Australian Government
Department of Health and Aged Care
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 1.0, March 2025

Contents

Purpose of this guidance

We have prepared this guidance to help you as a sponsor or manufacturer understand your regulatory obligations under Australian therapeutic goods legislation. Specifically, this information covers:

- medical devices and in vitro diagnostic (IVD) medical devices in scope of the Unique Device Identification (UDI) regulations
- UDI labelling requirements
- data submission requirements
- specific device requirements.

This document outlines the requirements to get and apply a UDI and submit and maintain UDI data in the Australian UDI Database (AusUDID).

Information about UDI compliance dates is not included in this document. We have prepared a separate guidance to help you as a sponsor or manufacturer understand UDI implementation timeframes. Specifically, this information covers:

- voluntary compliance
- mandatory compliance
- transition periods for existing devices
- transition periods for European Union (EU) certified devices.

For this Guidance:

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

For a full list of definitions used throughout this document, see Appendix C.

Legislation

Federal Register of Legislation - Therapeutic Goods Legislation Amendment (Australian Unique Device Identification Database and Other Measures) Regulations 2025

Please refer to the official version of legislation on the Federal Register of Legislation. Legislative instruments are amended from time to time and may occasionally be replaced or new instruments made.

Introduction

The Australian Government is strengthening patient safety by introducing the Australian Unique Device Identification (UDI) system.

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 in the supply chain, clinical and other health systems, UDI can enable easier and faster identification of medical devices, supporting:

- 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.

It also allows patients, consumers, and health professionals to access product information in the Australian UDI Database (AusUDID) about the medical devices that they use. The AusUDID provides an easy to access and consistent location for up-to-date product information.

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

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

The introduction of UDI in Australia does not supersede or negate any existing requirements or obligations of a sponsor or manufacturer of medical devices supplied in Australia.

UDI requirements are in addition to existing requirements.

The Australian UDI system

The establishment of the Australian UDI system is one of the medical device reforms as outlined in An Action Plan for Medical Devices. It is a key pillar for the surveillance and monitoring of medical devices.

Development of UDI in Australia has involved:

- amending the *Therapeutic Goods Act 1989* (the Act) and the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Regulations)
- developing the AusUDID
- consulting with sponsors and manufacturers of medical devices
- consulting with the healthcare community about UDI and use in the healthcare supply chain
- working with the Australian Commission for Safety and Quality in Healthcare (ACSQHC)
- working with state-based healthcare pilot sites to inform use and adoption of UDI in healthcare organisations.

UDI in the Essential Principles

We have amended the Essential Principles in Schedule 1 of the *Therapeutic Goods (Medical Devices) Regulations 2002* to set out the requirements for UDI. This includes:

- requirements for obtaining the UDI-Device Identifier (UDI-DI) from a TGA recognised Issuing Agency
- requirements for formatting the UDI-Production Identifier (UDI-PI) per Issuing Agency requirements
- requirements for obtaining a new UDI-DI due to changes to the medical device that make the medical device a new model (UDI Trigger)
- requirements for applicable packaging of a medical device (if any) to be labelled with a Package DI
- requirements for UDI on Patient Implant Cards (PICs) per Essential Principle 13A
- requirements for the direct marking of a medical device with a UDI, where applicable
- requirements for the submission of UDI-DI(s) and related mandatory data in the AusUDID, including timing of submission of data
- mandatory compliance dates, including transition periods.

Non-compliance

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,

Application for consent to import, supply or export a medical device that does not comply with the Essential Principles

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.

Please note that a consent to supply 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 consent to supply 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.

Global alignment

We have worked to harmonise the Australian UDI requirements with global UDI requirements where possible. These include:

- 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:
  - GS1
  - Health Industry Business Communications Council (HIBCC)
  - International Council for Commonality in Blood Banking Automation (ICCBBA)
- accepting UDI Carriers compliant with European Union (EU) and United States (US) regulations
- minimising Australian only requirements, whilst maintaining robust regulation.

Unique Device Identifier (UDI)

A UDI is made up of 2 parts:

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

To be compliant with Australian UDI requirements, you must get your UDI-DI from one of our TGA recognised Issuing Agencies. Your UDI must conform with the rules of the Issuing Agency you choose.

