt from ARTG inclusion cannot be submitted to the AusUDID, as they lack an ARTG ID.

You also cannot submit UDI records for therapeutic goods that are not regulated as medical devices, as the AusUDID only permits goods regulated as a medical device.

You may still choose to meet labelling and packaging requirements for these products.

### Export only devices

You do not need to meet UDI requirements for medical devices and IVDs that are:

- intended for export only from Australia
- strictly not for supply in Australia.

However, you may need to meet UDI requirements of the country you supply the device to.

# Understanding UDI and associated identifiers

All medical devices in scope of UDI requirements must have a UDI. Some devices also require additional identifiers, depending on:

- the type of device
- how the device is packaged.

This section outlines the main identifiers in Australia's UDI and their relationships.

For more detailed information on each identifier, refer to the sections that follow in this document.

## Unique Device Identifier (UDI)

**A UDI identifies a specific model and production run of a medical device.**

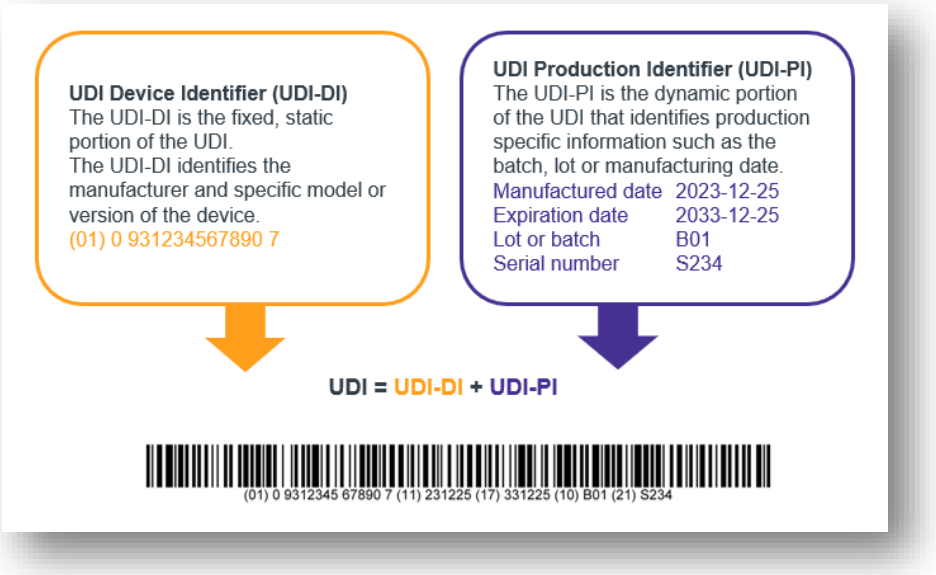
It has 2 parts:

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

The full UDI links a model to its production run and is used to trace the model of device down to the batch, lot or manufacturing date.

*Example: If a recall affects one production run, the UDI-DI identifies the model, and the UDI-PI identifies the affected batch.*

*Figure 1: Example of how a UDI-DI and UDI-PI form the full UDI*




## UDI-Device Identifier (UDI-DI)

**The UDI-DI is a globally unique numeric or alphanumeric code that identifies the device model.**

The UDI-DI must appear on the device label, packaging, and in some cases on the device itself. It is also submitted to the AusUDID as the 'Primary DI'.

The image below shows the UDI-DI portion of a UDI.

*Figure 2: Example of UDI-DI in a UDI Carrier*


The UDI-DI is used to:

- search the AusUDID
- identify models of device in regulatory events such as recalls and adverse events.

**A TGA recognised Issuing Agency must issue the UDI-DI to ensure global uniqueness.**

We accept the following identifiers as a UDI-DI:

- GS1 Global Trade Item Number (GTIN)
- Health Industry Bar Code – Universal Product Number (HIBC-UPN)
- ICCBBA ISBT 128 Processor Product Identification Code (PPIC).

Each model of medical device must have a unique UDI-DI. If you supply multiple models under a single ARTG inclusion, you must allocate a different UDI-DI to each model. In this scenario, each UDI record will link to the same ARTG inclusion.

**Sabrina the sponsor**

Sabrina supplies 5 models of medical device under a single ARTG inclusion.

Sabrina must allocate a UDI-DI for each model. This means that Sabrina has 5 UDI-DIs linked to one ARTG.

Sabrina applies a full UDs, consisting of the UDI-DI and UDI-PI, to each corresponding model of medical device.

Sabrina submits 5 UDI records to the AusUDID, linking each UDI record to the same ARTG inclusion. Sabrina does not incur any fees or charges for the 5 UDI records she created in the AusUDID.

## UDI-Production Identifier (UDI-PI)

**The UDI-PI identifies production details such as batch, lot, software version or manufacturing date.**

The UDI-PI must appear on the device label, packaging, and in some cases on the device itself. However, the UDI-PI is not stored in the AusUDID.

The image below shows the UDI-PI portion of the UDI.

*Figure 3: Example of UDI-PI in a UDI Carrier*


Production identifiers vary depending on your device type and labelling practices. There is no limit to the number of identifiers included in a UDI-PI.

As a manufacturer, you are responsible for determining which production identifiers to include based on device type and the information provided on the label. You should follow the specifications of your chosen Issuing Agency.

**UDI-PI requirements:**

- If your label includes a **lot number**, **serial number**, **software identification** or **expiry date**, it must be included in the UDI-PI.
- If your label includes a **manufacturing date** on the label, it does **not** need to be included in the UDI-PI. If the manufacturing date is the **only** production identifier on the label, it **must** be used as the UDI-PI.
- If your device is an active implantable medical device, you must include the **serial number** in the UDI-PI.
- If your device is any other implantable device, you must include the **serial number** or **lot number** in the UDI-PI.
- If your device is software, the **software version** is considered to be the manufacturing control mechanism and must be included in the UDI-PI. Note that minor software revisions require a new UDI-PI, but not a new UDI-DI.

- If your device contains a **Donation Identification Number** (DIN) or a **division identifier,** it must be included in the UDI-PI.

Your chosen Issuing Agency may have specific requirements for production identifiers. You are responsible for confirming whether your device requires any specific inclusions in the UDI-PI.

You must not remove other production information from the device label, even if it is also part of the UDI. This includes the expiry date, manufacturing date and lot number.

## Primary DI

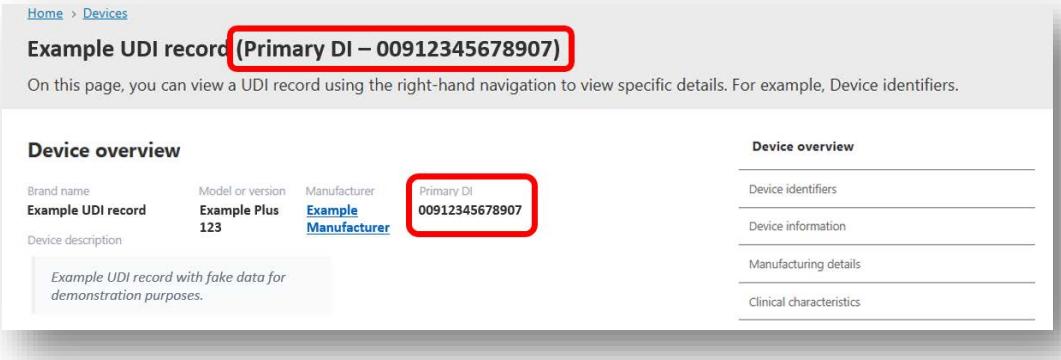
The Primary DI is not an additional identifier – it is synonymous with the UDI-DI. It is referred to as the Primary DI in the AusUDID, as it is the primary lookup value.

The Primary DI is the UDI-DI portion of the UDI applied to the lowest level of packaging of a device.

The images below show how the UDI-DI and Primary DI are the same.

*Figure 4: Example of UDI-DI matching a UDI record*


*Figure 5: Example of Primary DI in a UDI record matching UDI-DI*




## Direct Marking DI

Some devices are required to have the UDI directly marked onto the device itself. The UDI permanently marked on the device is referred to as the Direct Marking DI. The Direct Marking DI ensures reusable devices remain identifiable after it is removed from its packaging or the label is removed.

It may match or differ from the UDI-DI on the label.

*Example: A reusable surgical instrument must have the UDI directly marked onto the device itself. The UDI engraved, etched or marked onto the device is the Direct Marking DI. It may be the same as the UDI on the device label, or it may be different.*

*Figure 6: Example of a UDI Carrier directly marked on a device*

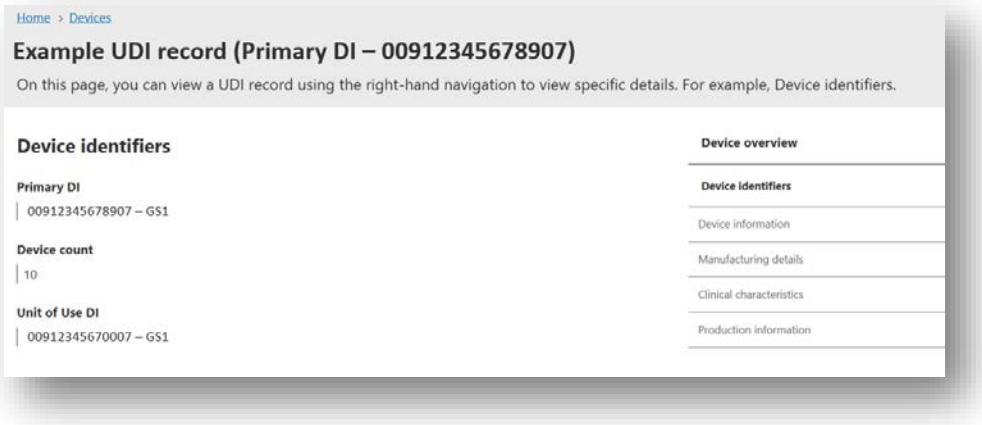

For more information, see: Direct marking.

## Unit of Use DI

If a base package contains multiple instances of the same model of device and the devices are not individually labelled with a UDI, the devices must be allocated a Unit of Use DI. This identifier is virtual. It does not appear on the label, packaging, or the device but it must be provided in the UDI record in the AusUDID.

The image below shows how the Unit of Use DI is included in a UDI record.

*Figure 7: Example of Unit of Use DI included in a UDI record*




The Unit of Use DI allows the use of the individual device to be associated with a patient.

*Example: A base package contains 10 syringes. The syringes are not individually labelled with a UDI. The base package is allocated a UDI-DI (Primary DI), and the syringes within the base package are allocated a Unit of Use DI.*

For more information, see: Unit of Use.

## Package DI

Package DI(s) are UDIs applied to packaging levels above the base package. They follow standard UDI requirements, and they are submitted to the AusUDID as Package DI(s).

Package DIs help find devices when multiple packaging levels exist between the device and the outer carton(s).

*Example: A base package contains one medical device. A box contains 5 base packages. A carton contains 5 boxes. A Package DI must be allocated to the box and the carton. If the carton is used for shipping purposes only, it is considered a logistics unit and is exempt from UDI requirements.*

For more information, see: Packaging levels.

## Secondary DI

You are not required to allocate more than one UDI-DI to a model of device. However, in some cases, devices may be allocated with a UDI-DI from more than one Issuing Agency. The Secondary DI enables identification of the device using any of these identifiers.

While the Primary UDI-DI is the only UDI-DI on the label, you may include the Secondary DI in your UDI record and support scenarios when the Secondary DI is used.

*Example: A device bears a HIBCC UDI-DI but is also supplied through GS1's National Product Catalogue. Because of this, the device will also be allocated a GS1 UDI-DI. Both UDI-DIs can be submitted in the UDI record, with the UDI-DI on the label must be submitted as the Primary DI. If a hospital's inventory management system refers to the GS1 allocated UDI-DI, the device can still be identified and located.*

## Previous DI

A Previous DI allows for the identification of a device that was assigned a new or substitute device identifier for reasons other than changes to the device physical specifications or new indications for use that changed the version or model.

When a device changes in a way that triggers a new UDI-DI, the Australian UDI requirements stipulate that you create a new UDI record. The Previous DI provides a means to link the 2 UDIs via 2 records in the AusUDID

*Example: A devices brand name changes, which is a UDI Trigger, and a new UDI-DI must be assigned to the device with the new brand name. A new UDI record must be created for the new UDI-DI and the Previous DI will allow linking of the 2 UDI records, showing the relationship between the different brand-named devices.*

## Summary of identifiers

The below table summarises the various identifiers, their use and whether they are included in the AusUDID.

| Identifier | Purpose | Required on label? | Required in the AusUDID? |
|---|---|---|---|
| UDI-DI | Identifies device model | Yes | Yes |
| UDI-PI | Identifies production run of the device | Yes | No |
| Direct Marking DI | Identifies reusable devices when separated from their packaging | Required on the device itself | Yes |
| Unit of Use DI | Identifies devices at unit-of-use level | No | Yes |

| Identifier | Purpose | Required on label? | Required in the AusUDID? |
|---|---|---|---|
| Package DI | Identifies device at higher packaging levels | Required on packaging | Yes |
| Secondary DI | Additional UDI-DI | No | Optional |
| Previous DI | Links old and new UDI records | No | Optional |

# Getting a UDI

All identifiers required under the UDI framework must be issued by a TGA recognised Issuing Agency. This same Issuing Agency must issue the:

- UDI-DI
- Direct Marking DI
- Unit of Use DI
- Package DI.

Secondary DIs and Previous DIs can be issued by a different Issuing Agency.

The UDI-PI is not issued by an Issuing Agency. Instead, it is created using your device's production information and must conform with the coding standard provided by your chosen Issuing Agency.

UDI-DIs issued by any other organisation or unrecognised Issuing Agency do **not** comply with Australia's UDI requirements.

You will **not** be compliant if you create your own UDI-DI(s).

## Manufacturer and sponsor responsibilities

In most scenarios, it is the manufacturer's responsibility to obtain and apply a UDI to a device. This is because this process is most effectively and efficiently carried out during the manufacture process.

As a manufacturer, you are responsible for selecting a TGA recognised Issuing Agency to issue identifiers for the devices you manufacture.

As a sponsor, you should liaise with your manufacturer(s) if you have a preferred Issuing Agency.

## TGA recognised UDI Issuing Agencies

We recognise the following UDI Issuing Agencies, consistent with those accepted in the United States and European Union:

| Issuing Agency | Contact |
|---|---|
| GS1 | customer.service@gs1au.org |
| Health Industry Business Communications Council (HIBCC) | info@hibcc.org |

| Issuing Agency | Contact |
|---|---|
| The International Council for Commonality in Blood Banking Automation (ICCBBA) | Support@isbt128.org |

## United States (US) and European Union (EU) UDI compliant labels

We accept UDI Carriers that meet EU or US UDI requirements, if:

- the UDI-DI has been issued by a TGA recognised Issuing Agency, and
- the label complies with Australia's existing regulatory and labelling requirements.

*Example: A device bears a US FDA compliant UDI Carrier and meets all existing Australian regulatory and labelling requirements. The UDI-DI was issued by a TGA recognised Issuing Agency. This UDI Carrier can be used in Australia to meet UDI requirements.*

You may supply devices in Australia with US or EU UDI-complaint labels, even if those devices are exempt from UDI requirements. However, we recommend submitting a UDI record to the AusUDID for these devices to help reduce confusion for end users.

If you are an Australian manufacturer exporting to the US or EU, you may use the same UDI Carrier for devices supplied in Australia. It is your responsibility to determine if there are any additional requirements you must meet for these other jurisdictions.

# UDI labelling and packaging

As a manufacturer, you must apply a UDI to:

- the device label
- the device itself, if direct marking applies
- all applicable higher levels of packaging
- Patient Implant Cards (PICs), if applicable.

UDIs are applied in the form of a UDI Carrier.

## UDI Carrier

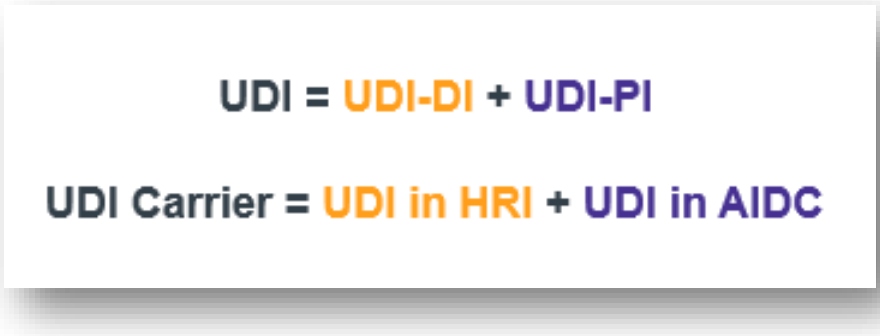
The UDI Carrier is the physical means to convey the UDI. The UDI Carrier displays the full UDI (UDI-DI and UDI-PI) in 2 forms:

- Human Readable Interpretation (HRI)
- Automatic Identification Data Capture (AIDC).

This is to ensure the device can be both read by humans and machines.

The image below demonstrates how the UDI-DI plus the UDI-PI form the full UDI, and how the full UDI in HRI and AIDC form the UDI Carrier.

*Figure 8: Example of UDI-DI and UDI-PI forming a full UDI, and the full UDI in HRI and AIDC forming a UDI Carrier*




## Human Readable Interpretation (HRI)

The HRI form is a legible version of the data encoded in the UDI Carrier. It is typically placed next to or below the AIDC form. This form allows for the UDI to be captured manually when the AIDC form cannot be captured.

In the HRI form:

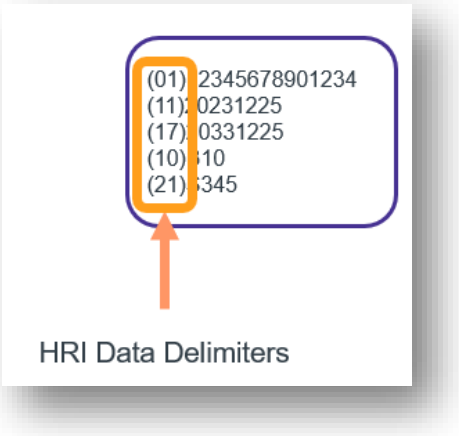
- list the UDI-DI first, followed by the UDI-PI, including HRI data delimiters
- include any non-UDI elements after the UDI-PI, if applicable.

*Figure 9: Example of HRI*


**HRI data delimiters**

The HRI portion of the UDI Carrier must include data delimiters, unless exempt*. These may also be known as qualifiers or application identifiers.

*Figure 10: Example of HRI data delimiters*




Data delimiters help to:

- distinguish the information in the UDI
- access the encoded data in case of damaged or unreadable AIDC forms.

Data delimiters vary between Issuing Agencies. Your chosen Issuing Agency can provide guidance on the correct data delimiters and formatting.

## Non-HRI

Non-HRI refers to human-readable formats that are not structured as HRI, such as plain text. Devices principally sold in retail do not require the UDI in HRI. Instead, they can display the UDI in a non-HRI or plain text format.

Because HRI is not required for these devices, HRI data delimiters are also not required.

*Figure 11: Example of non-HRI*

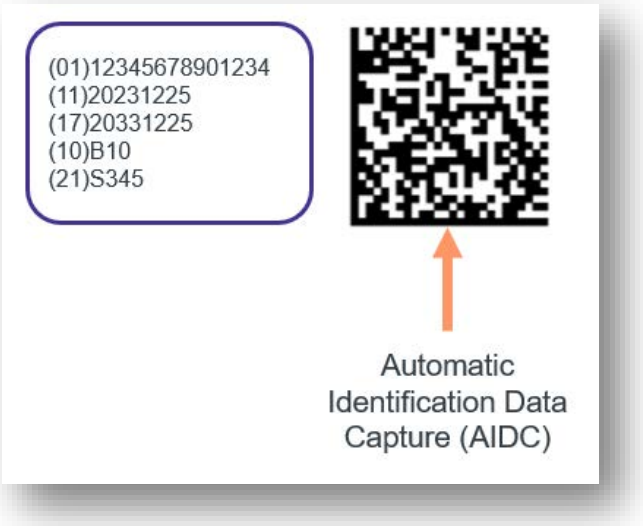

## Automatic Identification and Data Capture (AIDC)

We do not restrict AIDC to a specific symbology, recognising that different formats may suit different settings and use. Acceptable AIDC technologies include:

- linear barcodes (1D)
- data matrix barcodes (2D)

- smart cards, biometrics
- Radio Frequency Identification (RFID).