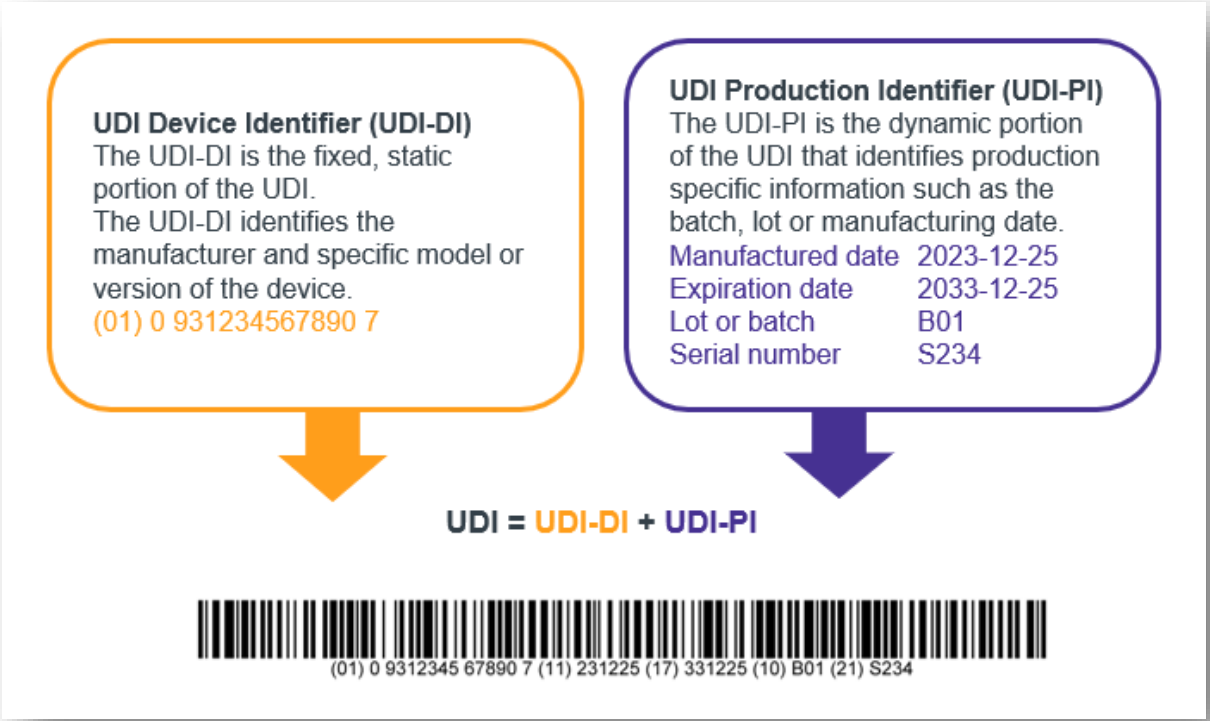


Figure 1: Example of a UDI

UDI-Device Identifier (UDI-DI)

The UDI-DI is the unique numeric or alphanumeric code that identifies the model of medical device.

The UDI-DI is the 'access key' to information stored in the AusUDID. It is used when reporting medical device related regulatory events such as adverse events and recalls. It is used to distinguish a model of medical device and find up-to-date information about the device in the AusUDID. In the AusUDID, the UDI-DI is referred to as the 'Primary DI'.

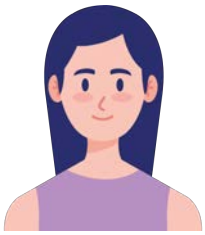
UDI-DI requirements

The UDI-DI is globally unique and must be issued by a TGA recognised Issuing Agency.

Examples of identifiers from an Issuing Agency that can be a UDI-DI include:

- GS1 Global Trade Item Number (GTIN)
- Health Industry Bar Code – Universal Product Number (HIBC-UPN)
- International Council for Commonality in Blood Banking Automation Information Standard for Blood and Transplant 128 - Processor Product Identification code (ICCBBA ISBT 128-PPIC).

Each model of medical device must have a unique UDI-DI. If you supply multiple models of medical devices under a single ARTG inclusion, you must allocate a different UDI-DI to each model, and link all models supplied under the ARTG entry to the ARTG ID.



Sabrina the sponsor

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

Sabrina must have one UDI-DI for each model of medical device she supplies under this ARTG. This means that Sabrina has 5 UDI-DIs for one ARTG.

Sabrina applies the 5 full UDIs, including the UDI-DI and UDI-PI, to each corresponding model of medical device.

Sabrina supplies the 5 UDI-DIs and related data for each model of device to the AusUDID and links her ARTG to each of the 5 UDI records.

UDI-Production Identifier (UDI-PI)

The UDI-PI identifies the production specific information such as the batch, lot, software version or manufacturing date of the medical device's production run.

The UDI-PI is present on the medical device itself or the medical device base package but is not stored in the AusUDID. The UDI-PI supports device related reporting of regulatory events such as adverse events and recalls.

UDI-PI requirements

Production identifiers will vary by medical device type and manufacturer current practice. There is no maximum number of production identifiers allowed within a UDI-PI. As a manufacturer, it is your responsibility to determine which production identifiers you are required to include in your UDI-PI based on your medical device type and information you provide on your medical device label. You should follow the recommendations and specifications of your chosen Issuing Agency.

Requirements for the UDI-PI include:

- if a lot number, serial number, software identification or expiry date appears on the label, these must be part of the UDI-PI
- if there is a manufacturing date on the label, it does not need to be included in the UDI-PI. If there is only a manufacturing date on the label, this must be used as the UDI-PI
- the serial number is a mandatory UDI-PI for active implantable medical device
- the serial number or lot number is a mandatory UDI-PI for other implantable medical devices
- the software version is considered to be the manufacturing control mechanism and must be displayed in the UDI-PI. Note that minor software revisions require a new UDI-PI, but not a new UDI-DI
- If the medical device contains a Donation Identification Number (DIN) or a division identifier these must be part of the UDI-PI.

Your chosen Issuing Agency may have specific requirements for production identifiers that must be included in the UDI-PI. You are responsible for liaising with your chosen Issuing Agency to determine if your device requires any specific UDI-PI inclusions.

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

If your device is sold principally in retail premises, some UDI requirements are reduced. See devices that are sold principally in retail premises.

Summary of roles and obligations

Sponsors and manufacturers both have roles in meeting UDI requirements. These obligations for meeting UDI requirements are in addition to, and do not override, any existing obligations.

Manufacturer role and obligations

As a medical device manufacturer, your role and obligations include:

- choosing a TGA recognised Issuing Agency
- allocating a UDI-DI and UDI-PI to your device using the relevant coding standard set by your chosen Issuing Agency
- ensuring the UDI is applied per Issuing Agency requirements
- containing both the UDI-DI and the UDI-PI in the UDI Carrier, unless exempt
- ensuring the chosen UDI Carrier is appropriate for expected use

- applying the UDI Carrier in Human Readable Interpretation (HRI) and Automatic Identification Data Capture (AIDC) forms on:
    - the label
    - on the device itself, if applicable
    - all higher levels of packaging, if applicable
- ensuring that the UDI Carrier is in addition to, and does not replace any existing labelling requirements for Australia
- ensuring all packaging levels of the device bear a Package DI, where required
- direct marking the UDI Carrier on reusable medical devices, where applicable
- allocating a Unit of Use DI, where applicable
- assigning a new UDI-DI when there is a change to your device that could lead to misidentification or ambiguity in its traceability (UDI Trigger)
- providing the UDI-DI and related data to the AusUDID, either yourself or through your Australian sponsor
- designing, producing, packaging and labelling of the medical device
- demonstrating compliance with the relevant Essential Principles for your medical device, including those that relate to labelling
- ensuring that you meet all requirements in the Essential Principles.

Your obligations for UDI requirements are in addition to, and do not override, any existing obligations you have as a manufacturer.

Sponsor role and obligations

As a sponsor, your role and obligations include:

- ensuring that your manufacturer has complied with their obligations relating to UDI requirements
- ensuring that, where applicable, your manufacturer has assigned a UDI to devices you supply, before making the device available
- ensuring that the chosen UDI Carrier format is appropriate for the expected use
- ensuring the UDI-DI and related data for the devices you supply to the AusUDID is submitted to the TGA according to UDI requirements
- meeting record keeping requirements
- ensuring your device meets all Essential Principles.

Your obligations for UDI requirements are in addition to, and do not override, any existing obligations you have as a sponsor.

Sponsor of medical devices supplied by multiple sponsors

In Australia, it is possible that a medical device has more than one sponsor.

Your obligations as a sponsor do not change even if the device(s) you supply are also supplied by other sponsors. You are still responsible for submitting and maintaining the UDI-DI and related data to the AusUDID according to the UDI requirements.

Learn more about multiple sponsors here.

Third party role and obligations

As a manufacturer, you may choose to allow a third party to apply the UDI Carrier on your behalf. In this circumstance, you remain responsible for the conformity of the UDI Carrier.

As a sponsor, you may choose to allow a third party to submit the UDI-DI and related data to the AusUDID on your 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.

Devices required to meet UDI requirements

Medical devices and IVDs that you supply in Australia that must be included in the ARTG must comply with UDI requirements, unless otherwise exempt from these requirements.

To comply with UDI requirements, you must meet all your obligations. If applicable, you must also:

- meet any extra requirements, such as Unit of Use or Direct Marking
- meet any device specific requirements
- meet all further requirements as stipulated in the Regulations.

Medical devices in scope of UDI requirements

The following table describes which medical device classes must meet UDI requirements. These devices must meet all UDI requirements, unless specifically exempt.

Device 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 choose to assign and apply a UDI to your Class I and Class Im medical devices. If you do apply a UDI to these devices, we recommend you meet all UDI requirements to reduce confusion for end users such as healthcare.

As a sponsor, you may choose to submit and maintain the relevant data to the AusUDID for Class I and Class Im medical devices. If you do submit the data for these devices to the AusUDID, your data must comply with the validation checks enforced by the AusUDID.

Note that your device must have an applicable ARTG inclusion to make the data available in the AusUDID.

In vitro diagnostic devices in scope of UDI requirements

The following table describes which IVD classes must meet UDI requirements. These devices must meet all UDI requirements, unless specifically exempt.

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

*IVDs that are instruments and software are required to comply with the UDI requirements. Such devices are typically covered under the following Global Medical Device Nomenclature Collective Term:

- 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 choose to assign and apply a UDI to other exempt IVDs. If you do apply a UDI to these devices, we recommend you meet all UDI requirements to reduce confusion for end users such as healthcare.

As a sponsor, you may choose to submit and maintain the relevant data to the AusUDID for other exempt IVDs. If you do submit the data for these devices to the AusUDID, your data must comply with UDI requirements. Note that your device must have an applicable ARTG inclusion to make the data available in the AusUDID.

Devices exempt from UDI requirements

You are not required to meet UDI requirements for:

- ✘ medical devices that are Class I non measuring nonsterile
- ✘ medical devices that are Class I measuring (Im)
- ✘ 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.

While these devices are exempt from complying with UDI requirements, you may choose to meet UDI requirements for these devices.

Note that to submit UDI records to the AusUDID, you must link an ARTG ID and provide all mandatory data. As such, devices that are exempt from inclusion in the ARTG will not be able to be supplied to the AusUDID as you will be unable to link an ARTG.

Similarly, you are unable to submit UDI records for therapeutic goods that are not regulated as a medical device, as you must provide certain information from the ARTG inclusion such as device class.

You may still meet labelling and packaging requirements for these products if you choose to do so.

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.

You may however need to meet UDI requirements of the country you supply the device to.

Australian UDI requirements

Getting a UDI

As a manufacturer, you must apply and get a UDI-DI from one of our recognised Issuing Agencies. This is to ensure that the UDI is globally unique and complies with global standards.