*Figure 12: Example of AIDC*




If you use RFID technology, you must:

- comply with open and commercially acceptable, international standards such as ISO/IEC 17360:2023, and
- also provide a linear, 2D barcode or another type of barcode on the label to maintain usability for systems with varying technological capabilities.

If you use linear bar codes, you may present the UDI-DI and UDI-PI as either:

- concatenated (combined) barcodes
- non-concatenated (separate) barcodes.

Regardless of format, all elements must be clearly distinguishable and identifiable.

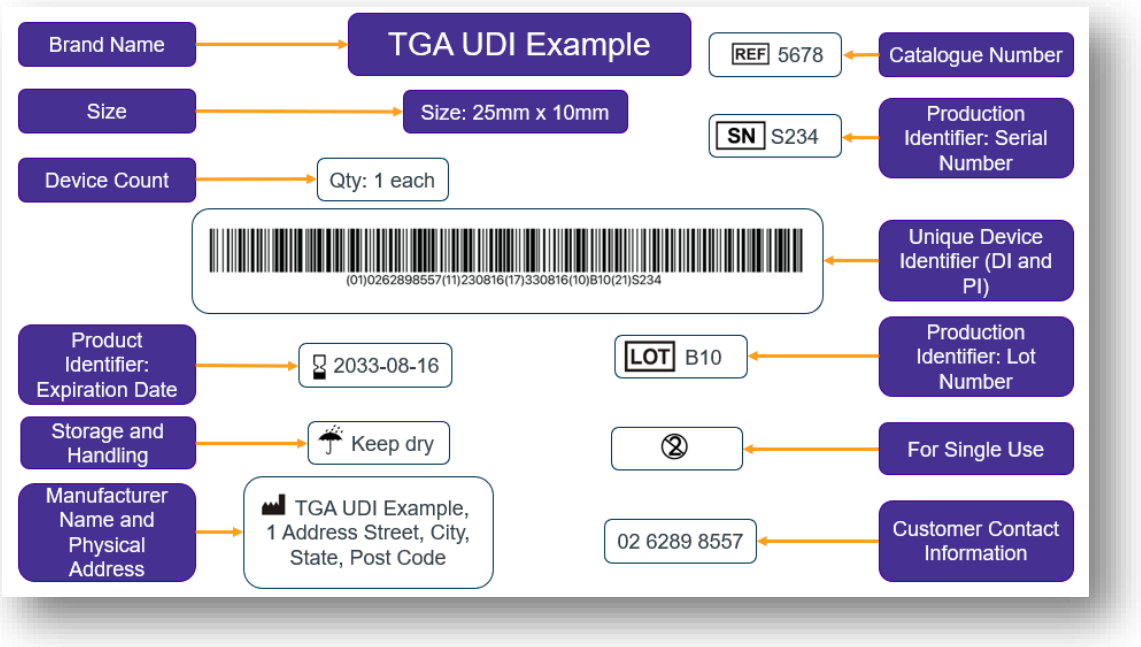
While non-concatenated barcodes are acceptable under UDI regulations, they may cause confusion for end users. Manufacturers must decide whether concatenated or non-concatenated are more appropriate.

Issuing Agencies may recommend specific formats, such as 2D data matrix over linear barcodes. You must consult with your chosen Issuing Agency to confirm the appropriate format for your device.

For examples of UDI Carrier conventions, see: Appendix A: Examples of UDI Carriers.

## UDI Carrier and device label example

*Figure 13: Example of a UDI Carrier included in a device label*




## UDI Carrier placement

As a manufacturer, you are responsible for placing the UDI Carrier on the device label and all applicable higher levels of packaging. You must also determine the most appropriate placement of the UDI Carrier. It should be positioned so that the AIDC format is accessible during normal use or storage.

If the device is subject to direct marking requirements, the UDI Carrier must be directly marked onto the device itself, unless exempt.

Each Issuing Agency provides its own technical specifications for UDI Carriers, including:

- type
- size
- placement
- quality.

As a manufacturer, you should consult your chosen Issuing Agency to select the most appropriate UDI Carrier.

## Multiple barcodes on a single label

We recommend you avoid placing multiple barcodes on a label.

If a label contains multiple barcodes, you should ensure that consumers and healthcare can easily distinguish the UDI Carrier from other barcodes.

We recommend the use of UDI ISO symbol (ISO 15223-1, UDI Graphical Symbol 5.7.10, 2021) to assist the identification of the UDI.

*Figure 14: UDI ISO symbol*


If your device is packaged with a medicine and bears medicine serialisation, we recommend you use the UDI ISO symbol to clearly distinguish the UDI.

## Exemptions for UDI Carrier

**Significant space constraints limiting the use of HRI or AIDC**

If there are significant constraints that prevent the use of both AIDC and HRI on the label, you should prioritise the AIDC form. However, in certain environments, such as home care, HRI may be more appropriate than AIDC. It is the manufacturer's responsibility to determine which form is best suited.

The manufacturer is responsible for determining whether the constraints are significant and limit the use of both HRI and AIDC. You may be required to justify this decision to the TGA, when requested.

**Significant space constraints limiting the UDI Carrier being applied to the base package**

If there are significant constraints that prevent the UDI Carrier being applied to the base package, it is acceptable to apply the UDI to the next higher level of packaging.

The manufacturer is responsible for determining whether the constraints are significant and limit the application of the UDI on the base package. You may be required to justify this decision to the TGA, when requested.

**Devices principally sold in retail**

Devices that are principally sold in retail are not exempt from UDI requirements. However, these devices have reduced labelling requirements.

See: devices principally sold in retail.

# Packaging levels

To allow the device to be tracked throughout the supply chain, UDIs must be applied to every applicable level of packaging across every packaging configuration. The UDI-DI on the base package is referred to as the Primary DI, and all other UDI-DIs on packaging levels are Package DIs.

The Package DI allows for all packages containing a specific device to be easily identified when in storage.

## Applicable packaging levels

Applicable levels of packaging include:

- the base package
- secondary package

- tertiary package
- any additional higher levels of packaging.

Logistics or shipping units are **not** applicable levels of packaging. These units do **not** require a Package DI; however, you may choose to apply one.

Examples of logistics units that do **not** need a Package DI include:

- shipping units
- Shelf Ready Packaging (SRP) used as advertising
- cartons used only for shipping
- shipping invoices
- any other form of shipper.

## Base package

The base package is the **lowest level** of the device packaging. It is typically the smallest package distributed commercially. Sometimes, it is the only packaging and may be called the base unit or 'each'.

If there are significant constraints that prevent the UDI Carrier being applied to the base package, it is acceptable to apply the UDI to the next higher level of packaging, which is then considered the base package from the perspective of UDI.

The Primary DI is assigned to the Base Package.

If the base package contains more than one unpackaged and unlabelled instance of the device, you must also allocate a Unit of Use DI, unless otherwise exempt.

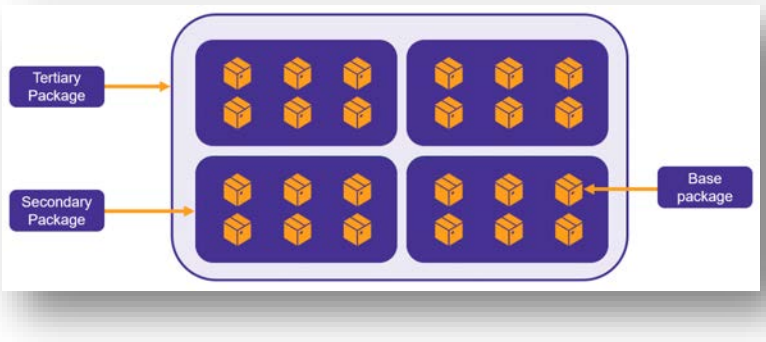
## Secondary, tertiary and additional packaging levels

Packaging levels above the base package can be referred to as 'Secondary' and 'Tertiary' packages.

Secondary packages contain a set number of base packages. Tertiary packages contain a set number of secondary packages. Additional packaging levels are any above tertiary.

The example below shows how these levels may appear in a packaging configuration.

*Figure 15: Example of how packaging levels appear in packaging configurations*

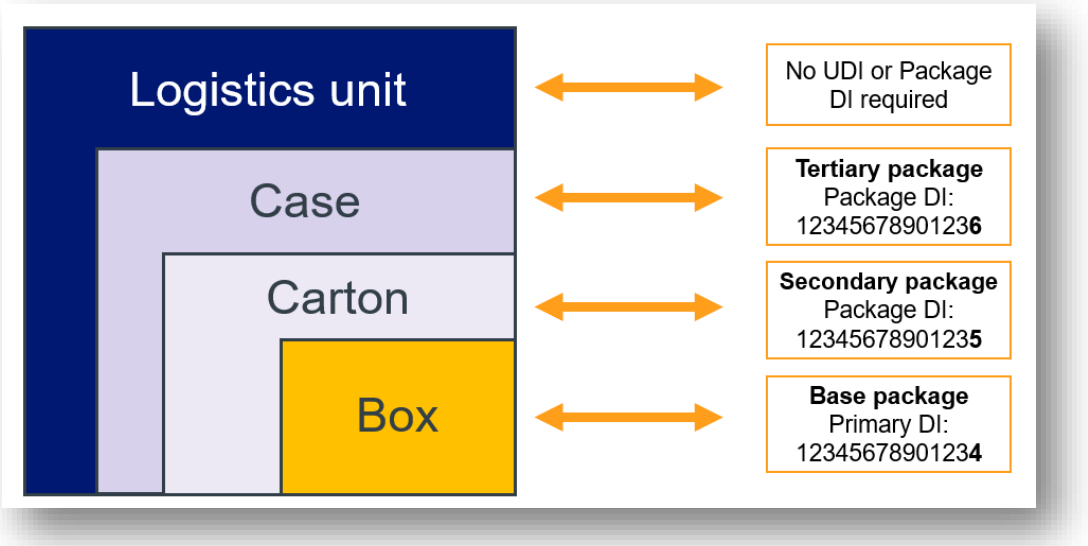


## Applying UDIs to packaging levels

Each packaging level is allocated its own full UDI. The UDI-DI on the base package is the Primary DI, and the UDI-DI on higher levels of packaging is the Package DI. Every Package DI must be unique to the level of packaging.

The example below shows the relationship between different packaging levels, UDI requirements at each level, and how each UDI-DI is unique.

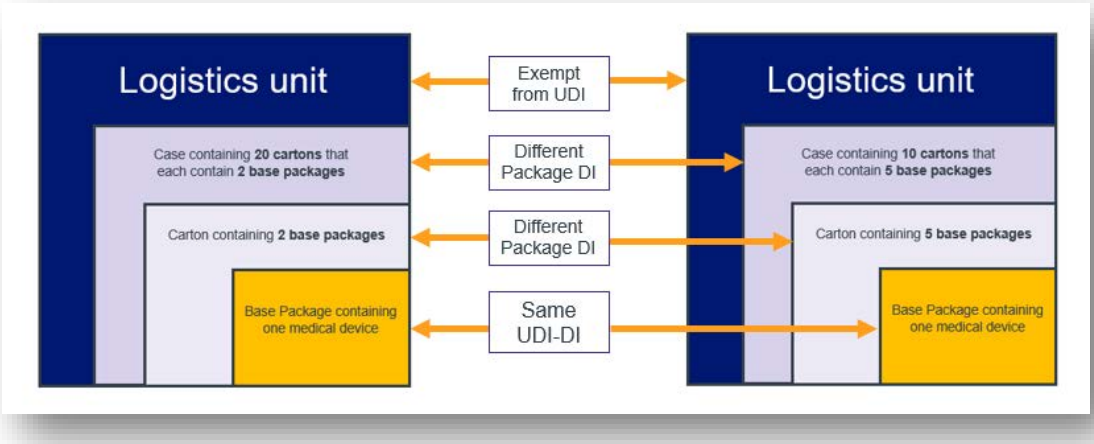
*Figure 16: Example of relationship between different packaging levels*




Where a device is supplied in multiple configurations, a unique Package DI must be applied to each packaging level for each packaging configuration.

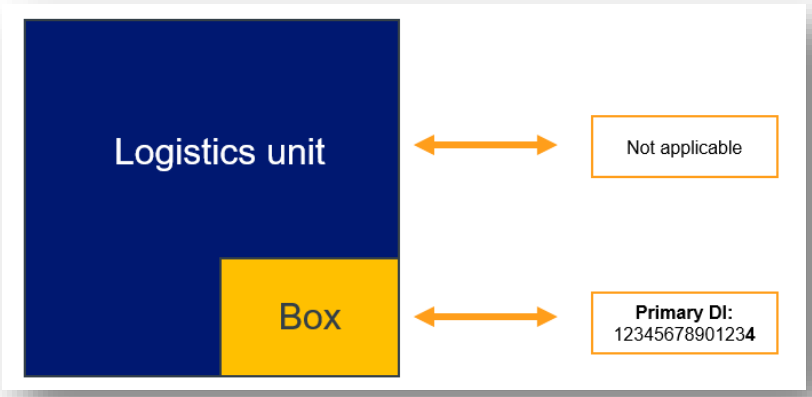
In the example below, there would be one Primary UDI-DI and 2 packaging configurations representing the different packaging options.

*Figure 17: Example of different packaging configurations*




Where the base package is the only packaging level, no Package DIs are required. The below image shows how a device may be packaged that does not require Package DIs.

*Figure 18: Example of a base package*

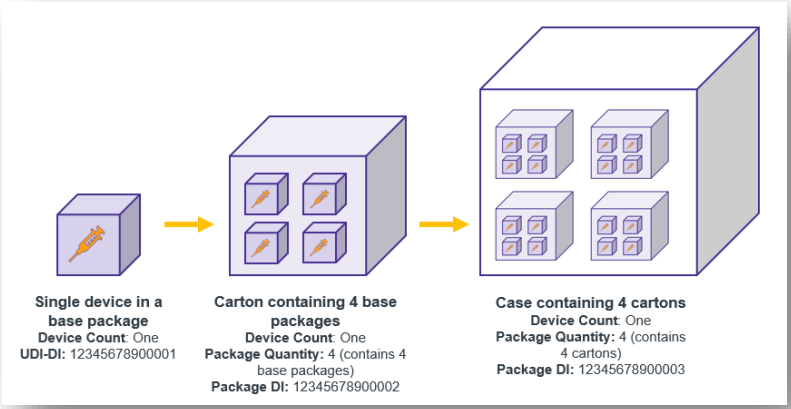



## Examples of UDI on packaging

The image below shows a syringe with 3 packaging levels:

- **Base package**: One syringe with UDI-DI 12345678900001.
- **Secondary package**: Carton with 4 base packages, with Package DI 12345678900002
- **Tertiary package**: Case with 4 cartons (each with 4 syringes), with Package DI 12345678900003.

*Figure 19: Example of a full packaging configuration*

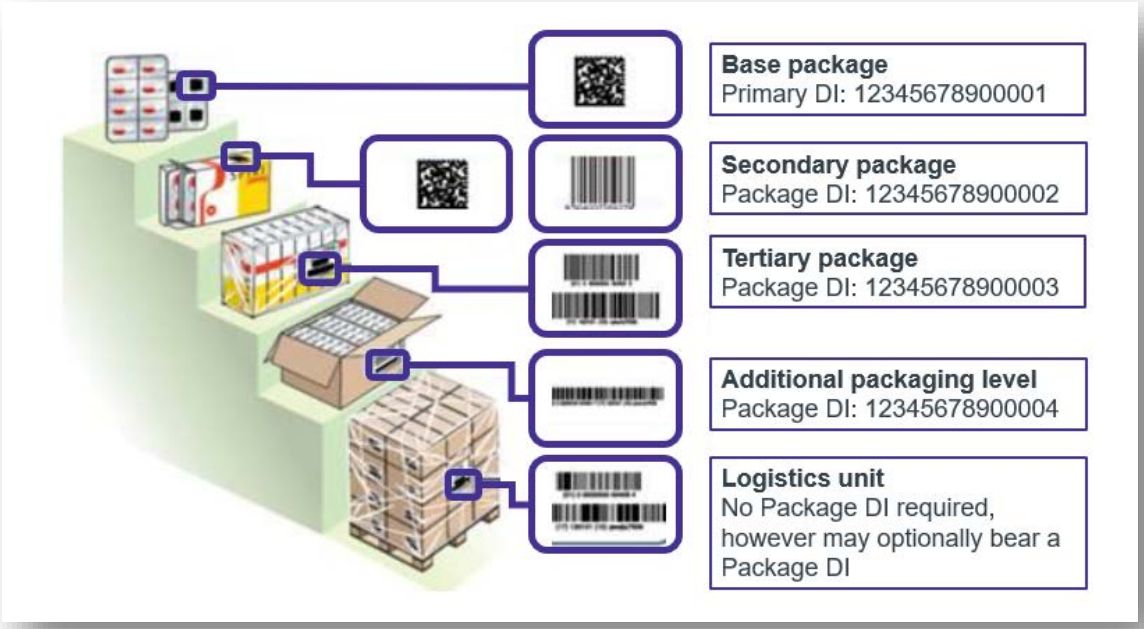



The image below shows how a unique UDI is applied to each level of packaging using GS1 issued identifiers.

In this example:

- Primary DI 12345678900001 is the base package UDI-DI or Primary DI
- The higher levels of packaging have unique GTINS representing the Package DIs for each level.

*Figure 20: Example of GS1 issued UDI-DIs allocated to every applicable packaging level*



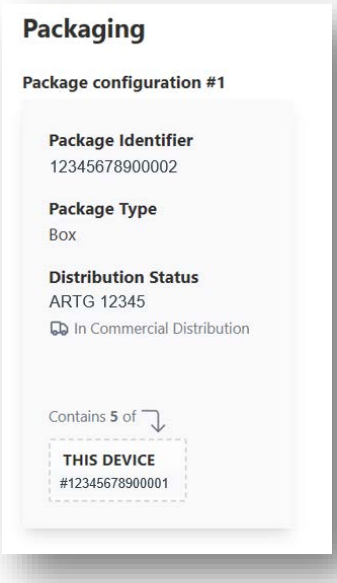

## Packaging level data in the Australian UDI Database

**The UDI-DI on the base package is submitted in the UDI record as the 'Primary DI'.**

Where your device has higher levels of packaging that must bear a UDI, the UDI-DIs on the higher levels of packaging are submitted in the UDI record as a 'Package DI'.

The image below shows how packaging information displays in a UDI record the AusUDID. The Primary DI on the device label is 12345678900001 and 5 of these devices are supplied in a box that has the Package DI of 12345678900002 on the label.

*Figure 21: Example of packaging information displayed in a UDI record*



If your device has no higher packaging levels, you do not need to allocate a Package DI or submit packaging information to the AusUDID.

In the circumstance where there are multiple sponsors for a medical device that bears the same UDI, packaging configurations may differ for each sponsor. The manufacturer should still allocate the UDI for the device and all applicable levels of device packaging.

As a sponsor, if you choose to distribute your devices in different packaging configurations, you must obtain the Package DIs from the manufacturer, apply them to each applicable level of packaging and provide the Package DIs in your UDI record.