It is the responsibility of the manufacturer to choose an Issuing Agency. As a sponsor, it is your responsibility to liaise with your manufacturer if you have a preferred Issuing Agency.

You will **not** be compliant with Essential Principles if your UDI-DI is allocated by any Issuing Agency or other party that is **not** one of our 3 recognised Issuing Agencies. You will **not** be compliant if you create your own identifiers to use as a UDI-DI or any other DI allocated by Issuing Agencies.

TGA recognised UDI Issuing Agencies

We recognise the following UDI Issuing Agencies:

Issuing Agency	Contact
GS1	customer.service@gs1au.org info@gs1.org
Health Industry Business Communications Council (HIBCC)	info@hibcc.org
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 the UDI requirements of the EU or US, if:

- the UDI-DI has been issued by one of our recognised Issuing Agencies
- the label complies with the existing regulatory and labelling requirements for Australia.

You can supply devices in Australia that have US or EU UDI compliant labels even if they are exempt from Australian UDI requirements. We recommend that you supply this data to the AusUDID to minimise confusion for the end users.

As an Australian manufacturer that exports to the USA or Europe, you can use the US or EU UDI compliant UDI Carrier in Australia.

Applying a UDI

UDI Carrier

The UDI Carrier is the means to convey the UDI. The UDI Carrier contains 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.

> Not all medical devices require the UDI in HRI and AIDC form. Devices principally sold in retail premises are exempt from using HRI and AIDC forms. However, these devices must still meet reduced UDI labelling requirements.

The UDI Carrier must be on the label or on the device itself, and all applicable higher levels of packaging. This is to ensure that the device can be identified throughout the supply chain. Note that logistics units do not require a UDI or Package DI.

The combination of both the AIDC and HRI forms create a standard UDI Carrier.

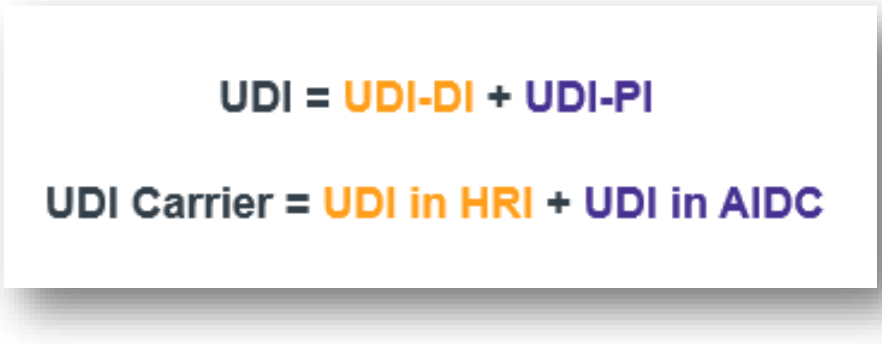


Figure 2: Example of how a UDI in HRI and a UDI in AIDC forms create a UDI Carrier

For examples of UDI Carriers on device labels, see Appendix A.

Figure 3 illustrates how a UDI Carrier combines with existing labelling to form the full UDI compliant label. Please note that this example is fictitious and for illustrative purposes only.

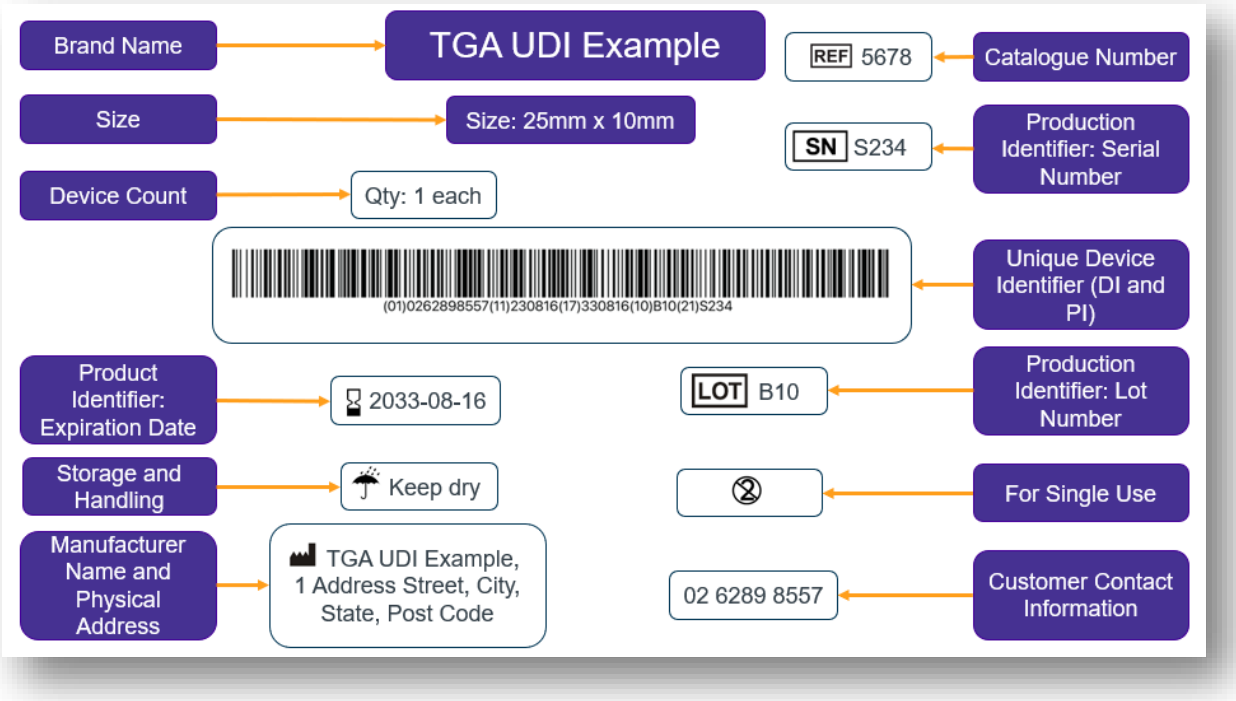


Figure 3: Example of UDI Carrier in a fictitious label

Exemptions for UDI Carrier

Significant constraints

If there are significant constraints limiting the use of both AIDC and HRI on the label, the AIDC form is favoured. However, certain environments or use situations, such as home care, may warrant the use of HRI over AIDC.

As a manufacturer, you are responsible for determining whether the constraints are significant and limit the above use. We may check this as part of our existing audits.

Devices principally sold in retail

Devices that are principally sold in retail are not required to bear the UDI in HRI and AIDC form. For more information, see devices principally sold in retail.

Automatic Identification Data Capture (AIDC)

We have not restricted the AIDC form to a specific symbology, noting that some symbologies may be more appropriate for specific settings or use.

AIDC technology that you may use includes:

- linear barcodes (1D)
- data matrix barcodes (2D)
- smart cards, biometrics
- Radio Frequency Identification (RFID).

As a manufacturer, if you use RFID technology, you must comply with open and commercially acceptable, international standards such as ISO/IEC 17360:2023. You must also provide a linear, 2D

barcode or another type of barcode on the label to maintain usability for systems with varying technological capabilities.

Each Issuing Agency has their own general technical specifications about UDI Carrier types, size, placement and quality. We recommend that manufacturers liaise with their chosen Issuing Agency to determine the preferred and most appropriate UDI Carrier for their devices.

Human Readable Interpretation (HRI)

The HRI is to be:

- a legible interpretation of the data characters encoded in the UDI Carrier
- usually presented next to or below the AIDC form of the UDI Carrier.

In the HRI portion of the UDI Carrier, the UDI should precede any non-UDI elements. You should order the HRI portion of the UDI to specify the UDI-DI first, followed by the UDI-PI.

If there are any non-UDI elements in the UDI Carrier, the non-UDI elements should follow the UDI-PI. The HRI data and the applicable data delimiters allow for UDI data to be accurately captured manually when the AIDC porting cannot be captured.

HRI data delimiters

The HRI portion of the UDI Carrier must include data delimiters. These may also be known as qualifiers or application identifiers. The purpose of data delimiters is to distinguish the information in the string of characters that follow the data delimiter.

Data delimiters are particularly important in case of damaged or unreadable AIDC forms. The HRI allows the encoded data to be accessed manually.

Data delimiters vary between Issuing Agencies. Your chosen Issuing Agency can help you with data delimiters and formats.

Non-HRI

Some device types, such as devices principally sold in retail, do not require the UDI in HRI form. Instead, non-HRI or plain text format is required.

UDI Carrier placement

As a manufacturer, it is your responsibility to place the UDI on the label, or on the device itself, and on all applicable higher levels of device packaging unless exempt. If your device is reusable and must meet UDI requirements, then your UDI must be directly marked on the device itself.

As a manufacturer, you are responsible for determining the most appropriate placement of the UDI Carrier. You should place the UDI Carrier in a way that the AIDC can be accessed during normal operation or storage.

UDI requirements do not override any existing medical device labelling requirements. The UDI Carrier is not to replace any other existing labelling requirements that apply under either:

- the *Therapeutic Goods Act 1989*
- the *Therapeutic Goods (Medical Devices) Regulations 2002*.

UDI Carrier conventions

If you use linear bar codes, the UDI-DI and UDI-PI can be concatenated or non-concatenated in 2 or more bar codes. All parts and elements of the linear bar code must be distinguishable and identifiable.

While acceptable under UDI regulations, using non-concatenated barcodes may make it difficult for users of the barcodes, such as warehouse staff, to understand the order and need to scan both barcodes. It is the manufacturer's responsibility to decide whether concatenated or non-concatenated are more appropriate.

Some Issuing Agencies may recommend one UDI Carrier convention over another, such as a 2D data matrix instead of linear barcodes. We recommend you liaise with your chosen Issuing Agency to ensure your UDI Carrier is most appropriate for your device.

Examples of UDI Carrier conventions

Concatenated barcode

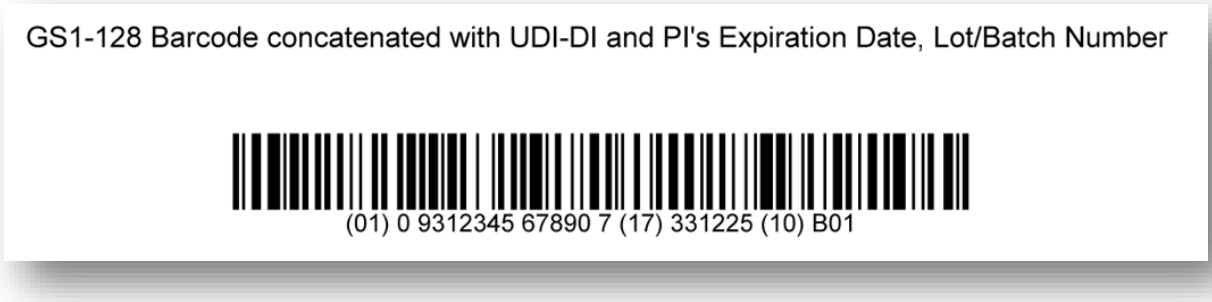


Figure 4: A single linear barcode that includes UDI-DI and UDI-PI in the AIDC and HRI