## Retail packaging

Devices principally sold in retail premises have reduced labelling requirements. These devices:

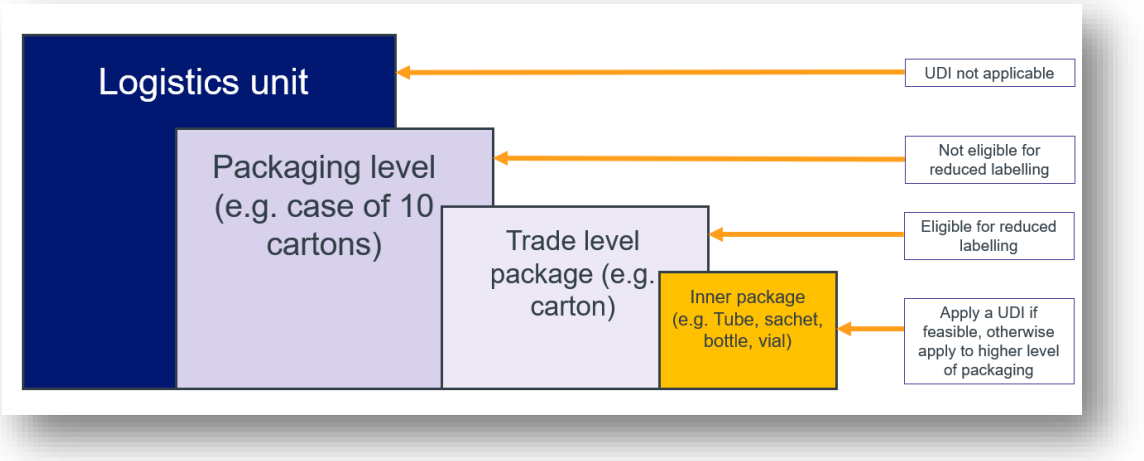
- can have reduced labelling on the trade level of packaging, which is generally considered the level of packaging that is consumer-facing
- must have full UDI-compliant labelling on any other levels of packaging, including secondary and tertiary packaging levels.

As with devices supplied to healthcare, devices principally sold in retail premises:

- do not require UDI on Shelf Ready Packaging (SRP)
- do not require UDI on logistics units, as logistics units are not required to meet UDI requirements.

The image below shows how UDI applies to different levels of retail packaging.

*Figure 22: Example of retail packaging levels*




# Direct marking

Direct marking permanently applies a UDI to the device itself. The UDI that is directly marked is called the Direct Marking DI.

Direct marking helps identify reusable devices when they are no longer accompanied by packaging or labels.

As a manufacturer, you must directly mark the full UDI on the device if it:

- is reusable, and
- is reprocessed between use on different patients.

It must withstand the normal use and cleaning for the device's lifetime.

Applying the label directly to the device or printing the label directly onto the device will meet the UDI labelling requirements however this is not referred to as direct marking.

Direct marking applies when the device requires permanent marking on the device, if the label cannot withstand the reprocessing of the device. If the label will not be damaged by the cleaning of the device through its lifetime, direct marking is not required. For example, capital equipment such as a MRI machine could have the UDI label affixed to the machine as a sticker or metal plate; it does not need the UDI directly marked if the label will remain intact after the intended cleaning that takes place over the life of the device.

While you are expected to label these devices with a UDI (unless otherwise exempt); the 'direct marking' requirements do not apply.

For more information, see capital equipment.

## Direct marking placement

We do not specify how or where you directly mark your device. There are many options available for direct marking of devices. Your chosen Issuing Agency can give you recommendations on aspects of direct marking, considering factors such as:

- substrate requirements
- dimensions
- quality
- placement
- suitable methods.

As a manufacturer, you are responsible for:

- selecting the direct marking method
- ensuring the directly marked UDI can withstand normal use and cleaning procedures for the device's lifetime.

If there are significant constraints limiting the direct marking of both AIDC and HRI on the device, the AIDC form is favoured. However, you should consider the environments or use situations for the device. For example, home care use may warrant the use of HRI over AIDC. As a manufacturer, it is your responsibility to give your reasoning for the direct marking form selected, when requested by us.

A Direct Marking DI can be the same or different to the UDI-DI on the base package (Primary DI). As a manufacturer, it is your responsibility to decide if you wish to make this distinction. As the sponsor, it is your responsibility to ensure the data in the AusUDID reflects this decision.

Cases where the direct marking UDI-DI may be different to the UDI-DI for a device include where a device is:

- packaged in both single and multiple packs
- provided both in sterile and non-sterile packaging
- provided in different sizes which are sold together.

## Direct marking exemptions

Direct marking exemptions apply for:

- devices that are reprocessed between uses on the same patient*
- implantable devices
- devices where any type of direct marking would interfere with the safety or performance or effectiveness of the device
- devices where it is not technically feasible to directly mark the device
- devices that are manufactured and labelled prior to the direct marking compliance date for the device.

*If the device is subsequently reprocessed for use on another patient, the direct marking exemption does not apply.

When a medical device is exempt from direct marking, the UDI must be on the next level of packaging.

As a manufacturer, it is your responsibility to give your reasoning for not meeting the direct marking requirements, when requested by us.

You may not be required to directly mark capital equipment. However, you are required to meet UDI labelling requirements for these devices.

Devices that you manufacture and label before their direct marking mandatory compliance dates are exempt from direct marking requirements for the lifetime of the device.

# Unit of Use

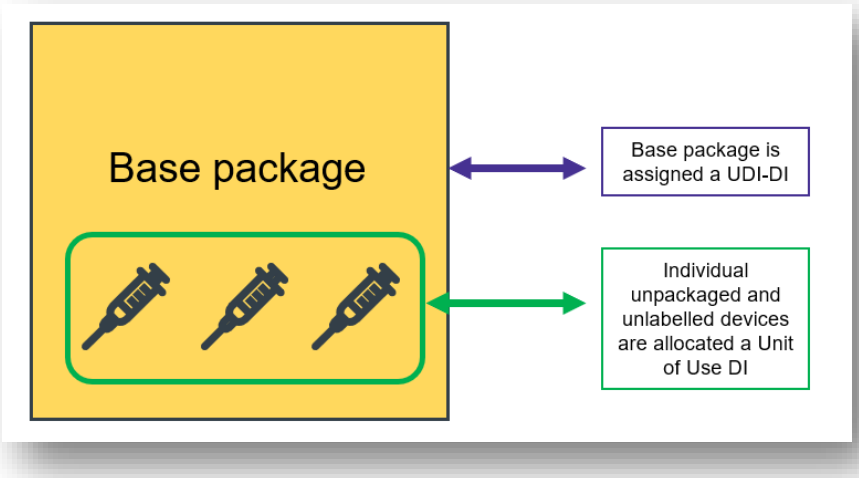
The Unit of Use Device Identifier (Unit of Use DI) is a virtual identifier allocated to an individual medical device when:

- you supply more than one of the same device in a base package, making the device count in the base package greater than one, and
- you are unable to label or directly mark the individual devices in the base package.

The purpose of the Unit of Use is to associate the use of a device to or on a patient when a base package contains more than one of the same device.

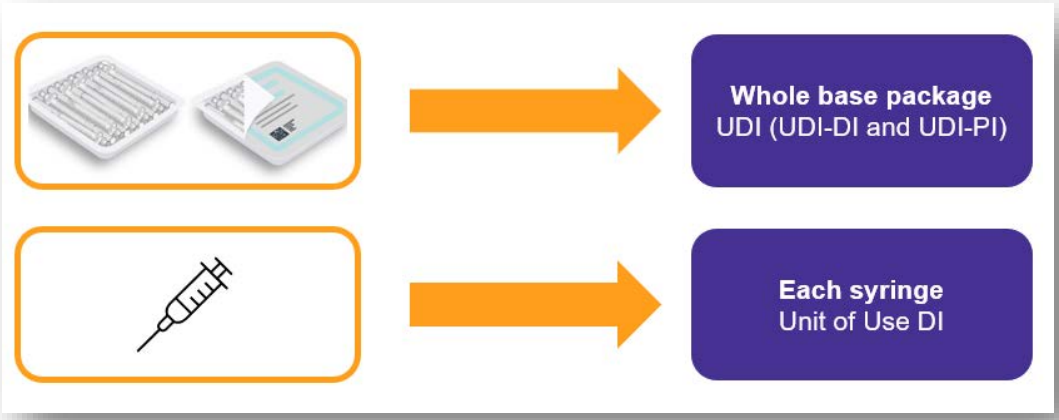
The image below shows how a Unit of Use DI is allocated to devices below the base package. Note that all devices below the base package level are the same and therefore share the same Unit of Use DI. That is, you do not allocate a different Unit of Use DI to each individual item within the base package.

*Figure 23: Example of Unit of Use allocation*




The Unit of Use DI is not the Primary DI, as it does not replace the UDI-DI for the base package. The UDI-DI applied to the base package remains the Primary DI, even when a Unit of Use DI is allocated. However, the Unit of Use DI allows distinction between the individual device and the grouping at the base package level. In healthcare, there may be clinical reasons why the tracking of individual items is necessary.

*Figure 24: Example of Unit of Use allocation*




Though the Unit of Use DI is used to identify devices below the base package, the Unit of Use DI is a 'Virtual UDI', meaning you do not need to label your devices or device packaging with the Unit of Use DI. However, you must enter the Unit of Use DI in the AusUDID, allowing traceability back to the Primary DI. The Unit of Use DI must follow the UDI rules of the Issuing Agency chosen by the manufacturer for the Primary DI.

The table below further explains:

- the device identifier required for each packaging level
- whether you must apply the device identifier to the label
- whether you must supply the device identifier to the AusUDID.

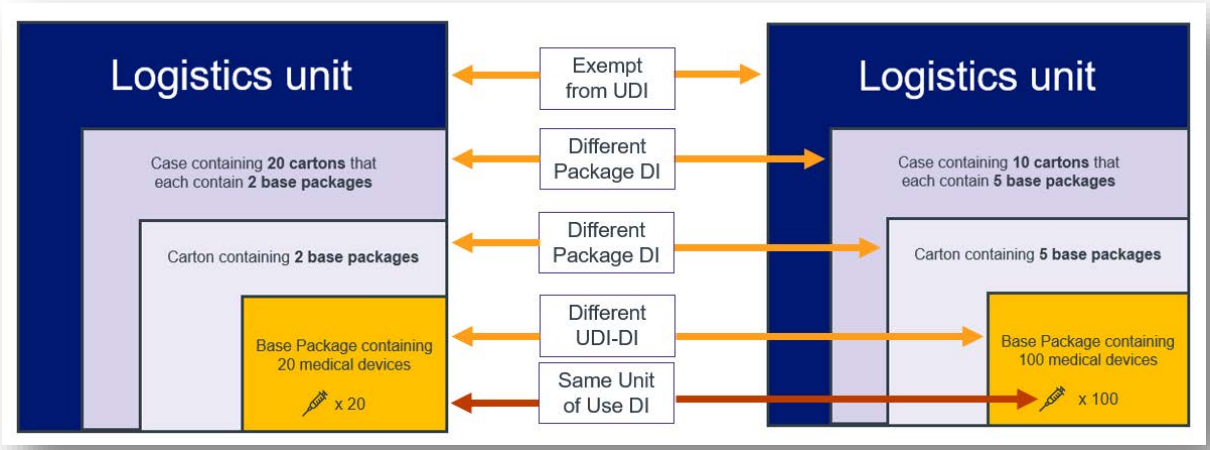
| Unit of measure (packaging level) | Quantity | Device Identifier | Applied to device package or label? | Supplied to AusUDID? |
|---|---|---|---|---|
| Single item | 1 single item | Unit of Use DI | No | Yes |
| Base package | 10 single items | UDI-DI, or Primary DI | Yes | Yes |
| Secondary package | 50 base packages | Package DI | Yes | Yes |
| Tertiary package | 500 cartons | Package DI | Yes | Yes |

**Unit of Use DI can be the same for multiple packages**

As the same device can be present in more than one base package, a Unit of Use DI can be associated with more than one base package with different Primary DIs.

For example, if the same syringe is packed into 2 different box configurations where one box contains 20 syringes and another box contains 100, each box would have a different Primary DI; however, the Unit of Use DI, identifying the actual syringe, can be the same. The image below demonstrates how the Unit of Use DI can be the same when the Primary DI and Package DIs differ.

*Figure 25: Example of 2 packaging configurations sharing the same Unit of Use DI*



## Unit of Use examples

**Sam the manufacturer and sponsor**

Sam manufacturers a tray of 25 of the same syringes. The devices within the tray cannot be individually packaged or labelled.

In this scenario:

- the tray is the base package and allocated a UDI-DI
- a UDI Carrier is applied to the base package
- the syringes in the tray are allocated a Unit of Use DI
- all the syringes share the same Unit of Use DI
- the Unit of Use DI is virtual and is not applied to the syringes or the tray.

When submitting the UDI record, Sam records:

- the UDI-DI from the base package as the Primary DI
- the Unit of Use DI allocated to the individual devices as the Unit of Use DI
- the Device Count of the base package, which in this instance is 25.

**Mary the sponsor and manufacturer**

Mary manufactures a box of 5 of the same scalpels. The scalpels are not individually labelled so the box represents the base package. Mary applies a UDI Carrier to the box. The UDI Carrier contains the UDI-DI and the UDI-PI. The UDI-DI of the UDI Carrier applied to the box is the Primary DI.

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 allocate a Unit of Use DI.

If Mary directly marked her devices with the Primary DI (same as the base package), Mary does not need to enter it in the AusUDID as the Direct Marking DI or Unit of Use DI. Mary does need to select 'No' for the *'Direct Marking DI Different from Primary DI?'* field in the AusUDID.*'*

If Mary choses to distinguish the individual scalpels from the base package and provide a specific Direct Marked DI, Mary must select 'Yes' for the *'Direct Marking DI Different from Primary DI?'* field and provide the Direct Marked DI to the AusUDID.

It is Mary's responsibility to decide if she makes this distinction.

## Unit of Use exemptions

Some specific types of medical device are exempt from Unit of Use requirements.

**Devices intended for a single patient or user**

When the UDI is applied to a package containing multiple devices of the same model or version, generally the manufacturer must allocate a Unit of Use DI. However, where all devices are intended for use on or by the same patient and intended to remain in the package until use, Unit of Use is optional because it is assumed the patient or user will consume all the devices.

This includes devices principally sold in retail, as it is expected that all devices within the base package will be used by the same user, and as such, the Unit of Use DI is not required to link usage to a patient.

**Kits**

Unit of Use requirements do not apply to any kind of kit, as kits are a collection of different devices rather than the same device. Unit of Use DI is specifically intended for situations where multiple identical devices are packaged together and the individual items are not labelled with a UDI.

**System or Procedure Packs (SOPPs)**

Unit of Use requirements do not apply to SOPPs, as SOPPs are treated as a single device.

# Managing UDI Triggers

The purpose of UDI is to identify and track devices down to the model and production run. As such, it is important to allocate a new UDI-DI to a device when key information about the original device changes in such a way that it should be identified differently from the previous iteration of the device.

The UDI-DI may change due to:

- changes to the safety or performance of a device
- changes to a UDI Trigger data element in the AusUDID
- changes that your chosen Issuing Agency determines will require a new UDI.

Not all changes to safety or performance will require a new UDI-DI. Changes to safety or performance of a device are likely only a UDI Trigger where:

- the changes result in clinical change
- the changes result in a new major version number for software
- the changes result in a new model or version.

While the UDI-PI will change with each production run, as this is not a change to a UDI-DI it does not need to be recorded in the AusUDID.

## UDI Triggers

When certain changes to a device or its UDI data elements mean that the device can no longer be unambiguously identified by its existing UDI, it is considered a new model of medical device. When these attributes of the device change, a new UDI-DI must be assigned and new UDI record created.

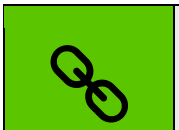
### UDI Trigger data elements

A UDI Trigger data element is a specific attribute in the UDI database that, when changed, requires assignment of a new UDI-DI because the change could affect device identification or traceability of the device. These are:

- Primary DI
- Primary DI Issuing Agency
- Device Count
- Direct Marked DI*
- Direct Marked DI Issuing Agency*

- Brand Name
- Model or Version
- Is the medical device software or does it incorporate software?
- Is the medical device a kit?
- MRI Safety Status*
- Intended for Single Use?
- Restricted Number of Reuses
- Device required to be labelled as containing natural rubber latex or dry natural rubber?
- Device Packaged as Sterile?
- Requires Sterilisation Prior To Use?
- Clinical Size* (recorded in the AusUDID in a combination of data elements: Clinical Type, Clinical Size Value, Clinical Size Unit of Measure, Clinical Size Type Text).

*The rules and requirements for these data elements varying depending on the value stored in the data element or a related data field.



For a full list of all UDI data elements and details regarding when UDI Trigger rules apply, see the *Australian UDI Data Dictionary*.

Please note that the UDI Trigger data elements listed above apply to the Australian implementation of UDI. Other jurisdictions may include these data elements as well as additional requirements.

As the manufacturer, you are responsible for ensuring UDI compliance in other jurisdictions where applicable.

As a manufacturer, you are responsible for determining whether changes to the device are UDI Triggers. Note that the AusUDID is designed to indicate which data elements are UDI Trigger data elements, recognise changes to UDI Trigger data elements and will enforce the creation of a new UDI record when you change the value of a UDI Trigger data element.

## Changes to device information

If a change to the device information impacts the clinical characteristics, safety, or performance of the device, then the UDI Trigger rules are likely to apply, and a new UDI-DI required. If the change does not affect the clinical characteristics, safety, or performance of the device a new UDI may not be required.

This includes changes to Software as a Medical Device (SaMD). If SaMD undergoes a major software change, such as modified algorithms, added functionality or new user interface, and results in a new ‘major’ software version, this will be considered a UDI Trigger. The new UDI-DI is required to reflect the changed model of the device, enabling it to be distinguished from the previous model of device.

While the AusUDID will allow the linking of this new UDI record to the same ARTG inclusion, you are responsible for ensuring any changes are considered within the full context of other regulatory obligations.

**Mac the manufacturer**

Mac manufactures a device that monitors heart rate. He updates the software so it now can monitor heartrate and diagnose arrhythmias. This represents a change both to software functionality and intended purpose. As a result, a new UDI-DI must be allocated.

## Managing UDI Triggers

As a manufacturer, you are responsible for:

- allocating a new UDI-DI to your changed device(s)
- labelling your changed device(s) with the new UDI-DI
- allocating new Package DIs for any higher levels of packaging
- meeting all other UDI requirements for your changed device(s)
- notifying your sponsor(s) of the new UDI-DI
- meeting any other applicable obligations.

As a sponsor, you are responsible for:

- creating a new UDI record for the new UDI-DI for the changed device
- including the Previous DI in the new UDI record of the changed device, if possible
- meeting any other applicable obligations.

**Daniel the manufacturer**

Daniel manufactures local anaesthesia needles under the brand name ‘ABC Needles’. He changes the brand name to ‘XYZ Needles’. Changing the brand name is a UDI Trigger, and therefore he must allocate a new UDI-DI to these local anaesthesia needles.

In this scenario:

- Daniel allocates a new UDI-DI for ‘XYZ Needles’
- the existing UDI record for ‘ABC Needles’ remains in the AusUDID indefinitely and Daniel does not update this UDI record to display the new UDI-DI
- Daniel creates a new UDI record for ‘XYZ Needles’ in the AusUDID
- the new UDI record may include the UDI-DI for ‘ABC Needles’ as a Previous DI.

Daniel’s new local anaesthesia needles are supplied with 10 in a base package, and are not individually labelled with a UDI. Daniel must also allocate a new Unit of Use DI.

| | |
|---|---|
| | Daniel's new local anaesthesia needles are supplied with higher levels of packaging. Daniel must allocate a new Package DI for every higher level of packaging. |

There are circumstances, outside the requirements of the TGA and UDI Triggers, where a new UDI-DI is assigned to a device. For example, when a device has new supply chain requirements. As the sponsor, you must ensure a UDI record is created for these UDI-DIs if they will be supplied in Australia

# UDI for specific device types

Generally, all devices in scope of UDI requirements must meet all UDI requirements for UDI allocation, UDI labelling and packaging, and UDI record creation and maintenance.

However, some devices are exempt from certain requirements or have additional requirements due to the nature of the device. It is important to understand if the devices that you supply have any specific requirements.

For a summary, see Appendix C: Summary of UDI requirements for device types.

This section describes each specific device type and the UDI requirements it must meet. Please note that if the device is of a device class that is not in scope of UDI, it does not need to meet UDI requirements.

*Example: Reusable devices must meet UDI requirements. However, Class I devices are not in scope of UDI. Therefore, Class I reusable devices do not need to meet UDI requirements. However, Class Is, IIa, IIb and III reusable devices must meet UDI requirements.*

## Reusable devices

**Reusable devices must meet UDI requirements.**

Reusable devices must also have the UDI Carrier directly marked onto the device itself if they are intended to:

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

As a manufacturer, you are responsible for determining if your reusable devices must be directly marked.

The UDI Carrier directly marked onto the device itself must be:

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

**Tash the manufacturer**

Tash manufactures reusable scalpels. Because Tash's devices are intended to be reprocessed and used on another patient, Tash must directly mark her scalpels with a 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. Tash must still meet all other labelling requirements for her single use syringes.

## Reusable devices exempt from direct marking requirements

Reusable devices do not need to be directly marked if they are:

- intended to be used on one patient only and no subsequent patients
- not intended to undergo high-level disinfection or sterilisation before each use
- devices principally sold in retail premises.

Additionally, reusable devices are exempt from direct marking where:

- any type of direct marking would interfere with the safety or performance or effectiveness of the device
- it is not technically feasible to directly mark the device
- the device was manufactured and labelled prior to the direct marking compliance date.

For more information on direct marking, see Direct marking.

## Restricted number of reuses

When creating a UDI record for reusable devices, you must include information about the number of reuses.

Where the device has a maximum number of reuses, you must provide this information in the field '*Restricted number of reuses.*'

Where the number of reuses is not restricted to a maximum number, you select 'N/A' in the field '*For single use?*' This indicates that while the device is reusable, the number of reuses is not restricted.

Reusable devices where 'N/A' would apply includes:

- capital equipment
- devices that are restricted based on lifetime or shelf life of a device rather than a set number of reuses
- devices that are consumed during use, and the smallest trade item comprises a maximum number of tests greater than one
- devices supplied via Surgical Loan Kits (SLKs), where the manufacturer does not enforce any restrictions on the number of reuses and provides instructions on how to detect signs of material degradation.

# Capital equipment

**Capital equipment must meet UDI requirements.**

As industry informally refers to and defines capital equipment as large, durable medical devices that are repeatedly used over time, for example MRI machines or CT scanners, the UDI requirements for these types of devices are grouped here.

This grouping reflects operational practice rather than regulatory terminology. For regulatory purposes, capital equipment is assessed under the general definition of a medical device in the *Therapeutic Goods Act 1989*.

You must label capital equipment devices with a UDI on the equipment itself, however, is not required to be directly marked. The UDI Carrier may be applied as a sticker, plate, printed directly onto the equipment itself, or be in any other form that can withstand the normal use and cleaning of the equipment.

**Catherine the manufacturer**

Catherine manufactures MRI machines. As capital equipment, they are in scope of UDI requirements and must bear a UDI.

Catherine applies a metal plate with the UDI to the MRI machines, making them UDI compliant. As the labelling of her devices can withstand the normal use and cleaning, they do not require direct marking.

She may choose another form of label, such as a durable sticker, provided the UDI Carrier withstands normal cleaning processes for the device's lifetime.

If the UDI-DI for the device changes, the label must be replaced with a new UDI-DI. If the UDI is presented through an electronic display, it is acceptable to display the new UDI-DI on an easily accessible screen such as an 'About' box.

# Single use devices

**Single use devices must meet UDI requirements.**

A single use device is used on a single patient during a single procedure and then discarded. It is not intended to be reprocessed for use on another patient.

Generally, a single use device must bear a UDI on its label. However, where individual single use devices of a single model or version are distributed together in a single package, and intended to be stored in that package until removed for use:

- the UDI is not required on the device label
- the UDI must be applied to the device package.

This exception is not applicable to:

- any implantable device
- single use devices intended for individual commercial distribution
- where more than one model or version are distributed together in a single package.

When the end user (for example, healthcare provider) is not expected to have access to the package, the UDI Carrier should be on the individual device packaging. All other levels of packaging must bear a Package DI, except logistics units.

When the UDI is applied to a package containing multiple devices of the same model/version, the manufacturer must allocate a Unit of Use DI, unless all devices are intended for use by the same patient or user. In that case, Unit of Use is optional because it is assumed the patient or user will consume all the devices.

For more information, see Unit of Use.

| | |
|---|---|
|  | **Josh the manufacturer**<br><br>Josh manufactures surgical gloves. Josh supplies his surgical in a box of 100.<br><br>Josh's surgical gloves are single use; however, they are intended to stay in the box until use. Josh is not required to apply a UDI to each individual glove in the box. To support traceability of the gloves, Josh is required to apply the UDI on the box.<br><br>In this scenario, Josh must also allocate a Unit of Use DI to his gloves. |

| | |
|---|---|
|  | **Nick the manufacturer**<br><br>Nick manufactures wound dressings for healthcare clinics. Nick supplies his wound dressings in a box of 10.<br><br>Nick's wound dressings are single use; however, they are expected to be removed from the base package before use. Because they are expected to be separated from the package bearing the UDI, Nick applies the UDI Carrier to each individual device.<br><br>Because the devices are individually labelled with the UDI, he does not need to allocate a Unit of Use DI. If Nick is unable to apply the UDI Carrier to each individual wound dressing, he must allocate a Unit of Use DI. |

# Personalised Medical Devices (PMDs)

**Certain types of Personalised Medical Devices (PMDs) must meet UDI requirements.**

PMDs are devices designed and manufactured, or adapted or modified, to meet the needs of an individual.

We use 3 specific terms to describe personalised medical devices:

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

For guidance specific to PMDs, see Patient-matched medical devices | Personalised medical devices | Therapeutic Goods Administration (TGA).

You must meet UDI requirements for:

- adaptable medical devices
- patient-matched medical devices.

You do not need to meet UDI requirements for custom-made medical devices.

## Patient-matched medical devices (PMMDs)

PMMDs are exempt from inclusion in the ARTG until 1 July 2029. As UDI requirements only apply to devices included in the ARTG, PMMDs are exempt from UDI requirements until they are included.

Once your PMMD is included in the ARTG, you must meet UDI requirements for your PMMD – if it is in scope of the UDI requirements.

If your PMMD is eligible for the low volume exemption or specified articles exemption, your PMMD is exempt from UDI requirements.

## Adaptable medical devices

Adaptable medical devices are personalised *after* they are manufactured.

They are modified, adapted or assembled to suit a specific individual. This is done in line with the manufacturer's instructions.

Examples include:

- a limb prosthesis assembled from pre-manufactured components in line with the manufacturer's instructions
- an off-the-shelf bruxism mouthguard, to be moulded by the patient themselves
- a prefabricated (non-prescription) orthotic insole, shaped and trimmed to the right size for a patient.

Adaptable medical devices need to be included in the ARTG and must meet UDI requirements, if they are in scope of devices required to meet UDI requirements.

## Custom-made medical devices

A custom-made medical device (CMMD) is designed and made for a particular person. Unlike a PMMD, a CMMD is rare and unique, and the manufacturer cannot adequately and fully validate the design or production processes used. A health professional may determine that a CMMD is needed when no other device like it is included in the ARTG.

An example is an acetabular implant made for a person who is 2.26 metres tall and weighs 160 kilograms. The dimensions and tolerances of the implant needed to suit this person are outside the manufacturer's usual design envelope. The implant is genuinely a 'once-off' and therefore is a CMMD.

Custom-made medical devices are exempt from UDI requirements.

# Dental devices

**Dental devices must meet UDI requirements.**

## Dental practitioners

As a registered dental practitioner, you have regulatory responsibilities to the TGA when:

- importing dental devices (a sponsor)
- manufacturing dental devices away from chair-side (a manufacturer and a sponsor).

You can find more information about regulatory responsibilities for dental practitioners, including information on what makes a dental practitioner a sponsor, here.

If these cases apply to you, you must meet UDI requirements for dental devices where:

- you are the sponsor of the dental device, and
- the dental device is in scope of devices that must meet UDI requirements.

You do not need to meet UDI requirements if you buy:

- finished devices from an Australian-based sponsor
- materials and components to manufacture non-implantable dental medical devices from an Australian-based sponsor who has already met UDI requirements.

## Implantable dental devices

As a sponsor, or a dental practitioner acting as a sponsor, you must meet UDI requirements for implantable dental devices.

Implantable dental devices are not exempt from ARTG inclusion or UDI requirements when made using materials included in the ARTG. Examples of implantable dental devices 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.

# Medical device and IVD device software

**Medical device and IVD software must meet UDI requirements.**

This includes:

- Software as a Medical Device (SaMD)
- medical devices incorporating software.

Software incorporated or embedded into a device does **not** need its own UDI if:

- it is not supplied as a standalone device
- it is not commercially available on its own.

The table below summarises software types that must meet UDI requirements.

| Type | Requires UDI? | AusUDID submission |
|---|---|---|
| Software as a Medical Device | Yes, if in scope of devices required to meet UDI requirements | Submit in UDI record as 'Software as a medical device'. |
| Medical device incorporating software | Yes, if in scope of devices required to meet UDI requirements | Submit in UDI record as 'Medical device incorporating software'. |
| Software incorporated into a medical device | No, if not standalone | No individual UDI record required. |

## Medical devices incorporating software

### Allocating a UDI

The manufacturer must allocate a UDI to the physical medical device that incorporates software. The embedded or incorporated software does not require its own UDI unless it is also supplied as a standalone product.

**Kobe the manufacturer**

Kobe manufactures an infusion pump with embedded software. He allocates a UDI to the physical device. He does not allocate a separate UDI to the software because it is not supplied on its own.

Kobe submits the UDI record for the infusion pump to the AusUDID and records 'Medical device incorporating software' in the data field titled '*Is the medical device software or does it incorporate software?*'.

### Medical devices incorporating software UDI placement

The UDI Carrier must be applied to the physical device's label and packaging according to standard UDI requirements. If the device includes a user interface, you should also display the UDI in an accessible location such as an 'About' screen.

## Software as a Medical Device (SaMD)

### Allocating a UDI

The manufacturer must allocate the UDI-DI at the system level of the SaMD. The version number acts as the manufacturing control mechanism and must be included in the UDI-PI.

**Kevin the manufacturer**

Kevin develops a diagnostic app classified as SaMD. Kevin allocates a UDI at the system level of the app. He includes the version number in the UDI-PI.

Kevin's UDI for his SaMD:

(01)12345678901234(21)v.3.2.1(17)251118.

Kevin displays the UDI in the app's 'About' screen.

### SaMD UDI placement

If you supply SaMD in a physical medium, for example a DVD, standard UDI labelling requirements apply:

- apply the UDI Carrier to the base package

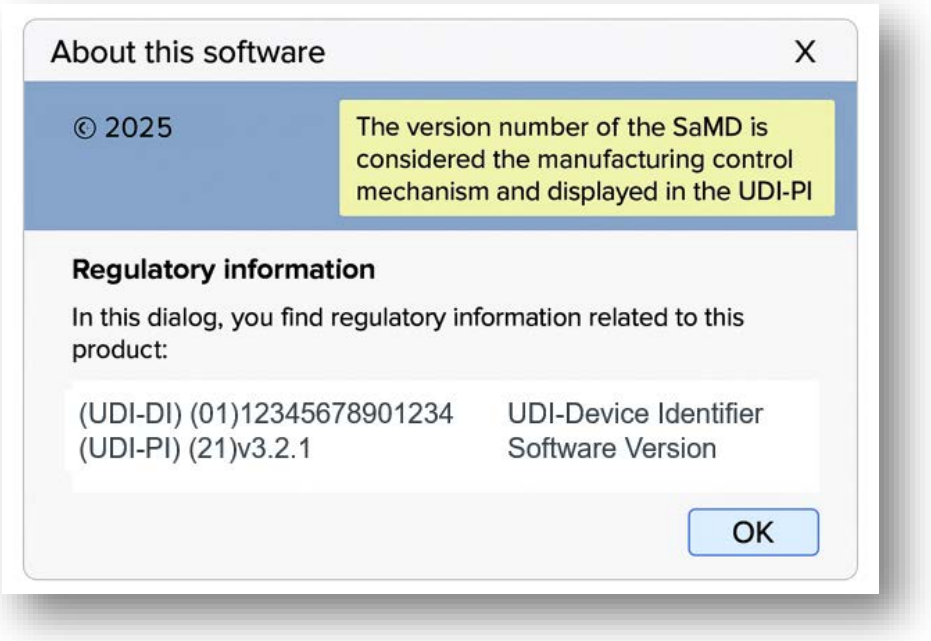
- apply the UDI Carrier with unique Package DI(s) to all applicable higher levels of packaging.

The UDI-DI that is applied to the base package of the physical medium containing the SaMD and its packaging must be identical to the UDI-DI allocated to the system level SaMD.

If you supply SaMD in an electronic format, for example an app, you must display the UDI on screen a readily accessible by the user in an easily readable format. For example, an ‘About’ file or startup screen. When the UDI is provided via an electronic display, only the HRI form is required. You do not need to include the AIDC form in the electronic displays.

The image below shows how a UDI may be displayed in a pop-up box.

*Figure 26: Example of UDI displayed via an 'About' box*




If your SaMD lacks a user interface, it must be capable of transmitting the UDI through an Application Programming Interface (API) or similar.

You include the Data Delimiter in the HRI form. This helps the end user to identify the UDI and determine which standard you have used to create the UDI.

If you label your SaMD with a physical UDI Carrier but later perform an upgrade that requires your device to be assigned a new UDI-DI, you may provide this new UDI-DI through the electronic display method. We recommend you inform the end user to remove the physical UDI Carrier to minimise confusion.

## Software UDI Triggers

**SaMD version changes**

You must allocate a new UDI-DI if a major software revision significantly changes:

- the original performance and effectiveness
- the safety or intended use of the SaMD.

These changes include but are not limited to:

- new or modified algorithms
- database structures

- operating platform
- architecture
- new user interfaces
- new channels for interoperability.

  You must also submit a new UDI record when your SaMD is allocated a new UDI-DI.

You must allocate a new UDI-PI for minor revisions such as:

- bug fixes
- usability enhancements (not for safety purpose)
- security patches
- operating efficiency.

You should identify minor revisions by manufacturer specific identification methods such as:

- version
- revision number
- serial number.

We recommend that you record changes and how changes are communicated to users of the SaMD in your quality management system. Note that minor changes to software do not need to be recorded in the AusUDID.

# Devices principally sold in retail

**Devices principally sold in retail must meet UDI requirements.**

Devices 'principally sold in retail' are those intended for sale in retail premises such as supermarkets and retail pharmacies. These devices are eligible for reduced labelling requirements.

The manufacturer must determine whether a device is principally sold in retail and must justify this if requested. The manufacturer may choose to liaise with their sponsor(s) to determine whether the device will be principally sold in retail.

If your device is supplied in both retail and healthcare settings, however, is predominantly supplied in healthcare settings, you must meet full UDI labelling requirements for this device. If your device is supplied in both retail premises and healthcare settings, you must meet full UDI requirements where the device is predominantly supplied in healthcare settings.

*Example: An adhesive bandage is sold through a national Supermarket. This device is considered principally sold in retail. If the bandage is also used in medical centres as a secondary supply purpose, but the main supply destination is retail, this device still qualifies as principally sold in retail.*

## Reduced labelling requirements for devices principally sold in retail

Devices principally sold in retail has flexibility in the labelling of the trade level of packaging for the device:

- UDI-DI
  - must be in human-readable form, however, does not need to be HRI
  - must be in a machine-readable form, however you may use standards that better support retail use rather than the more comprehensive healthcare standards.

- UDI-PI
  - must be in human-readable form, however, does not need to be HRI
  - not required in machine-readable form, but you may choose to do so.
  - production identifiers provided on the label may vary depending on the medical device type and current practice, but at least one production identifier must be included on the label.
- Unit of Use DI
  - Because of their nature, devices principally sold in retail premises are exempt from Unit of Use requirements.
  - Device Count for devices principally sold in retail should be set to '1' in the AusUDID, as these devices are intended for a single user.
- Direct Marking DI
  - Because of their nature, devices principally sold in retail premises are exempt from direct marking requirements.

The image below shows an example of a UDI compliant label for devices principally sold in retail.

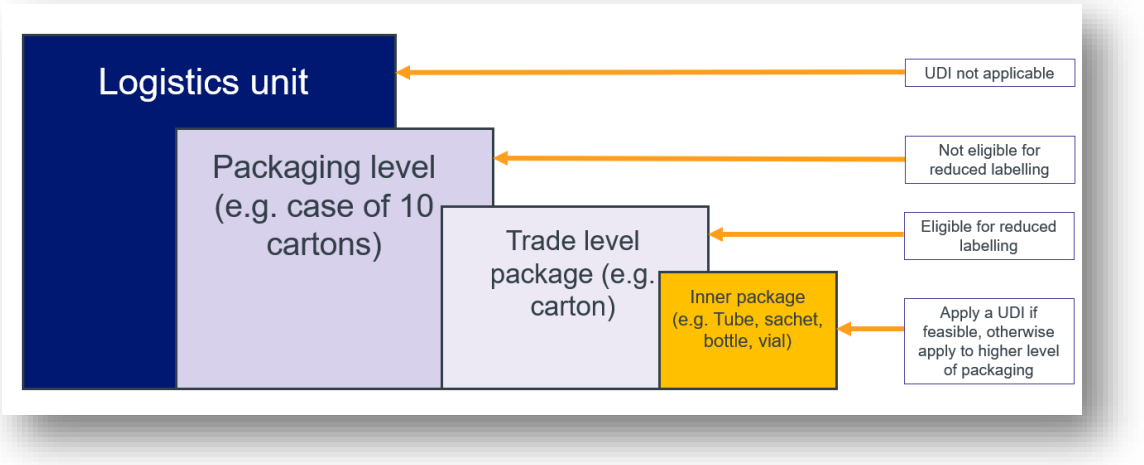
*Figure 27: Example of acceptable UDI labelling for devices principally sold in retail*


The image below shows how UDI applies to packaging levels for devices principally sold in retail. In this example:

- UDI is not applicable to logistics units, as they are not required to meet UDI requirements
- the packaging level must bear full UDI labelling
- the trade level is eligible for reduced labelling
- if multiple devices are contained in the trade level, apply the UDI to the individual devices if possible. If not feasible, apply to the higher level of packaging – in this case, the trade level.

Note that Unit of Use and direct marking are not applicable to retail devices.

*Figure 28: Example of retail packaging levels*




The table below summarises the UDI-DI and UDI-PI requirements for devices principally sold in retail.

| Carrier form | UDI-DI | UDI-PI |
|---|---|---|
| HRI | Optional | Optional |
| Non-HRI | Required* | Required* |
| Machine readable or AIDC | Required | Optional |

You do not need to include both HRI and non-HRI if you choose to use HRI form.

You must meet **all** UDI requirements for all other applicable levels of packaging. Higher levels of packaging are not eligible for the reduced labelling.

## Retail devices redirected to healthcare settings

There are some scenarios where devices principally sold in retail are redirected to healthcare settings.

**Devices temporarily redirected due to shortages**

In some situations, retail devices may be temporarily redirected to hospitals or healthcare providers. This can happen due to stock shortages, hospital purchasing decisions or similar circumstances. In these cases, it is not necessary to relabel the devices with the full UDI compliant labelling as this may create unnecessary burden and impact the supply of the products. These devices remain eligible for the reduced labelling requirements.

**Devices redirected due to business changes**

If a device that was originally intended for retail sale is supplied to healthcare settings on a more permanent basis, then full UDI labelling will be required on the device. This will ensure the device supports the traceability that is required for clinical environments.

**Devices that frequently change supply channels**

For devices that frequently shift between retail and healthcare supply channels, it is recommended that manufacturers apply full UDI labelling for these devices. This approach helps ensure consistent compliance and reduces the need for relabelling as distribution patterns change.

**Aidan the manufacturer and sponsor**

Aidan manufactures and supplies wound dressings to retail premises and medical centres. Most go to retail premises, so Aidan applies reduced UDI labelling:

- UDI-DI in non-HRI
- UDI-DI in machine readable
- UDI-PI in non-HRI.

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 in retail, so that any changes to where he supplies his device will not impact his ability to supply the device.

# Refurbished devices, reprocessed single use devices, own brand or private labellers

UDI requirements for refurbished, reprocessed and relabelled devices depends on a range of factors, including:

- whether you are the original manufacturer of the device you are refurbishing or relabelling
- whether the device has undergone changes that have altered the intended purpose of the device
- whether the device that is being reprocessed is single use or reusable.

Note that reprocessing reusable devices in ways described in the manufacturer's Instructions for Use does not make you the manufacturer. Reprocessing of reusable medical devices is part of the intended purpose for the medical device, and part of clinical practice. We do not regulate clinical practice.