Non-concatenated barcode

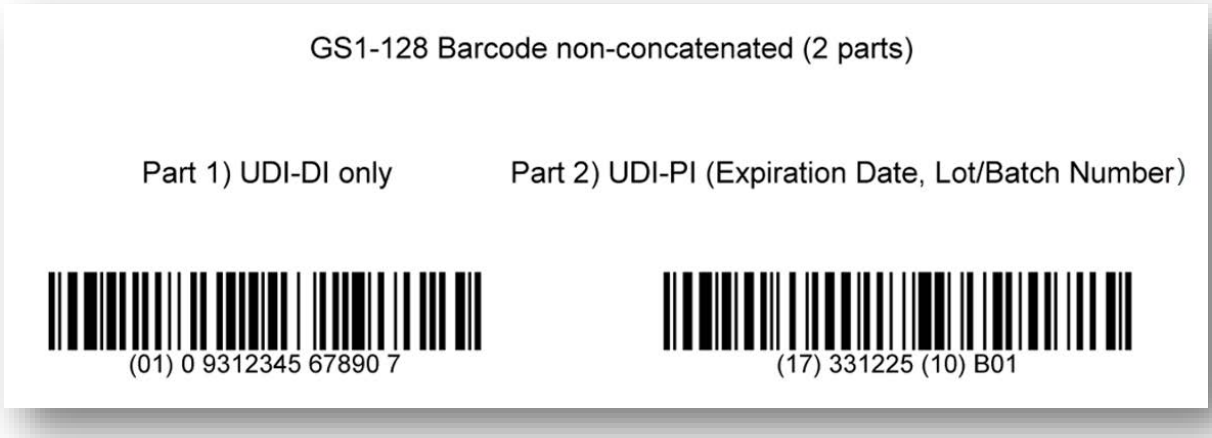


Figure 5: 2 separate barcodes, one represents UDI-DI and the second represents the UDI-PI

2D barcode

Figure 6: Combines UDI-DI and PI into a single 2D barcode

Multiple barcodes on a single label

We recommend that you do not apply multiple barcodes on a label. This is to assist consumers and healthcare identify the correct barcode.

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.

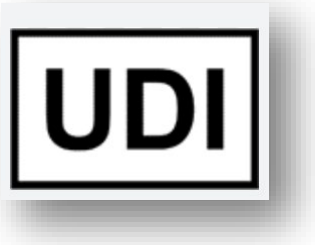


Figure 7: UDI ISO symbol

Packaging levels

As well as the UDI Carrier on the device label or device itself and its packaging, you must apply a UDI to all applicable higher levels of packaging. This is to ensure that the device can be tracked and identified throughout the supply chain.

The UDI-DI assigned to the base package, or the lowest trade level, is known as the Primary DI. DIs assigned to higher levels of packaging are known as the Package DI(s).

As a manufacturer, you must assign a different Package DI to each level of packaging containing a quantity of medical devices. For example, a single device, carton or case. The Package DI(s) must be unique at all levels of packaging and must follow the rules of your chosen Issuing Agency.

You do not need to assign a Package DI to levels of packaging that are logistics units.

Overview of packaging levels

The example below shows the relationship between different packaging levels and the UDI requirements at each level.