## Refurbished devices

Refurbishment is defined as a substantial rebuild from one or more used medical devices that may render it a 'new' medical device under the Regulations.

If you refurbish an already used medical device, you are considered the manufacturer of the device.

Your responsibilities as a manufacturer of a refurbished device depend on whether you are also the original manufacturer of the device.

**Refurbishing a device originally manufactured by different manufacturer**

If you refurbish a device that was originally manufactured by different manufacturer, you are considered the manufacturer of the refurbished device. In this scenario, you are required to allocate a UDI-DI to the refurbished device. You must meet all relevant UDI requirements for this device. Your device also requires an ARTG inclusion.

Refurbishers must create their own, new UDI for the refurbished medical device which will replace the original manufacturer's UDI where it exists. This includes removing any UDI that has been directly marked onto the device.

**Refurbishing your own device**

If you refurbish a device that you originally manufactured, you may be able to resupply this device under the existing ARTG with the same UDI-DI, where:

- the refurbishment has not changed its intended purpose
- the device is considered the same model of device.

If you have changed the intended purpose of the device when refurbishing the device, you must allocate a new UDI-DI to this device. If the device is no longer considered to be within the set limits of specifications, performance, size and composition of the original model of device, it is considered a new model of device. In this case, you must allocate a new UDI-DI.

If you refurbish a device that you originally manufactured that is now required to meet UDI requirements, however this device does not yet have a UDI-DI allocated to it, you must allocate a UDI-DI to this device and meet all UDI requirements applicable. For example, if the device was previously not required to meet requirements as it was not mandatory at the time of manufacture, however the device is now in scope of UDI requirements at the time of remanufacture, you must meet UDI requirements for this device.

**Angus the refurbisher**

Angus refurbished a Class Is medical device that was originally manufactured by a different manufacturer to supply for reuse. In the process, Angus:

- stripped the device
- checked the components and replaced components not suitable for re-use
- assembled the device and tested the device against the original specifications of the device
- identified the device as a refurbished device.

Angus has certified the device is suitable for reuse. He has also assumed the legal liability for the quality, safety and performance of the device. Since he did these activities, Angus has become the manufacturer of the device and must now meet UDI requirements. This includes Angus allocating and applying the UDI to the device.

Angus is responsible for ensuring that the previous UDI on the device, if any, is removed entirely.

As Angus is also the sponsor of the device, he must meet the obligations of a sponsor. These include submitting the UDI-DI and related data to the AusUDID and linking the relevant ARTG to the UDI record.

## Reprocessed single use devices

Reprocessing of single use devices makes them a new medical device and requires an ARTG and a UDI-DI. This includes refurbished single use devices and single use devices where the intended purpose has been altered, allowing the device to be reusable.

Note that some single use devices are marketed as non-sterile which require processing to make them sterile and ready for use. You are not considered the manufacturer if you process a single use device to prepare it for use, per the Instructions for Use.

**Reprocessing a single use device originally manufactured by a different manufacturer**

If you reprocess a single use device originally manufactured by a different manufacturer, you are considered the manufacturer of the single use device.

**Reprocessing your own single use device**

If you reprocess a single use device that you originally manufactured, and the intended purpose remains the same, you may be able to supply the reprocessed single use device under the existing ARTG entry and retain the existing UDI-DI. However, if the single use device intended purpose has changed, for example the device is now reusable, you must allocate a new UDI-DI as this is a UDI Trigger.

## Own brand or private labellers

Own brand or private labellers who re-label a medical device are considered the manufacturer of these devices and are required to meet UDI requirements for these devices.

Relabelling devices under the manufacturer's instructions (sponsors and subcontractors) doesn't make you the manufacturer.

# In vitro diagnostic (IVD) medical devices

## IVD devices

**IVDs must meet UDI requirements.**

In most scenarios, IVDs share the same UDI requirements with medical devices.

## IVD kits

Although the term ‘kit’ has a specific meaning in the Australian legislation, some products that are regulated as medical devices include the word kit in their name and include at least one medical device. For example, SARS-CoV antigen test kits, which only contain medical devices (including IVD devices).

You must meet UDI requirements for an IVD kit as well as for any components of the kit, where the component is:

- is sold separately from the kit
- has its own ARTG inclusion, and
- is in scope of devices required to meet UDI requirements.

If the kit does not include any components that are in scope of UDI requirements, you only need to meet UDI requirements for the kit itself.

If your IVD kit contains single use medical devices, these devices do not need a UDI where:

- the person(s) intending to use the device generally know the uses*
- the single use medical devices are not intended for individual use outside the context of the IVD kit, or
- they are not in scope of devices required to meet UDI requirements.

*You may be required to justify this on our request.

Because of their nature, the Unit of Use DI is not appropriate for IVD kits.

**Placement of UDI on IVD kits**

You should apply the UDI Carrier to the outside of the packaging. It must be readable or scannable whether placed on the outside of the IVD kit package or inside a transparent package.

**Submission of IVD kit data to the AusUDID**

As a sponsor, you are responsible for ensuring that the following data is supplied to the AusUDID:

- UDI-DI and related data of the IVD kit
- UDI-DI of each component of the IVD kit that has a UDI.

You are not required to link the UDI record for the components to the UDI record of the IVD kit.

**Brooke the manufacturer**

Brooke manufactures a Rapid Antigen Test Kit. Brooke's RAT kit is a Class 3 IVD and is in scope of devices that must meet UDI requirements.

Brooke does not supply any of the components of the IVD kit separately and all components are single use.

Brooke must allocate and apply a UDI to the IVD kit itself, but Brooke is not required to allocate and apply a UDI to any of the individual components.

# Implantable devices

Because of the high risks with implantable devices, the UDI for an implantable device should be identifiable and able to be recorded before implantation. This can minimise the risks of misidentification of the implanted device.

The following UDI requirements apply for implantable devices:

- all base packages of implantable devices need to be identified by checking the UDI before surgery and captured at the point of implantation
- the UDI must be in both HRI and AIDC formats
- the UDI-PI should include:
  - for an active implantable device, the serial number
  - for other implantable devices, the serial number or lot number per the manufacturer's quality management system.

You do not need to directly mark the UDI on implantable devices.

Examples of labels that you may use 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.

# Surgical Loan Kits (SLK)

**SLKs are exempt from UDI requirements at the kit level; however, component medical devices in the SLK must meet UDI requirements.**

SLKs typically include reusable surgical instruments, implantable medical devices, or single-use medical devices that are supplied on loan or long-term consignment to hospitals for specific surgical procedures. They can be customised for the hospital, procedure, surgeon, or patient.

SLKs are assembled by an SLK manufacturer using medical devices, also known as component medical devices, that were manufactured by component manufacturers and included in the Australian Register of Therapeutic Goods (ARTG) by component sponsors.

## Component manufacturer

The **component manufacturer** is the entity that manufactures the individual component medical devices included in a SLK. They are responsible for design, production, packaging, labelling, and assigning the intended purpose to the component medical device. The component manufacturer is responsible for ensuring each component medical device is allocated a UDI-DI and UDI-PI and meets any other UDI labelling requirements applicable.

## Component sponsor

The **component sponsor** is the entity that includes the component medical device in the ARTG for supply in the Australian market. The component sponsor is responsible for ensuring a UDI record for each component medical device they supply is submitted to the AusUDID.

## SLK manufacturer

The **SLK manufacturer** is the entity that assembles, packages, or labels the kit using ready-made component medical devices from component manufacturers and arranges distribution to hospitals.

The SLK manufacturer is responsible for providing UDIs to the hospital when supplying the SLK.

An entity may hold several roles. For example, an entity may be both the component sponsor and the SLK manufacturer.

## SLK at kit-level

SLKs are exempt from UDI requirements at **the kit level**. The tray, tub, case, or caddy used for transport is considered a logistics unit which is not required to meet UDI requirements.

## SLK components

Component medical devices in an SLK are **not** exempt from UDI requirements. All component medical devices must meet UDI requirements if in scope of UDI requirements.

As a component manufacturer, you must assign a UDI including the UDI-DI and UDI-PI to each model of device.

As a sponsor, you must ensure that a UDI record is submitted to the AusUDID for each model of device.

## Providing UDI for SLK components

As a component manufacturer, you must provide the full UDI for each device to the SLK manufacturer.

With some exceptions for small non-sterile devices, the SLK manufacturer must provide the full UDI for each component medical device in the kit to the hospital when they supply the SLK, ready to be easily accessible at the point of care.

We do not prescribe a specific method for providing the UDI for SLK components. Component manufacturers and SLK manufacturers may adopt flexible approaches consistent with international regulators to provide the UDIs to the SLK manufacturer and hospital. These methods include:

- stickers
- tags
- inventory sheets
- data carrier strips.

| | |
|---|---|
|  | **Ruby the component manufacturer**<br>Ruby manufacturers component medical devices. She must meet UDI requirements for all medical devices that are Class Is, Class IIa, Class IIb, or Class III.<br>Ruby provides the full UDI for each applicable device to Emily. |
|  | **Emily the SLK manufacturer**<br>Emily assembles SLKs. Each SLK includes reusable surgical instruments, implantable medical devices and single-use devices. Emily ensures each component medical device is included in the ARTG and meets UDI requirements, where applicable.<br>Emily's SLK contains 4 Class I medical devices and 10 Class III medical devices.<br>Emily must ensure each of the 10 Class III medical devices meet UDI requirements. However, UDI requirements do not apply to Class I medical devices.<br>Emily does not need a UDI for the SLK itself.<br>Emily provides the full UDI for each applicable to the hospital when she supplies the kit, with some exceptions for small non-sterile devices. |

**John the component sponsor**

John is the sponsor of Ruby's component medical devices. He must ensure that any medical devices that are Class Is, Class IIa, Class IIb, or Class III meet UDI requirements.

John must also ensure that a UDI record for each model of device is submitted to the AusUDID.

## Small non-sterile devices

We recognise the challenges in providing and retaining production information with small non-sterile devices in SLKs. These challenges include:

- Loss of UDI Carrier during sterilisation
  - Before surgery, small non-sterile devices are often sterilised and removed from their packaging or labelling, which could contain the UDI. Once separated from the UDI Carrier, the device may be difficult to identify later in the hospital or after the SLK is returned.
- Replenishment issues
  - When small non-sterile devices are replenished in an SLK, they may come from different production batches. This makes it difficult to maintain accurate production information and track individual components.
- Direct marking impracticalities
  - While direct marking is not required for implantable medical devices, industry advised that even if required, direct marking would be technically infeasible for small non-sterile devices due to their size.

To address these challenges, small non-sterile devices have reduced UDI requirements:

- SLK manufacturers **must** provide the UDI-DI for small non-sterile devices that are supplied in an SLKs
- SLK manufacturers are **not** required to provide the UDI-PI for small non-sterile devices that are supplied in an SLK.

All devices must still be allocated a UDI-DI, and the UDI-DI must be easily accessible at the point of care.

As a component manufacturer, you may voluntarily directly mark small non-sterile devices where technically feasible, enabling UDI-Pi availability at point of care.

The manufacturer is responsible for determining what is considered a small device. You may be required to justify this decision to the TGA, when requested.

**Emily the SLK manufacturer**

Emily assembles SLKs. Because of the challenges related to providing and maintaining production information for small non-sterile devices, Emily provides the UDI-DI for these devices but not the UDI-PI to the hospital.

### Small non-sterile devices supplied in SLKs and outside SLKs

When a small non-sterile device is supplied both inside an SLK and outside an SLK, it must carry both the UDI-DI and the UDI-PI when supplied outside the SLK. The UDI Carrier for devices supplied outside an SLK should follow standard UDI labelling requirements. This does not change how the UDI is provided for devices within an SLK, where alternate methods are acceptable.

**Ruby the component manufacturer**

Ruby supplies small non-sterile devices both in an SLK and outside of an SLK.

For the devices **supplied in an SLK**, Ruby provides the full UDI to Emily the SLK manufacturer. When Emily assembles the SLK, she provides the hospital with the UDI-DI for the small non-sterile devices but not the UDI-PI.

For the devices **supplied outside of an SLK**, Ruby applies a UDI Carrier that includes both the UDI-DI and the UDI-PI per standard UDI labelling requirements.

### Implications for market actions

Where the UDI-PI is not provided for small non-sterile devices in an SLK:

- any market action, device incident report, or adverse event notification cannot be limited to a subset of production
- actions must include **all** production of the device with the relevant UDI-DI
- SLK manufacturers must extend regulatory actions to all SLKs containing devices with that UDI-DI.

**Arabella the SLK manufacturer**

Arabella recalls a screw type that is supplied in multiple SLKs. Because the UDI-PI was not provided to hospitals, Arabella must recall **all** screws with that UDI-DI. She cannot recall individual batches.

The table below provides a summary of UDI requirements for SLKs and components medical devices.

| Item | UDI required? | Details |
|---|---|---|
| SLK kit (tray, tub, case, caddy) | No | • Considered a logistics unit.<br>• Exempt from UDI requirements. |
| Component devices | Yes, if in scope of UDI requirements | • Full UDI required. |

| Item | UDI required? | Details |
|---|---|---|
| Small non-sterile devices supplied in an SLK | Partial | • The component manufacturer must provide the full UDI to the SLK manufacturer.<br>• The SLK manufacturer only needs to provide the UDI-DI to the hospital.<br>• The SLK manufacturer does not need to provide the UDI-PI to the hospital.<br>• The component manufacturer may optionally directly mark the UDI-PI on the device, if technically feasible.<br>• Where a small non-sterile device is also supplied outside an SLK, it must bear full UDI labelling (UDI-DI and UDI-PI). |
| Method of UDI provision | Flexible | • Stickers<br>• Tags<br>• Inventory sheets<br>• Data Strips |

# System or Procedure Packs (SOPPs)

**System or Procedure Packs (SOPPs) must meet UDI requirements.**

## SOPPs at pack-level

You must allocate a UDI to a SOPP if it contains one or more medical device in scope of UDI requirements.

Your SOPP does not need a UDI on the pack if it only contains:

- Class I non-sterile non-measuring medical devices, or
- Class I measuring (Im) medical devices.

However, the assembler or manufacturer of the SOPP may choose to apply a UDI voluntarily.

## SOPP components

Any component of a SOPP that is a medical device that is in scope of UDI requirements must have a UDI assigned for the component unless it is:

- not commercially available on its own
- an individual single-use disposable device where:
  - the person(s) using them generally know the uses, and

  - the device is not intended for individual use outside the context of the SOPP. For example, an unpackaged sterile syringe in a sterile pack cannot be used for another procedure once removed from the pack

- exempt from UDI requirements.

Medical device components that you supply **separately** from the SOPP must:

- be included in the ARTG
- comply with UDI requirements, unless exempt.

**Breanna the manufacturer**

Breanna manufactures a SOPP that includes:

- 3 Class I medical devices
- 3 Class Is medical devices
- 3 Class IIb medical devices.

Because the pack contains devices in scope of UDI requirements, Breanna allocates a UDI to the SOPP.

For the individual components in the SOPP:

- Breanna does **not** need to apply a UDI to the 3 Class I medical devices, as Class I medical devices are not in scope of UDI requirements.
- Of the 3 Class Is medical devices, 2 are individual single-use devices. Breanna does not supply these separately, and they are discarded once the SOPP is opened. These devices do **not** need their own UDI.
- The third Class Is medical device is supplied both inside the SOPP and separately. Breanna must allocate a UDI to this device.
- Of the 3 Class IIb medical devices, Breanna supplies one separately from the SOPP. Only this Class IIb device needs its own UDI.

## Systems that are medical devices

**Systems that are medical devices must meet UDI requirements.**

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 separately.

A system is **not**:

- a single item
- 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.

As a manufacturer, you must allocate a UDI to the system that is a medical device.

As a sponsor, you must submit a UDI record for the system to the AusUDID.

Where all individual medical devices in the system comply with UDI requirements on their own, you are not required to allocate a UDI to the system as a whole; however, you may choose to do so.

UDI requirements for systems that are medical devices do not supersede or override any existing requirements, including Instructions for Use requirements.

## Systems that are configurable

**System UDI**

For systems that can be configured, you must allocate a UDI to the entire system. This UDI is referred to as the System UDI. It is **not** an additional identifier; it simply a term used to distinguish and reference the complete system.

As a manufacturer, you should place the UDI Carrier for the System on the assembly that most likely does not get exchanged in its lifetime.

The System UDI will comprise both a UDI-DI and UDI-PI.

**System UDI-DI**

As a manufacturer, you must allocate a UDI-DI to defined groups of configurations the same way you allocate a UDI-DI to defined models of medical devices. This UDI-DI is referred to as the System UDI-DI. Again, this is not an additional identifier, but a distinction used to identify configuration groups.

As a manufacturer, you are responsible for defining the groups as the collection of possible configurations for a given product line as described in a regulatory file.

**System UDI-PI**

You must allocate a System UDI-PI to each individual system. A later change of a component, sub-system or accessory of the system does not change the System UDI-PI.

The concept of System UDI, System UDI-DI and System UDI-PI is to help define configurations of systems. You are not required to provide an additional identifier, nor are you required to enter an additional identifier into the AusUDID. The System UDI-DI is the Primary DI for configurable systems.

**Example: Upgrade to system which impacts safety or performance**

**Claire the manufacturer**

**MRI system**

Claire manufactures an MRI system, 'Model A', and distributes it 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
- a combination of both.

These changes alter the safety profile, performance or intended use of the system.

Claire determines this results in a new model, Model B.

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 supply an upgrade kit as a separate medical device with its own UDI-DI. The UDI-DI of the upgrade kit and the original System UDI-DI together identify 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 replaces the 50kV generator with a 100 kV generator, which is not specified in the original configuration and changes system performance.

Alice determines this creates a new model or version. If she modifies the device as a new installation, she must allocate a new System UDI-DI. Alternatively, she may provide an upgrade kit as a separate medical device with its own UDI-DI. The UDI-DI of the upgrade kit and the original System UDI-DI together identify 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 diagnostic algorithm that enables new data calculations and imaging options. The algorithm introduces new indications for use and changes system features and performance.

Bella determines this creates a new model or version. If she modifies the device as a new installation, she must allocate a new System UDI-DI. Alternatively, she may provide an upgrade kit as a separate medical device

| | |
|---|---|
| | with its own UDI-DI. The UDI-DI of the upgrade kit and the original System UDI-DI together identify the changed device. |

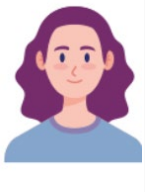
**Examples of changes where the UDI-DI remains unchanged**

As a manufacturer, you do not need to allocate a new UDI-DI when changes do not require the device to be distinguished from the original.

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

| | |
|---|---|
|  | **Indigo the manufacturer**<br>**CT system**<br>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.<br>Safety, performance and intended use remain unchanged. As such, Indigo determines this is not a new model, and the System UDI-DI does not change. |

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

| | |
|---|---|
|  | **Olivia the manufacturer**<br>**CT system**<br>Olivia manufactures a CT System with an ARTG inclusion that covers several diagnostic algorithms. Customers choose which algorithms they would like to activate when ordering. A customer later activates an approved algorithm on an installed system because of their changing business needs.<br>The extra algorithm may be installed or activated and does not change the model or version of the system. As such, the System UDI-DI does not change. |

**Example: Addition of an accessory for an installed device**

| | |
|---|---|
|  | **Matilda the manufacturer**<br>**System used with accessories**<br>Matilda manufactures a system designed for use with accessories.<br>Customers adding or using accessories with the System is covered by the original specifications for the defined groups of configurations and does not change the model or version of the system. As such, the System UDI-DI does not change. |

## System components or accessories

As a manufacturer you must allocate a UDI to each component, sub-system, consumable or accessory if it:

- is a medical device in its own right
- is commercially available on its own

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

For example, an Automated External Defibrillator (AED) supplied with electrodes and batteries must be included in the AusUDID as a system. If the batteries and electrodes require their own UDI, you must include them in the AusUDID as separate devices.

We recommend you link the UDI record(s) of the components or accessories to the ARTG ID for the System you supply them against, as well as their own ARTG ID.

**Maddie the sponsor**

**System used with accessories that are sold separately**

Maddie supplies a system that customers can use with accessories. Maddie also supplies the accessories separately. The accessories have a different ARTG inclusion from the system. In this case, Maddie:

- submits a UDI record for the system and links it to the ARTG inclusion for the system
- submits a UDI record for each applicable accessory, and links it to the ARTG inclusion for each accessory and the ARTG inclusion for the system.