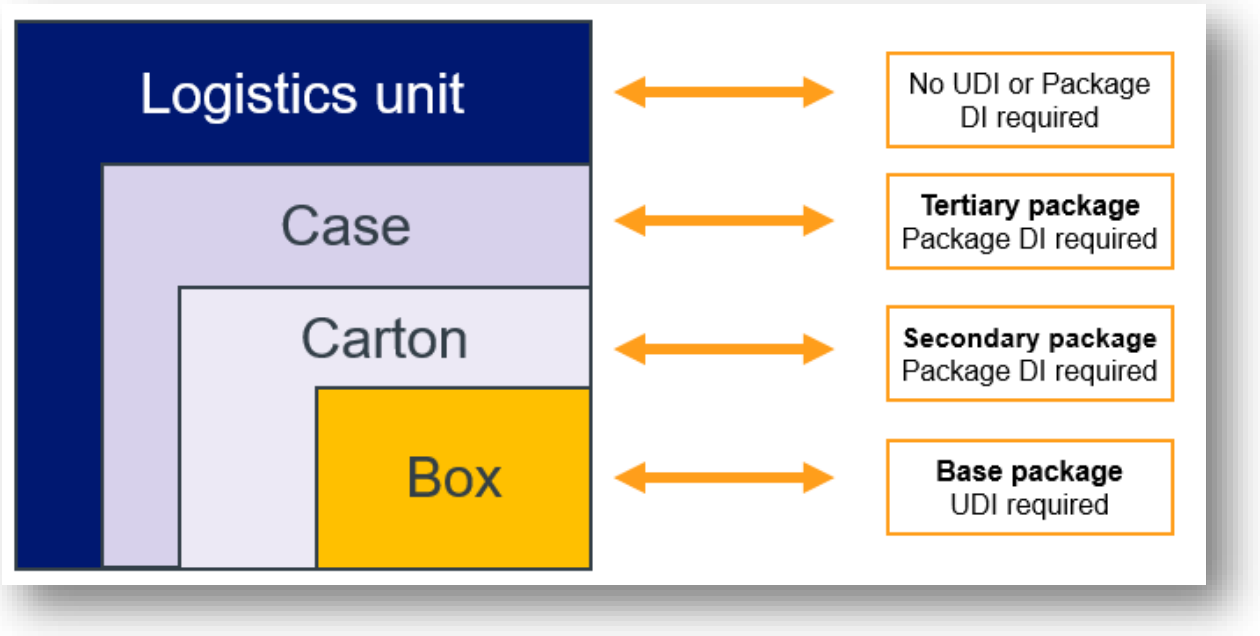


Figure 8: Example of UDI packaging levels

Base package

The base package is the lowest trade level of the device packaging. In some cases, the base package is the only device packaging. The base package may also be known as the base unit.

The UDI-DI that you apply to the base package is used as the Primary DI. The UDI-DI for the base package, or Primary DI, is the 'key' to the UDI record in the AusUDID. You must supply the Primary DI to the AusUDID.

If there is more than one unpackaged and unlabelled device in the base package, your device must also have a Unit of Use DI. You must supply the Unit of Use DI to the AusUDID.

The exception to this is that if there is more than one unpackaged device in the base package, but the devices are directly marked, your devices do not need a Unit of Use DI. However, you must provide the Direct Marking DI to the AusUDID.

Secondary and tertiary packages

The levels of packaging above the base package are known as 'Secondary' and 'Tertiary' packages.

Secondary packages contain a set number of base packages of a device.

Tertiary packages contain a set number of secondary packages of a device.

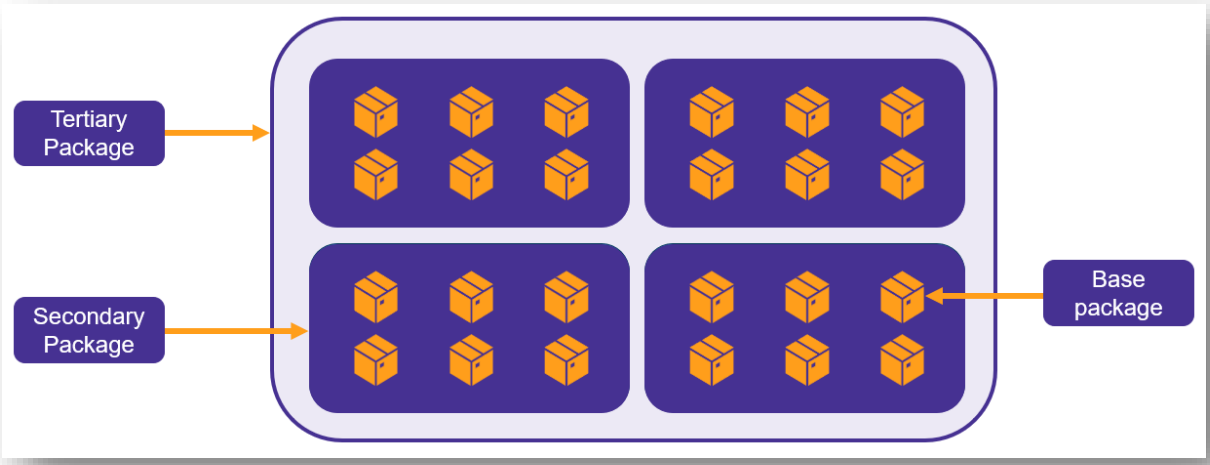


Figure 9: Example of the relationship between base package, secondary package and tertiary package

As a manufacturer, you must allocate Package DI to each level of a medical device package.

Each Package DI must be unique to the level of packaging.

Example of packaging configuration

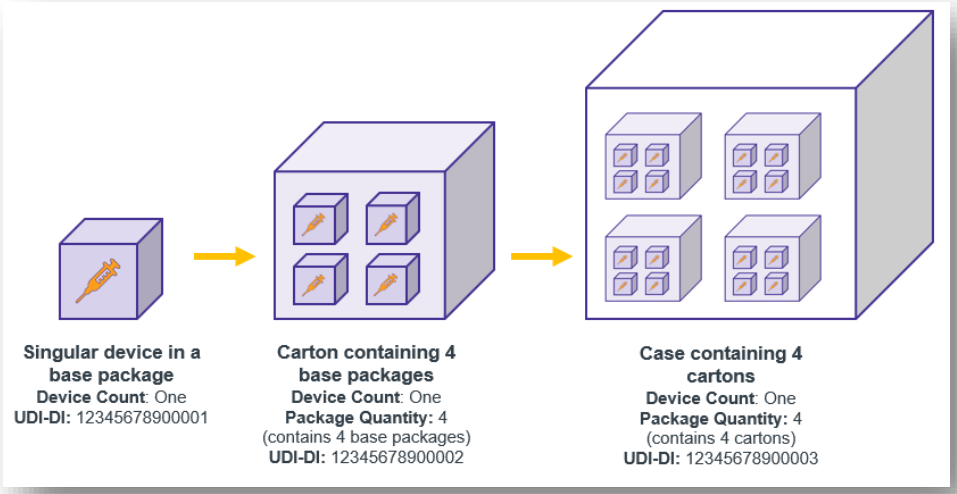


Figure 10: Example of a packaging configuration with a base package, a secondary package and a tertiary package

Figure 10 shows a base package that contains a single syringe with a UDI-DI for the base package of 12345678900001.