### IVD systems

Many IVD systems use test reagents and accessories that are higher-class medical devices than the instrument they are used with. You must include the reagents and accessories in the AusUDID separately from the instrument.

## Medical device accessories

**Medical device accessories must meet UDI requirements in certain circumstances.**

An accessory is a device intended to support, supplement or augment the performance of one or more parent devices. The accessory allows or helps the parent device to be used in a way that the manufacturer of the device intended.

Accessories must have their own UDI where the accessory:

- is individually labelled, packaged and sold separately from the parent device
- has its own ARTG inclusion (i.e. is not regulated under the parent device's ARTG inclusion)
- is in scope of devices required to meet UDI requirements.

Accessories do not need to meet UDI requirements where the accessory:

- is packaged and sold with a parent device that has its own UDI
- is exempt from inclusion in the ARTG, or
- is otherwise exempt from UDI requirements.

# Replacement parts or spare parts

**Replacement parts or spare parts must meet UDI requirements in certain circumstances.**

A replacement part or spare part is not a finished device in its own right. These are not considered an accessory for a device, as they would not normally be supplied separately for use with the device.

You are only required to meet UDI requirements for replacement parts or spare parts where the part:

- is sold separately from the device
- has its own ARTG inclusion, and
- is in scope of devices required to meet UDI requirements.

**Amanda the manufacturer and sponsor**

Amanda is both the manufacturer and sponsor of a system. A component in the system reaches the end of its life, and her customer orders a replacement. Amanda sells this component separately as well as part of the system. The component has its own ARTG inclusion and is classified as Class Is. Because the component is sold separately, has its own ARTG inclusion and falls within the scope of devices required to meet UDI requirements, Amanda allocates a UDI to the component.

The customer also requests a new screw for the system because the existing screw has lost its threading. Amanda does not sell screws separately, they do not have an ARTG inclusion, and they are not medical devices. Therefore, screws are not in scope for UDI requirements. Amanda provides the screw to the customer, but it does not require a UDI.

# Contact lenses

**Contact lenses must meet UDI requirements where they are included in the ARTG.**

Many contact lenses are not currently included in the ARTG because of they are subject to the Patient Matched Medical Devices transition period. Devices eligible for this transition are exempt from UDI requirements until **1 July 2029**.

You may choose to meet some UDI requirements before this date; however, you cannot meet UDI record submission requirements until your devices are included in the ARTG. UDI record submission requires linkage to an ARTG entry. Until then, you can only meet UDI labelling requirements.

## UDI allocation for contact lenses

You must allocate a unique UDI-DI for each device model. Each production run with different production identifiers must have a separate UDI-PI.

You may allocate the UDI-DI to align with a defined design envelope and use the UDI-PI to track specific quality combinations.

Applying a broader definition of model will affect actions for specific devices. Any market action, such as a recall or correction, would need to apply to all devices covered by that broader definition.

The number of UDI-DIs depends on how you define and manage models. For example:

- you may allocate one UDI-DI per design and use the UDI-PI to track materials and colours
- You may allocate a separate UDI-DI for each design, material or colour combination.

As the manufacturer, you are responsible for determining the design parameters and envelope for your contact lenses. You must justify this decision if requested.

## Boundary products

**Boundary products must meet UDI requirements** where the product is:

- Included in the ARTG as a medical device
- In scope of devices required to meet UDI requirements.

Examples include:

- Eye lubricating products that are only intended to lubricate the eye and do not have pharmacological components intended for antiseptic effect
- Liquid, spray, wipe or aerosol disinfectants to be used for disinfecting medical devices.

For guidance specific to boundary products, see: Understanding rules for boundary and combination products | Therapeutic Goods Administration (TGA)

## Combination products

**Combination products must meet UDI requirements** where the product is:

- Included in the ARTG as a medical device
- In scope of devices required to meet UDI requirements.

Examples include:

- Medical devices used to administer medicine that is supplied separately, such as syringes.

For guidance specific to combination products, see: Understanding rules for boundary and combination products | Therapeutic Goods Administration (TGA)

## Co-packaged medical devices

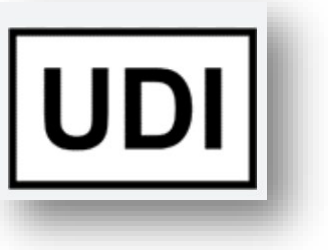
**Co-packaged medical devices must meet UDI requirements** where the product is:

- included in the ARTG as a medical device
- in scope of devices required to meet UDI requirements.

It is important to note that co-packaged medical devices are regulated differently depending on the regulatory jurisdiction. Where the device is regulated in Australia as a medical device, it must meet UDI requirements, regardless of the device containing a medicine component.

Where the device also bears medicine serialisation, we encourage manufacturers to include the UDI ISO symbol to clearly distinguish the UDI.

*Figure 29: UDI ISO symbol*




# The Australian UDI Database (AusUDID)

The AusUDID is Australia's repository for UDI-DIs and related data. It stores information about each model of medical device to improve traceability of devices supplied in Australia. Patients, consumers, clinical quality registries and health professionals can view and download device information at no cost.

You can access the AusUDID here: TGA AusUDID.

This document does not explain how to use the AusUDID. For information on accessing the AusUDID, managing user roles, and submitting and maintain UDI records, visit the UDI Hub: The Australian UDI Database for sponsors and manufacturers | Therapeutic Goods Administration (TGA).

The AusUDID stores UDI-DI and associated medical device data.

The AusUDID does **not** store the UDI-PI or any patient information.

## UDI records

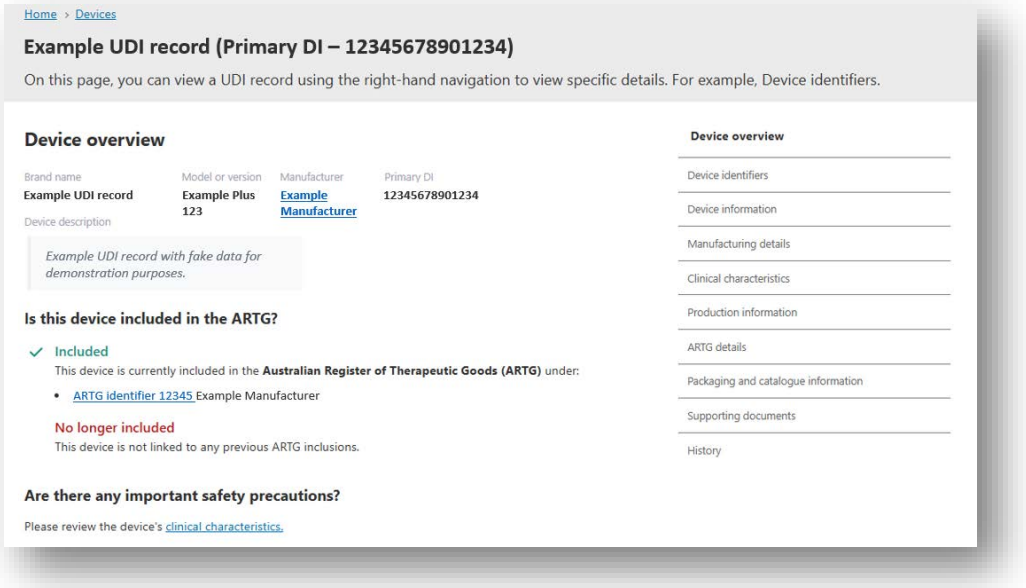
Device information is submitted to the AusUDID as a UDI record. A UDI record consists of the device's UDI-DI and other related data, including:

- device class
- GMDN
- manufacturer details
- sponsor details
- commercial distribution status.

For a complete list of data elements, see: *Australian UDI Data Dictionary*.

The image below shows how a UDI record is displayed in the AusUDID.

*Figure 30: Example UDI record*




## Timing of UDI record submission

UDI records must be submitted within 30 days of first supply of the device in Australia after the UDI compliance date for the device.

**Callum the sponsor**

Callum supplies a Class IIb reusable surgical device. He must comply with the UDI requirements from 1 July 2026.

His manufacturer allocates and applies a UDI to the device label and packaging.

Callum submits a UDI record to the AusUDID Production environment within 30 days of next supply in Australia. He supplies the device in Australia on 1 July 2026, so he must submit the UDI record by 31 July 2026.

Callum submits the UDI record on 1 July 2026 and is compliant.

## UDI record history

The AusUDID includes a history of changes to UDI records. This data is available in the AusUDID indefinitely to all users.

## UDI record retention

All UDI records in the AusUDID remain indefinitely. This is to ensure that historical information about medical devices is available, when necessary.

UDI records must never be deleted, even if the device is no longer in supply. When a medical device is no longer in commercial distribution, sponsors must update the Sponsor Commercial Distribution End Date in the UDI record to reflect this.

If an ARTG inclusion is made inactive (e.g. cancelled or suspended) the UDI record will continue to be accessible, and it will show the UDI is no longer included / approved for supply using the inactive ARTG.

# AusUDID and the Australian Register of Therapeutic Goods (ARTG)

All UDI records must link to an ARTG inclusion to meet UDI submission requirements. This link:

- validates key data fields such as manufacturer details
- associates the device with its approval to supply.

The ARTG remains the single record of the authorisation to supply a medical device or an IVD. The AusUDID supports this approval by providing detailed information about individual models of devices supplied under the ARTG inclusion.

# AusUDID data elements and rules

The *Australian UDI Data Dictionary* provides detailed information about each data element, including: This document includes a list of the fields in the database, as well as:

- data element names
- descriptions
- permitted values
- edit rules
- other useful metadata.

When changes are made to Australian UDI data elements, we will publish any changes to the data elements and rules on the UDI Hub.

## Mandatory, voluntary and conditionally mandatory data elements

Data elements are separated into 3 categories:

- Mandatory – must be included in every UDI record. Examples include:
  - Primary DI
  - Model of Version
- Optional – optional but strongly recommended. Examples include:
  - Catalogue Number
  - Device Description
- Conditionally mandatory – required in specific circumstances. Examples include:
  - If Device Count is greater than one, you must provide either Unit of Use DI or Direct Marking DI
  - If the device has applicable higher levels of packaging, you must provide Package DI(s)
  - If the device requires sterilisation prior to use, you must provide Sterilisation Methods.

## UDI Trigger data elements

Data elements are further grouped into:

- UDI Trigger data elements – data elements where changes require a new UDI-DI and UDI record. Examples include:
  - Brand Name
  - Device Count
  - Model or Version
- Non-UDI Trigger data elements – data elements that can be edited at any time without requiring a new UDI-DI and UDI record. Examples include:
  - Device Description
  - Catalogue Number
  - Previous DI.

The *Australian UDI Data Dictionary* describes which data elements are not UDI Triggers.

## Device data elements and sponsor data elements

Data elements are also categorised as:

- Device data elements – general to the device, usually provided by the manufacturer either directly to the AusUDID or via the sponsor. Examples include:
  - Sterilisation Methods
  - Clinical Size information
  - Storage and Handling information
- Sponsor data elements – specific to the sponsor and can only be added by a sponsor. Examples include:
  - ARTG ID
  - Catalogue Number
  - Sponsor Commercial Distribution End Date.

The AusUDID will apply different rules for these types of data elements if the device has multiple sponsors.

## Data element summary table

The table below summarises how data elements are categorised in the AusUDID. For additional information, refer to the *Australian UDI Data Dictionary*.

| Category | Description | Examples |
|---|---|---|
| Mandatory | Must be included in every UDI record | • Primary DI<br>• Brand Name |
| Voluntary | Optional, but recommended | • Catalogue Number |

| Category | Description | Examples |
|---|---|---|
| | | • Device Description |
| Conditionally mandatory | Required only in specific circumstances | • If Device Count is greater one, Unit of Use DI or Direct Marking DI required |
| UDI Trigger data elements | Changes require a new UDI-DI and UDI record | • Brand Name<br>• Device Count |
| Non-UDI Trigger data elements | Can be edited at any time without a new UDI-DI and UDI record | • Device Description<br>• Catalogue Number |
| Device data elements | General device details, usually from the manufacturer | • Sterilisation Methods<br>• Clinical Size information |
| Sponsor data elements | Sponsor-specific details, added only by sponsor | • ARTG ID<br>• Catalogue Number |

# Data entry rules

Submitting a UDI record successfully requires meeting the AusUDID data validation rules. These rules help ensure accuracy of the data and correct compliance with the UDI requirements.

## Accurate and up to date data

Data submitted in a UDI record must be accurate at the time of submission and it must be kept up to date while the device is in commercial distribution.

If changes occur to a device that change a UDI Trigger data element, a new UDI record must be submitted within 30 days of supply of the changed device in Australia.

If changes occur to a device that does not change a UDI Trigger data element, the UDI record must be updated within 30 days of supply of the device in Australia.

## Data validation

The AusUDID validates each UDI record to ensure:

- the manufacturer matches the manufacturer in the linked ARTG inclusion
- the UDI-DI format complies with the selected Issuing Agency - for example, correct length, numeric or alphanumeric structure
- mandatory fields are complete and meet permitted value requirements
- conditional fields are provided when required - for example, Unit of Use or Direct Marking DI provided if Device Count is greater than one.

*Tip: Use the Australian UDI Data Dictionary to check permitted values and rules before submission.*

## UDI record submission responsibilities

Both sponsors and manufacturers can submit UDI records to the AusUDID. However:

- UDI records submitted by manufacturers are **published but not publicly available** until a sponsor links an ARTG ID
- sponsors must add sponsor-specific details and link the ARTG ID to make the UDI record publicly available.

Sponsors and manufacturers must work together to decide:

- how UDI records will be submitted
- whether the manufacturer will submit the initial device data.

If both parties want to contribute data:

- the manufacturer can submit the device data
- the sponsor can add the sponsor data.

A UDI record is not compliant until it is linked to the applicable ARTG inclusion.

The sponsor remains legally responsible for all UDI records associated with their organisation. Sponsors must:

- ensure the accuracy of all data in their UDI records
- keep records up to date
- verify that mandatory and conditionally mandatory data elements comply with UDI requirements
- confirm that linked ARTG IDs are correct.

*Tip: Where both the sponsor and manufacturer may seek to provide the required UDI data, to simplify the management and co-ordination of the data, a manufacturer can add their data to the Australian UDI Bulk Upload Template and provide it to the sponsor to add the remaining sponsor data. The sponsor can then submit the entire template, with both organisations' data.*

**Jennifer the manufacturer**

Jennifer submits a UDI record with all device data.

Because she is a manufacturer, she cannot:

- add sponsor data
- link the UDI record to an ARTG inclusion.

Jennifer's UDI record is **published but not publicly available**. It is visible to logged-in users, but not to public users such as consumers and healthcare.

The sponsor must link the UDI record to their applicable ARTG inclusion(s) within 30 days of first supply of the device after its UDI compliance start date.

**Penelope the sponsor**

Penelope wants to link her ARTG to a UDI record that was published by her manufacturer, Jennifer.

Penelope locates the UDI record and adds:

- ARTG ID
- Catalogue Number
- Sponsor Commercial Distribution End Date
- Supporting Documents, such as a Patient Information Leaflet.

The UDI record is published **and** publicly available. It is now visible to all users including consumers and healthcare.

# Correcting and updating UDI records

We recognise there are many scenarios in which data in a UDI record can change over time. Common scenarios include:

- correcting data entry errors
- applying clinically relevant changes to the device
- meeting new Issuing Agency requirements
- supplying a device to multiple countries with different UDI rules.

The AusUDID allows both **corrections** and **updates** to accommodate these changes. The type of change depends on its purpose.

## Update a UDI record

Updates occur when the device or its characteristics change.

Key rules:

- updates are changes to non-UDI Trigger data elements
- updates to UDI Trigger data elements are not permitted; these require a new UDI-DI and UDI record
- sponsors must update UDI records within 30 days of the changed device being supplied in Australia.

*Example: The device's label used to include the lot number and serial number. It now includes the lot number, serial number and manufacturing date. The sponsor must update the UDI record to change 'Manufactured Date on the Label?' to 'Yes'. As this is not UDI Trigger field this a change to the existing UDI record.*

## Correct a UDI record

Corrections fix incorrect data for UDI Trigger data elements which are genuine errors caused by data entry or technical errors.

Key rules:

- you can correct errors in the AusUDID at any time
- the AusUDID maintains an audit trail of changes, including who made the change and when
- you must provide a reason for the correction, and it may be reviewed by the TGA
- corrections should be made as soon as possible after an error is identified.

*Example: A device's Brand Name was spelt incorrectly. Even though this is a UDI Trigger data element, the sponsor can fix this error without needing a new UDI-DI or UDI record. When correcting the error, the sponsor must provide the reason for the correction, which may be reviewed by the TGA.*

## Grace Period

The Grace Period is designed to allow users to fix errors in the UDI data that are identified after publication.

The Grace Period begins after the UDI record is first published. This includes when the UDI record is published by a manufacturer, even if the UDI record is not yet linked to any ARTG inclusion and publicly available.

During the Grace Period, you can change any data element, including UDI Trigger data elements, without needing a new UDI-DI and UDI record or requiring a Correction action.

**Grace Period length**

The length of the Grace Period is subject to change; however, it will generally be:

- 30 days in AusUDID Production
- 1 day in AusUDID Pre-Production.

The reduced Grace Period in AusUDID Pre-Production allows for users to test the corrections functionality without needing to wait out the entire Grace Period.

**Changing data during and after Grace Period**

During Grace Period:

- you can edit any data element
- UDI Trigger rules will not apply.

After Grace Period:

- you can update non-UDI Trigger data elements freely
- updates to UDI Trigger data elements will require a new UDI-DI and UDI record
- you can correct UDI Trigger data elements, if it is a genuine error in the data.

## Corrections or updates by third party data providers

An agent or third party data provider that is appointed to submit data under the authority of the sponsor can action corrections and updates. The AusUDID includes privileges and checks that require a third party to have the authority of the sponsor before they are permitted to act on the sponsor's behalf.

# Multiple sponsors of the same device

Because of the nature of therapeutic good regulation in Australia, it is possible that more than one sponsor supply the same medical device with the same UDI-DI. The AusUDID is designed to manage these scenarios.

## Submitting UDI records

As a sponsor, you are responsible for submitting UDI records for your devices. Where you are the first sponsor submitting the UDI record, you can submit the UDI record as normal.

If another sponsor has already submitted the UDI record for the device, you only need to:

- add your sponsor data, such as ARTG ID and Catalogue Number (if applicable)
- ensure your data is accurate and complete.

You do **not** need to duplicate or resubmit the existing UDI record. Once you add your sponsor data, you meet UDI compliance requirements.

**Louise the sponsor**

Louise supplies the same device with the same UDI-DI as Kayla. Kayla has already submitted the UDI record for this device.

Louise locates the existing UDI record and adds her:

- ARTG ID
- any additional sponsor data, such as Catalogue Number.

Louise does not resubmit the UDI record or the device data because it has already been provided by Kayla.

## Data elements for multiple sponsors

For UDI records linked to multiple sponsors, the AusUDID will manage changes to the data based on whether the data element being changed is a Device data element or a Sponsor data element:

- Device data elements are to be consistent across all sponsors of the device; this data should be controlled by the manufacturer
- Sponsor data elements are unique to each sponsor and editable only by that sponsor.

The assignment of Device and Sponsor categories to each UDI data element is indicated in the online screens of the AusUDID and included in the *Australian UDI Data Dictionary*.

All other data element rules remain the same, including UDI Trigger data element rules. For more information, see AusUDID data elements and rules.

## Updating or correcting UDI records

If you change a UDI record that is linked to multiple sponsors:

- all changes to data elements that are categorised as Device data must be recorded as a correction action, as enforced by the AusUDID. This includes changes to non-UDI Trigger data elements
- the reason for the change must be provided.

All changes are logged and viewable using the device ‘History’ tab.

We may contact sponsors if a change appears incorrect.

| | |
|---|---|
|  | **Louise the sponsor**<br>Louise and Kayla share a single UDI record. Her manufacturer has let her know that a new sterilisation method can be used to sterilise their device.<br>Louise adds the new sterilisation method to the UDI record. She does this as a correction and provides the reason.<br>Louise’s change is logged in the ‘History’ tab of the UDI record and can be viewed by Kayla and other users. |

## Responsibility and resolution of data disputes

You are only responsible for the data that you provide. If you are the first sponsor to add the UDI record, you are responsible for the UDI record as a whole. If you are an additional sponsor who links an ARTG ID to the UDI record, you are responsible for ensuring that the data in the UDI record is accurate and up to date at the time of linking your ARTG ID.

If another sponsor changes data incorrectly, you are not responsible for this change. The sponsor who changed the data to be incorrect is responsible. If you believe a change to the UDI record is wrong, contact the UDI Support Team at UDI@health.gov.au.

| | |
|---|---|
|  | **Kayla the sponsor**<br>Kayla and Louise share a single UDI record. Kayla sees that Louise has added a new sterilisation method in the UDI record.<br>Their manufacturer did not let Kayla know that there was a new sterilisation method available for the device.<br>Kayla checks with her manufacturer to ensure that this is correct. Her manufacturer confirms that this is accurate, and Kayla leaves the change made by Louise. |
|  | **Louise the sponsor**<br>Louise makes another change to the UDI record, changing the Device Description to include additional information about the device. |
|  | **Kayla the sponsor**<br>Kayla disagrees with the Device Description change made by Louise. Kayla can:<br>• liaise with their manufacturer to obtain a general Device Description from the manufacturer<br>• contact the UDI Support Team for assistance. |

# UDI and other TGA processes or activities

UDI affects several existing TGA processes and activities. As a sponsor or manufacturer, it is your responsibility to understand where UDI impacts these processes.

## Consent to Supply (CTS) process for UDI

If you cannot meet the UDI requirements after the mandatory compliance date for your medical device you may choose to submit an application for consent to supply. You must lodge the application well in advance of the mandatory compliance date with supporting documentation. We must consider and make a decision on the application before you supply the non-compliant device.

We are establishing a simpler and lower impact CTS process for sponsors unable to comply with the UDI-related Essential Principles, reflecting the need to balance industry compliance with the UDI requirements with the safety risk if a device cannot be UDI compliant by the relevant UDI compliance start date.

The details on the streamlined process and commensurate fees for the UDI CTS will be published on the TGA's website once finalised.

## Market actions: Recalls, alerts and corrections

Where a UDI is available for a device, you must include it in any related:

- recalls
- market action customer letters.

When submitting a new market action notification through the TBS portal, enter UDIs in the applicable field on the 'Product Report' tab.

Where a UDI is not available, reports continue as per existing requirements and should include any applicable information.

## Adverse events

Where a UDI is available, you must include it in adverse event reports. As the adverse event reporting system currently does not include a dedicated UDI data field, enter the UDI(s) as text in the report.

## Patient Implant Cards

Manufacturers must provide Patient Implant Cards (PICs) for their implantable medical devices.

PICs must include:

- name of the device
- model of the device
- batch code, lot number or serial number of the device
- manufacturer's name, address, and website.

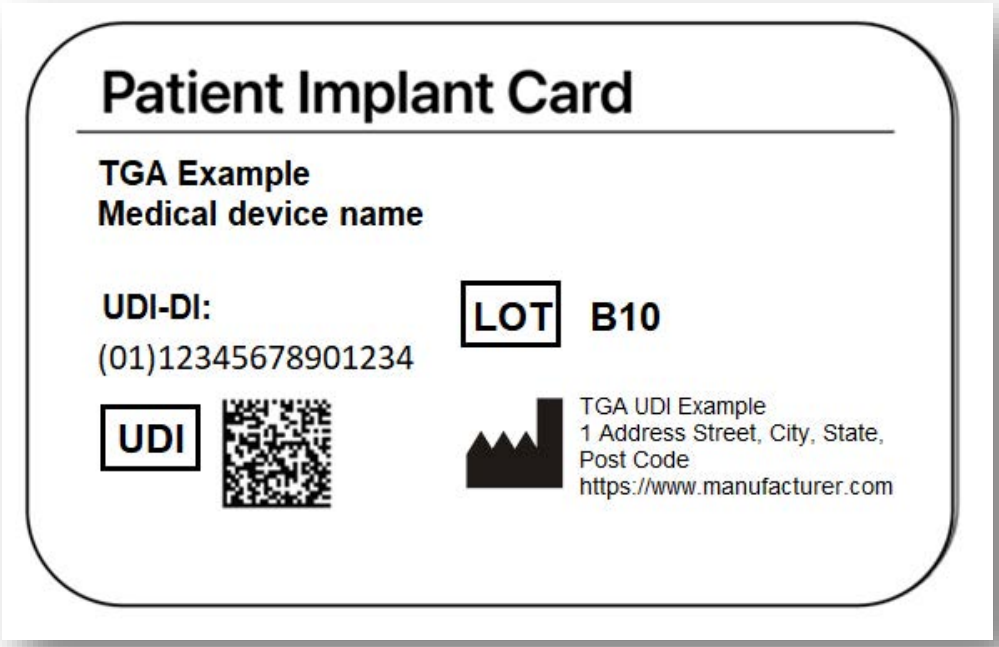
For devices in scope of UDI requirements, the PIC must also include:

- the full UDI (UDI-DI and UDI-PI) in AIDC form
- the UDI-DI in HRI form.

PICs are not required to bear the UDI-PI in HRI form, as production information such as batch code, lot number or serial number is already required per existing PIC requirements.

An example of a PIC with a UDI:

*Figure 31: Example of a UDI compliant PIC*




If you are unable to meet the UDI requirements for Patient Implant Cards, you will need to seek Consent to Supply.

### PICs for small non-sterile devices in Surgical Loan Kits (SLKs)

For small non-sterile devices in SLKs where only the UDI-DI is provided due to challenges associated with maintaining the UDI, only the UDI-DI is required on the PIC. The UDI-PI is not required.

Where the UDI-PI is not provided on the PIC for these devices, any market action must include all lots, batches or production runs of the device.

If the device is also supplied outside of the SLK, the PIC for the device supplied outside the SLK must have both the UDI-DI and the UDI-PI.

## Patient Information Leaflets

You are **not** required to include the UDI on Patient Information Leaflets (PILs). However, you may choose to include the UDI voluntarily.

As a sponsor, you may choose to submit PILs to the AusUDID as either a:

- URL link
- PDF attachment.

If you include a PIL in your UDI record, you must keep it up to date.

# Instructions for Use

You are **not** required to include the UDI on Instructions for Use (IFUs). However, you may choose to include the UDI voluntarily.

As a sponsor, you may choose to submit IFUs to the AusUDID as either a:

- URL link
- PDF attachment.

If you include an IFU in your UDI record, you must keep it up to date.

# Certifications

You do **not** need to re-register or re-certify your medical devices when you amend your medical device labelling to meet the UDI requirements. This includes changes to:

- device labels
- Patient Implant Cards (PICs)
- any other supporting documents.

You are **not** required to provide evidence to the TGA that devices have changed to meet UDI requirements. However, you must submit a UDI record for each device to the AusUDID.

# Audits

## TGA audits

The TGA may review compliance with UDI requirements during:

- post-market reviews
- targeted audits
- routine inspections.

These audits may focus on whether sponsors have:

- submitted UDI records for all applicable devices
- maintained accurate and up to date data
- include UDI in required processes such as recalls.

As the UDI requirements form part of the Essential Principles, we may take regulatory action if you are non-compliant, including:

- suspension or cancellation of your devices from the Australian Register of Therapeutic Goods (ARTG)
- applying civil penalties as outlined in Part 4-11, Division 1 of the Act
- issuing infringement notices.

You can learn more on our website about compliance actions.

## AusUDID reviews

The UDI Support Team will conduct periodic reviews of UDI records submitted to the AusUDID. These reviews will include checks for:

- **Completeness** – Mandatory and conditionally mandatory fields are populated
- **Accuracy** – The UDI data matches the ARTG inclusion and Issuing Agency rules
- **Timeliness** – Updates are made within the required timeframes
- **Corrections** – Reasons and descriptions for change are provided for corrections
- **UDI Trigger rules** – Changes to UDI Trigger data elements correctly result in a new UDI-DI and UDI record or are processed as a correction.

Review outcomes may include:

- requests for clarification or correction
- guidance on improving data quality
- escalation to TGA compliance teams, where required.

# Record keeping requirements

As a sponsor, one of your existing ongoing responsibilities is to maintain distribution records for medical devices supplied in or exported from Australia. For details on existing distribution record requirements, see Distribution records | Therapeutic Goods Administration (TGA).

## UDI specific record keeping requirements

For UDI compliance, you are responsible for maintaining records of all UDIs used to identify devices that are in scope of UDI requirements:

- **Sponsors must maintain records of the full UDI, including the UDI-DI and the UDI-PI** to enable market actions at the model level or production level when necessary. This means recording each value, for example if there are 1,000 batch numbers, all 1,000 must be recorded.
- **Sponsors must maintain a record of the types of production identifiers used** (for example, batch number, lot number, serial number). This information forms part of the UDI record, so either the UDI record itself or the sponsor's internal data either in your internal systems or prepared for AusUDID submission will satisfy this requirement.
- **Sponsors must maintain a record of whether the device was directly marked**, including whether the Direct Marking DI is the same or different from the Primary DI. Where the Direct Marking DI is different, the sponsor must maintain records of the Direct Marking DI itself. This information forms part of the UDI record, so either the UDI record itself or the sponsor's internal data either in your internal systems or prepared for AusUDID submission will satisfy this requirement.
- **If the UDI-PI includes production identifiers beyond those required for distribution records**, for example serial number or software version number, the sponsor must maintain records of these. We do not prescribe how sponsors maintain these records.

**We do not prescribe how sponsors hold this information**. You may keep records of individual UDI-DIs and UDI-PIs, the full UDI or the individual elements that make up the UDI and related information in one or more system or records. Whether these are stored together or separately is subject to your systems and processes. The key requirement is that the full UDI and any related data can be retrieved when needed, such as during a market action.

For example: where components of the UDI-PI are already recorded under distribution record requirements, this is sufficient for UDI purposes. If the expiry date, lot, or batch numbers are already captured in distribution records, and you are able to use this information to identify specific devices when required, this will satisfy the record keeping requirement.

## Retaining records of UDIs

As a sponsor, you must retain records for a minimum of 10 or 5 years, depending on the classification of your device.

| Classification of device | Record retention period |
|---|---|
| Class 4 IVDs | 10 years |
| Class III medical devices | 10 years |
| Class IIb implantable medical devices | 10 years |
| All other classifications | 5 years |

## Example of UDI record keeping

**Karolina the sponsor**

Karolina supplies a Class III medical device. Her device has a UDI consisting of a UDI-DI and a UDI-PI with expiry date, batch number, and serial number.

Karolina can:

- maintain records of the full UDI, or
- maintain records of the UDI-DI and serial number and rely on existing distribution records for expiry date and batch number.

Karolina's distribution records include expiry date and batch number but not the UDI-DI or serial number. She can:

- maintain records of the full UDI using her existing systems
- add the serial number and UDI-DI to her distribution records
- maintain each individual element in a way that suits her organisation.

As long as Karolina can retrieve the full UDI when needed, she meets UDI record keeping requirements. Because her device is Class III, she must keep these records for 10 years.

# Fees and charges

There are **no fees** for submitting or maintaining UDI records in the AusUDID.

Ongoing management and maintenance of the AusUDID are included in annual charges.

# Demonstrating compliance with UDI-related Essential Principles

Demonstrating compliance with the Australian UDI requirements will depend on the point in the device lifecycle and whether the device has an existing ARTG inclusion or is in a new Application for Inclusion.

## Existing ARTG inclusions

For devices that are already included in the ARTG, you are **not required to immediately or proactively demonstrate compliance**. However, sponsors and manufacturers are expected to ensure their records, documentation and internal systems reflect the UDI requirements that apply in line with the compliance dates that apply to the specific device risk classification and type.

**Essential Principle documentation**

Your Essential Principles (EP) documentation should be updated to include any available information that demonstrates compliance with UDI related EPs. For example:

- **EP13C.1** – A list of each device model and its associated UDI-DI is sufficient.
- **EP13C.2, EP13C.3 and EP13C.4** – A printout, screenshot, or link to the published UDI record in the AusUDID is acceptable.
- **EP13C.5** (if applicable) – Procedures for direct marking or images of the directly marked device will satisfy this requirement.

These updates do not need to be made immediately but should be in place by the applicable mandatory UDI compliance dates for the device.

**Quality Management System (QMS) updates**

Your QMS should reflect the UDI-related processes, decisions and actions taken, including:

- assignment and maintenance of UDI-DIs
- management of UDI-PIs
- labelling controls for UDI carriers
- direct marking procedures (if applicable)
- processes for UDI record updates in the AusUDID.

**Compliance monitoring**

Compliance with these obligations will be assessed through the TGA's regulatory activities, including:

- post-market reviews
- audits
- recalls and other market actions
- targeted compliance checks.

Please note that no separate or additional UDI-specific audit program is in place and UDI compliance will be integrated into existing processes.

## New ARTG inclusions

For new ARTG applications, assessment of UDI compliance will be incorporated into standard application review processes, including review of:

- product labels to ensure UDI Carrier requirements are met
- UDI-DI assignment information
- direct marking evidence (if applicable)
- Patient implant cards (if applicable).

The TGA is currently finalising the UDI-related compliance activities for new application processes. All information will be published on the TGA website once finalised.

# Summary of roles and obligations

Sponsors and manufacturers share the responsibilities for meeting UDI requirements. These obligations are **in addition to** existing regulatory requirements for Australia and do not override or replace them.

## Manufacturer role and obligations

Your key obligations include:

- choose a TGA recognised Issuing Agency to issue identifiers for your device
- allocate identifiers to your device using the relevant coding standard set by your chosen Issuing Agency, including:
  - UDI-DI
  - UDI-PI
  - Unit of Use DI, if applicable
  - Direct Marking DI, if applicable
  - Package DI(s), if applicable
- ensure your production processes will apply a UDI Carrier containing the UDI-DI and UDI-PI in HRI and AIDC forms on:
  - the device base package
  - the device itself, if direct marking is applicable
- ensure your production processes will apply a UDI Carrier containing the Package DI and UDI-PI in HRI and AIDC forms to all applicable higher levels of packaging
- allocate a new UDI-DI when there is a change to your device that could lead to misidentification or ambiguity in its traceability (UDI Trigger)
- agree the responsibilities for providing device data and submitting UDI records to the AusUDID with your Australian sponsor and putting these data submission and sharing arrangements in place
- demonstrating compliance with the relevant Essential Principles for your medical device, including those that relate to labelling when requested.

| | |
|---|---|
|  | **Vala the manufacturer**<br>Vala manufactures Class IIa reusable medical devices. To meet her obligations, she:<br>• chooses a TGA recognised Issuing Agency<br>• allocates a UDI-DI, UDI-PI and Direct Marking DI to her devices<br>• directly marks the reusable device with the UDI |

| | |
|---|---|
| | • applies a UDI Carrier containing the UDI-DI and UDI-PI to the base package of the device<br>• applies a UDI Carrier containing a Package DI and UDI-PI to all applicable higher levels of packaging<br>• provides the device data to her sponsor to submit to the AusUDID. |

# Sponsor role and obligations

Your key obligations include:

- confirm your manufacturer has met UDI requirements
- ensuring that your manufacturer has allocated all relevant identifiers to the device
- confirm that the chosen UDI Carrier format is appropriate for the expected use
- agree the responsibilities for submitting UDI records to the AusUDID with your manufacturer and ensuring the data submission and sharing practices are operating and the data is correct
- maintain accurate and up to date UDI records in the AusUDID
- meet applicable record keeping requirements
- ensure compliance with the Essential Principles.

## Sponsor of medical devices supplied by multiple sponsors

If a device has more than one sponsor:

- your obligations do not change
- you must submit a UDI record, or add sponsor details to an existing UDI record, for the devices you supply.

# Third party role and obligations

Manufacturers may choose to allow a third party to apply the UDI Carrier on their behalf. In this circumstance, the manufacturer remains responsible for the conformity of the UDI Carrier.

Sponsors may choose to allow a third party to submit UDI records on their behalf. In this circumstance, you remain responsible for the data submitted.

As a third party, you are responsible for ensuring that you meet UDI requirements.

# Resources

We have developed a range of resources to support you throughout UDI implementation.

## UDI Hub

You can find all resources we have developed on the UDI Hub.

## UDI requirements resources

- Getting started with UDI | Therapeutic Goods Administration (TGA)
- Australian UDI Data Dictionary | Therapeutic Goods Administration (TGA)
- UDI: Information for sponsors and manufacturers | Therapeutic Goods Administration (TGA)
- UDI glossary | Therapeutic Goods Administration (TGA)
- UDI videos | YouTube.

## UDI record submission resources

- The Australian UDI Database for sponsors and manufacturers | Therapeutic Goods Administration (TGA)
- Australian UDI Bulk Upload Template | Therapeutic Goods Administration (TGA)
- Machine to Machine (M2M) HL7 SPL | Therapeutic Goods Administration (TGA)
- Australian UDI Database Production environment: Release notes | Therapeutic Goods Administration (TGA)
- Australian UDI Database Pre-Production environment: Release notes | Therapeutic Goods Administration (TGA).

# UDI Support Team

We have a dedicated UDI Support Team that provides a range of services including:

- supporting you in understanding your obligations and meeting UDI requirements
- supporting you in using the AusUDID
- supporting healthcare organisations and professionals to understand the application and use of UDI in healthcare systems.

The UDI Support Team does not replace the broader medical device information or enquiry lines and support channels already offered by us.

**Contact us at** UDI@health.gov.au.

# Appendices

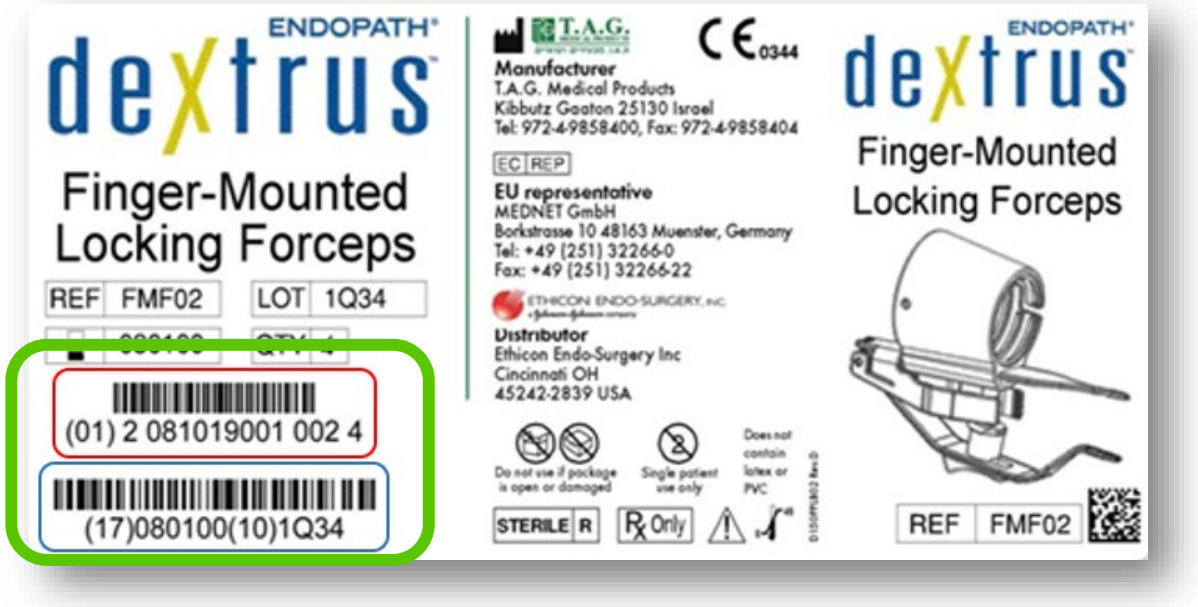
## Appendix A: Examples of UDI Carriers

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 Carrier example

*Figure 32: Example of a GS1 UDI Carrier*

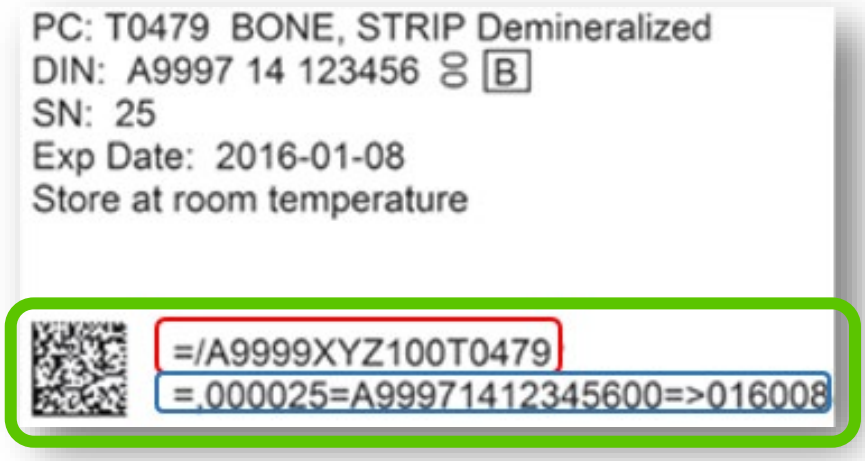


## HIBCC UDI Carrier example

*Figure 33: Example of a HIBCC UDI Carrier*


## ICCBBA UDI Carrier example

*Figure 34: Example of an ICCBBA UDI Carrier*



# Examples of UDI Carrier conventions

*Figure 35: Example of a concatenated barcode*

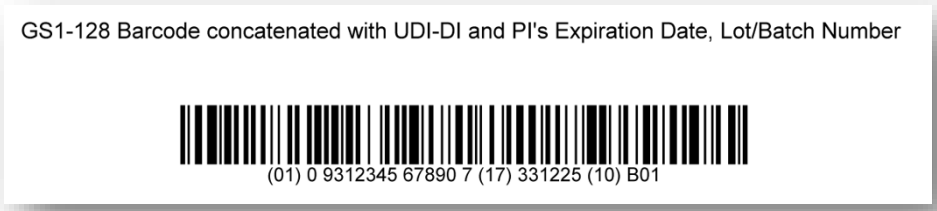



*Figure 36: Example of a non-concatenated barcode*

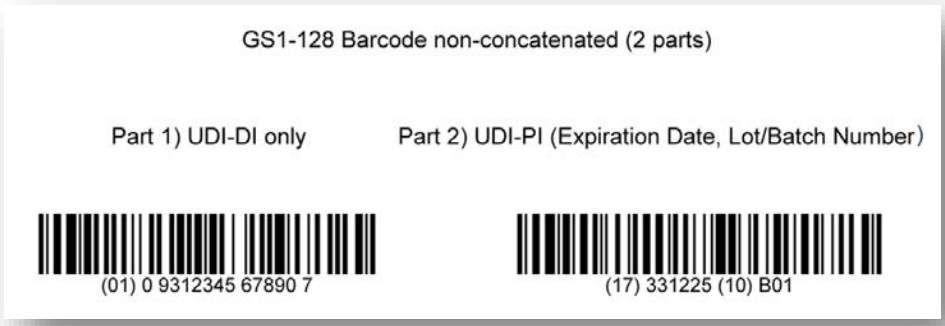



*Figure 37: Example of a 2D barcode*

# Appendix B: UDI data elements and UDI Trigger Data Elements

| Data element | Trigger? |
|---|---|
| Primary DI | Yes |
| Primary UDI-DI Issuing Agency | Yes |
| Device Count | Yes |
| Unit of Use DI | No |
| Device Subject to Direct Marking (DM), but Exempt? | No |
| Direct Marking DI Different from Primary DI? | No |
| Direct Marked DI | Yes*<br><br>Do not trigger a new UDI-DI if the field was blank prior to change. |
| Direct Marked DI Issuing Agency | Yes*<br><br>Do not trigger a new Primary DI if the field was blank prior to change. |
| Secondary DI | No |
| Secondary DI Issuing Agency | No |
| Previous DI | No |
| Previous DI Issuing Agency | No |
| Brand Name | Yes |
| Model or Version | Yes |
| Catalogue Number | No |
| Device Class (Manufacturer) | No |
| Is the medical device software or does it incorporate software? | Yes |
| Is the medical device a kit? | Yes |
| Device Description | No |
| DI Record Published Date | No |
| DI Record Status | No |
| Sponsor Commercial Distribution End Date | No |
| Sponsor Commercial Distribution Status | No |
| GMDN Code (Manufacturer) | No |
| MRI Safety Status | Yes*<br><br>Do not trigger a new UDI-DI if the field was set to ‘Labelling does not contain MRI safety information’ prior to the change. |

| Data element | Trigger? |
|---|---|
| Intended for Single Use? | Yes |
| Restricted Number of Reuses | Yes |
| Device required to be labelled as containing natural rubber latex or dry natural rubber? | Yes |
| Device labelled as 'Not made with natural rubber latex' | No |
| Device Packaged as Sterile? | Yes |
| Requires Sterilisation Prior To Use? | Yes |
| Sterilisation Method(s) | No |
| Clinical Size Type | Yes*<br><br>Do not trigger a new UDI-DI when adding Clinical Size (Combination of Type, Value, Unit of Measure, Size Type Text). |
| Clinical Size Value | Yes*<br><br>Do not trigger a new UDI-DI when adding Clinical Size (Combination of Type, Value, Unit of Measure, Size Type Text). |
| Clinical Size Unit of Measure | Yes*<br><br>Do not trigger a new UDI-DI when adding Clinical Size (Combination of Type, Value, Unit of Measure, Size Type Text). |
| Clinical Size Type Text | Yes*<br><br>Do not trigger a new UDI-DI when adding Clinical Size (Combination of Type, Value, Unit of Measure, Size Type Text). |
| Storage and Handling Type | No |
| Storage and Handling Special Conditions | No |
| Storage and Handling Unit of Measure | No |
| Storage and Handling Low Value | No |
| Storage and Handling High Value | No |
| ARTG ID | No |
| Sponsor ID | No |
| Sponsor Name | No |
| Manufacturer ID | No |
| Manufacturer Name | No |
| Package DI | No |

| Data element | Trigger? |
|---|---|
| Package Type | No |
| Package Contains DI | No |
| Quantity per Package | No |
| Sponsor Package Commercial Distribution End Date | No |
| Sponsor Package Commercial Distribution Status | No |
| Lot or Batch Number on the label? | No |
| Manufactured Date on the label? | No |
| Serial Number on the label? | No |
| Expiration Date on the label? | No |
| Donation Identification Number on the label? | No |
| Document type | No |
| Document Effective Date | No |
| Related ARTG | No |
| Document URL | No |
| Document attachment | No |
| Document Status | No |
| Document Status reason | No |

# Appendix C: Summary of UDI requirements for device types

| Device type | In scope of UDI requirements? | UDI-DI requirements | UDI-PI requirements | Unit of Use requirements | Direct marking requirements | Packaging requirements | Specific UDI record submission requirements | Device specific requirements |
|---|---|---|---|---|---|---|---|---|
| **Class I non-measuring non-sterile** | No (voluntary) | No (voluntary) | No (voluntary). | No (voluntary). | No (voluntary). | No (voluntary). | No (voluntary). | If you choose to comply, meet all UDI requirements to minimise confusion. |
| **Class I measuring** | No (voluntary) | No (voluntary) | No (voluntary). | No (voluntary). | No (voluntary). | No (voluntary). | No (voluntary). | If you choose to comply, meet all UDI requirements to minimise confusion. |
| **Class Is (supplied sterile)** | Yes | Must bear UDI-DI | Must bear a UDI-PI. | Yes, if applicable | Yes, if reusable. | Yes, if applicable | None | None |
| **Class IIa** | Yes | Must bear UDI-DI | Must bear a UDI-PI. | Yes, if applicable | Yes, if reusable. | Yes, if applicable | None | None |
| **Class IIb** | Yes | Must bear UDI-DI | Must bear a UDI-PI. | Yes, if applicable | Yes, if reusable. | Yes, if applicable | None | None |
| **Class III** | Yes | Must bear UDI-DI | Must bear a UDI-PI. | Yes, if applicable | Yes, if reusable. | Yes, if applicable | None | None |
| **Class 1 IVD** | Yes (partial) | Must bear UDI-DI | Must bear a UDI-PI. | Yes, if applicable | Yes, if reusable. | Yes, if applicable | None | None |

| Device type | In scope of UDI requirements? | UDI-DI requirements | UDI-PI requirements | Unit of Use requirements | Direct marking requirements | Packaging requirements | Specific UDI record submission requirements | Device specific requirements |
|---|---|---|---|---|---|---|---|---|
| **Class 2 IVD** | Yes | Must bear a UDI-DI per UDI requirements | Must bear a UDI-PI. | Yes, if applicable | Yes, if reusable. | Yes, if applicable | None | None |
| **Class 3 IVD** | Yes | Must bear UDI-DI | Must bear a UDI-PI. | Yes, if applicable | Yes, if reusable. | Yes, if applicable | None | None |
| **Class 4 IVD** | Yes | Must bear UDI-DI | Must bear a UDI-PI. | Yes, if applicable | Yes, if reusable. | Yes, if applicable | None | None |
| **In house IVD** | No (voluntary). | No (voluntary) | No (voluntary). | No (voluntary). | No (voluntary). | No (voluntary). | None | If you choose to comply, meet all UDI requirements to minimise confusion. |
| **Custom made medical devices** | No (voluntary). | No (voluntary) | No (voluntary). | No (voluntary). | No (voluntary). | No (voluntary). | None | If you choose to comply, meet all UDI requirements to minimise confusion. |
| **Adaptable medical devices** | Yes, if it is a device class in scope of UDI requirements. | Must bear UDI-DI | Must bear a UDI-PI. | Yes, if applicable | Yes, if reusable. | Yes, if applicable | None | None |
| **Patient matched medical devices** | Yes, if more than 5 supplied per year and it is a device class in scope of UDI requirements. | Must bear UDI-DI | Must bear a UDI-PI. | Yes, if applicable | Yes, if reusable. | Yes, if applicable | None | None |

| Device type | In scope of UDI requirements? | UDI-DI requirements | UDI-PI requirements | Unit of Use requirements | Direct marking requirements | Packaging requirements | Specific UDI record submission requirements | Device specific requirements |
|---|---|---|---|---|---|---|---|---|
| **IVD kits** | Yes, if it is a device class in scope of UDI requirements. | Must bear UDI-DI. | Must bear a UDI-PI. | Not applicable. | Yes, if reusable. | Yes, if applicable. | None. | None. |
| **Single use devices** | Yes, if it is a device class in scope of UDI requirements. | Must bear UDI-DI. | Must bear a UDI-PI. | Yes, if applicable. | Not applicable. | Yes, if applicable. | None. | UDI not required on individual devices if intended to be kept in base package. |
| **Reusable devices** | Yes, if it is a device class in scope of UDI requirements. | Must bear UDI-DI. | Must bear a UDI-PI. | Not applicable, unless exempt from Direct Marking. | Yes, unless exempt. | Yes, if applicable. | Must include restricted number of reuses in UDI record. Where no maximum number of reuses is stipulated, select 'N/A' in 'For single use?' field.<br>Must include Direct Marking DI information in | None. |

| Device type | In scope of UDI requirements? | UDI-DI requirements | UDI-PI requirements | Unit of Use requirements | Direct marking requirements | Packaging requirements | Specific UDI record submission requirements | Device specific requirements |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | UDI record, if applicable. | |
| **Capital equipment** | Yes, if it is a device class in scope of UDI requirements. | Must bear UDI-DI. | Must bear a UDI-PI. | Yes, if applicable. | No, but must have label applied to device. | Yes, if applicable. | In the field 'For single use?' select 'N/A'. | None. |
| **Implantable devices** | Yes, if it is a device class in scope of UDI requirements. | Must bear UDI-DI. | Must bear a UDI-PI per UDI requirements. Must include the serial number for active implantables. Must include the serial or lot number for all other implantables. | Yes, if applicable. | Not applicable. | Yes, if applicable. | None. | UDI must be identifiable before implantation. |
| **Dental devices** | Yes (partial). | Must bear UDI-DI. | Must bear UDI-PI. | Yes, if applicable. | Yes, if applicable. | Yes, if applicable. | None. | None. |
| **Contact lenses** | Yes, from 1 July 2029. | Must bear UDI-DI UDI-DI can be assigned at the | Must bear UDI-PI. | Yes, if applicable. | Not applicable due to infeasibility. | Yes, if applicable. | None. | None. |

| Device type | In scope of UDI requirements? | UDI-DI requirements | UDI-PI requirements | Unit of Use requirements | Direct marking requirements | Packaging requirements | Specific UDI record submission requirements | Device specific requirements |
|---|---|---|---|---|---|---|---|---|
| | | design envelope level. | | | | | | |
| **Boundary products** | Yes, if regulated as a medical device. | Must bear UDI-DI. | Must bear UDI-PI. | Yes, if applicable. | Yes, if applicable. | Yes, if applicable. | None. | None. |
| **Combination products** | Yes, if regulated as a medical device. | Must bear UDI-DI. | Must bear UDI-PI. | Yes, if applicable. | Yes, if applicable | Yes, if applicable. | None. | None. |
| **Co-packaged medical devices** | Yes, if regulated as a medical device and of a device class in scope of UDI requirements. | Must bear UDI-DI. | Must bear UDI-PI. | Yes, if applicable. | Yes, if applicable. | Yes, if applicable. | None. | If packaging includes medicine serialisation, use ISO UDI symbol to distinguish UDI Carrier. |
| **Refurbished devices** | Yes, if it is a device class in scope of UDI requirements. | Must bear UDI-DI. | Must bear UDI-PI. | Yes, if applicable. | Yes, if applicable. | Yes, if applicable. | None. | None. |
| **Own brand/private label devices** | Yes, if it is a device class in scope of UDI requirements. | Must bear UDI-DI. | Must bear UDI-PI. | Yes, if applicable. | Yes, if applicable. | Yes, if applicable. | None. | None |
| **Surgical Loan Kits (kit level)** | No.<br>You can comply voluntarily. | Not applicable. | Not applicable. | Not applicable. | Not applicable. | Not applicable. | Not applicable. | SLKs are exempt at kit level. SLK components that are a device in their own right and in scope of UDI requirements |

| Device type | In scope of UDI requirements? | UDI-DI requirements | UDI-PI requirements | Unit of Use requirements | Direct marking requirements | Packaging requirements | Specific UDI record submission requirements | Device specific requirements |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | must meet all applicable requirements. |
| **Surgical Loan Kit components (that are commercially available on their own, and in scope of UDI requirements)** | Yes, if it is a device class in scope of UDI requirements. | Must bear UDI-DI. | Must bear UDI-PI.<br>The UDI-PI does not need to be provided to hospitals for mall non-sterile devices. | Not applicable. | Yes, if reusable. | Not applicable. | None. | UDI must be accessible at point of care.<br>We are not prescribing the method to provide the UDI; however, recommend methods such as stickers, tags, inventory sheets or data carrier strips.<br>Exceptions for small non-sterile devices. |
| **System of Procedure Packs (SOPPs)** | Yes, if the SOPP contains one or more medical devices in scope of UDI requirements. | Must bear UDI-DI. | Must bear a UDI-PI. | Not applicable. | Yes, if reusable. | Yes, if applicable. | None. | None. |

| Device type | In scope of UDI requirements? | UDI-DI requirements | UDI-PI requirements | Unit of Use requirements | Direct marking requirements | Packaging requirements | Specific UDI record submission requirements | Device specific requirements |
|---|---|---|---|---|---|---|---|---|
| **SOPP components** | Yes, if:<br>• Sold separately<br>• In scope of devices classes required to meet UDI requirements. | Must bear UDI-DI. | Must bear a UDI-PI. | Yes, if applicable. | Yes, if reusable. | Yes, if applicable. | None. | None. |
| **Systems that are medical devices** | Yes, if it is a device class in scope of UDI requirements. | Must bear UDI-DI. | Must bear a UDI-PI. | Yes, if applicable. | Yes, if reusable. | Yes, if applicable. | None. | None. |
| **Software as a Medical Device** | Yes, if it is a device class in scope of UDI requirements. | Must bear UDI-DI. | Must bear a UDI-PI. | Yes, if applicable. | Not applicable. | Yes, if applicable. | | Can display the UDI via an electronic display in HRI form only. |
| **Medical devices incorporating software** | Yes, if it is a device class in scope of UDI requirements. | Must bear UDI-DI. | Must bear a UDI-PI. | Yes, if applicable. | Yes, if reusable.<br>No, if capital equipment. | Yes, if applicable. | None. | Can display the UDI via an electronic display in HRI form only. |
| **Devices principally sold in retail premises** | Yes, if it is a device class in scope of UDI requirements. | UDI-DI can be in non-HRI or HRI form. UDI-DI must be in a machine readable form. | UDI-PI must be in human readable form. UDI-PI not required in machine readable form. | Not applicable. | Not applicable. | Higher levels of packaging are not eligible for reduced labelling. | Include all devices with Device Count = 1. | Eligible for reduced labelling. |

| Device type | In scope of UDI requirements? | UDI-DI requirements | UDI-PI requirements | Unit of Use requirements | Direct marking requirements | Packaging requirements | Specific UDI record submission requirements | Device specific requirements |
|---|---|---|---|---|---|---|---|---|
| **Medical device accessories** | Yes, if:<br>• Sold separately<br>• In scope of devices classes required to meet UDI requirements. | Must bear UDI-DI. | Must bear a UDI-PI. | Yes, if applicable. | Yes, if reusable. | Yes, if applicable. | None. | None. |
| **Spare parts** | Yes, if:<br>• Sold separately<br>• In scope of devices classes required to meet UDI requirements. | Must bear UDI-DI. | Must bear a UDI-PI. | Yes, if applicable. | Yes, if applicable. | Yes, if applicable. | None. | If you choose to meet UDI requirements, we recommend you meet all UDI requirements to minimise confusion for end users. |
| **Replacement parts** | Yes, if:<br>• Sold separately<br>• In scope of devices classes required to meet UDI requirements. | Must bear UDI-DI. | Must bear a UDI-PI. | Yes, if applicable. | Yes, if applicable. | Yes, if applicable. | None. | If you choose to meet UDI requirements, we recommend you meet all UDI requirements to minimise confusion for end users. |

| Device type | In scope of UDI requirements? | UDI-DI requirements | UDI-PI requirements | Unit of Use requirements | Direct marking requirements | Packaging requirements | Specific UDI record submission requirements | Device specific requirements |
|---|---|---|---|---|---|---|---|---|
| **Listed Disinfectants** | No. | Not applicable. | Not applicable. | Not applicable. | Not applicable. | Not applicable. | Not applicable. | You may apply a UDI; however, this cannot be supplied to the AusUDID. |
| **Exempt Disinfectants** | No. | Not applicable. | Not applicable. | Not applicable. | Not applicable. | Not applicable. | Not applicable. | You may apply a UDI; however, this cannot be supplied to the AusUDID. |
| **Exempt Products** | No. | Not applicable. | Not applicable. | Not applicable. | Not applicable. | Not applicable. | Not applicable. | You may apply a UDI; however, this cannot be supplied to the AusUDID. |

# Version history

| Version | Description of change | Author | Effective date |
|---|---|---|---|
| V1.0 | Original publication | Device Reforms Taskforce | March 2025 |
| V2.0 | Updated to add new content and refine existing content following UDI Roadshows held in October 2025.<br><br>**New content:**<br>• Structure, terminology and symbols information<br>• UDI in the Essential Principles<br>• UDI and other identifiers section<br>• Requirements for:<br>  o Contact lenses<br>  o Boundary products<br>  o Combination products<br>  o Co-packaged medical devices<br>• Demonstrating compliance with UDI-related Essential Principles<br>• Summary of UDI requirements for device types.<br><br>**Updated content for clarification:**<br>• UDI labelling and packaging, specifically terminology (base package) and Unit of Use<br>• Surgical loan kit requirements<br>• Reusable device requirements<br>• Single-use device requirements<br>• Capital equipment requirements<br>• Personalised medical device requirements<br>• UDI Triggers. | Device Reforms Taskforce | February 2026 |



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Reference/Publication #