The secondary package is a carton containing 4 base packages of the syringe. The UDI-DI for the secondary package level is 12345678900002.

The tertiary package is a case containing 4 cartons that each contain 4 base packages of the syringe. The UDI-DI for the tertiary level of packaging is 12345678900003.

This demonstrates each level of packaging having a different UDI-DI.

If the base package contains more than one unpackaged and unlabelled medical device, you must assign a Unit of Use DI.

Example of UDI on packaging levels

The below image illustrates how a unique UDI is applied to each level of packaging using a GS1 issued identifier as an example.

In this image, GTIN A is the base package UDI-DI or Primary DI.

The additional GTINs are the Package DIs.

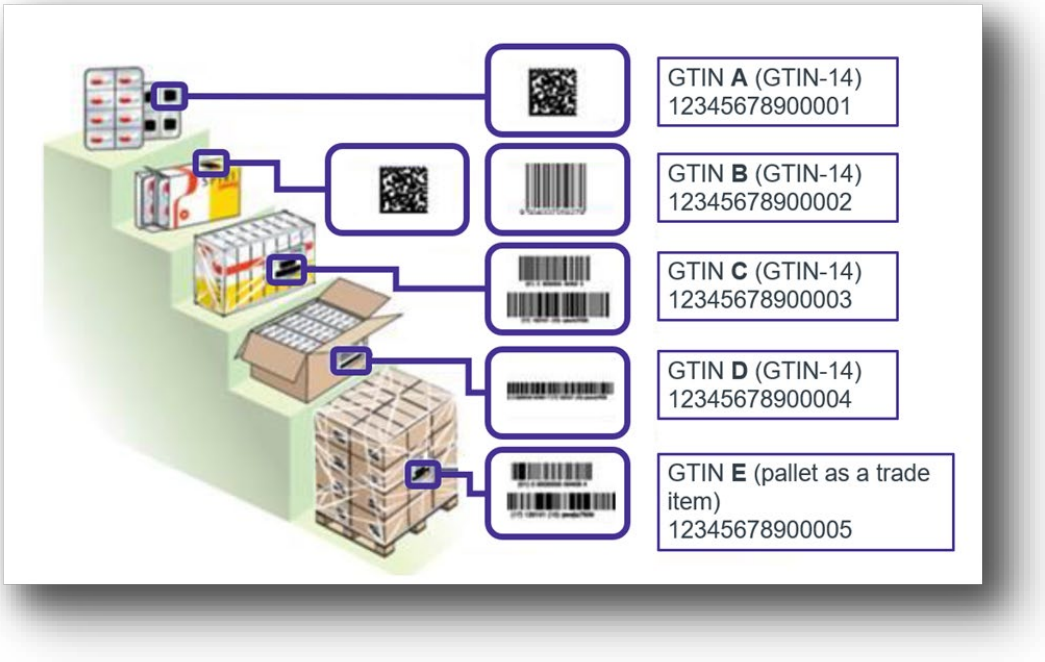


Figure 11: Example of UDI on packaging levels

Logistics units

Logistics units are levels of packaging that are traced in a controlled process specific to logistics system. Because of this, logistics units are not required to have a Package DI.

Forms of higher levels of packaging that are logistics units and do not require a Package DI include:

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

Packaging level data in the Australian UDI Database

You must link all Package DIs to your UDI record.

If your device does not have packaging levels higher than the base package, you are not required to provide Package DI data in the AusUDID.

In the circumstance where there are multiple sponsors for a medical device that bears the same UDI, packaging configurations may differ. In all scenarios, the manufacturer should still assign 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 allocate and apply Package DIs to each applicable level of packaging and provide the Package DIs in your UDI record.

Direct marking

Direct marking is the permanent marking of a UDI onto a device itself that can withstand normal usage and cleaning for the lifetime of the device.

Direct marking supports identification of reusable medical devices, when the device is no longer accompanied by its label or package that bears the UDI.

We do not consider equipment that contains labelling on the device itself or has a UDI printed directly on the device as part of labelling to be direct marked. Examples include:

- MRI machines
- IV pumps
- IVD bench top instruments.

You are expected to label these devices with a UDI (unless otherwise exempt); however, we do not use the term ‘direct marking’. For more information, see capital equipment.

Direct marking placement

As a manufacturer, you must directly mark the full UDI in a way that cannot be removed onto the device itself if your device is:

- intended to be reusable, and
- reprocessed between use on different patients.

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

- substrate requirements
- dimensions
- quality

- placement
- suitable methods.

As a manufacturer, you are responsible for:

- determining the method of direct marking
- ensuring the direct marking can withstand the normal usage and cleaning procedures for the lifetime of the device.

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, such as home care, as these may warrant the use of HRI over AIDC. As a manufacturer, it is your responsibility to give your reasoning for form selected, when requested by us.

A Direct Marking DI could be the same as the UDI-DI or different to distinguish it from the packaged device. 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.

*Note that 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.

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

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

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.

Example of direct marking

Figure 12 demonstrates one of the possible methods for direct marking. This example illustrates how a manufacturer has directly marked the UDI Carrier in both HRI and AIDC.

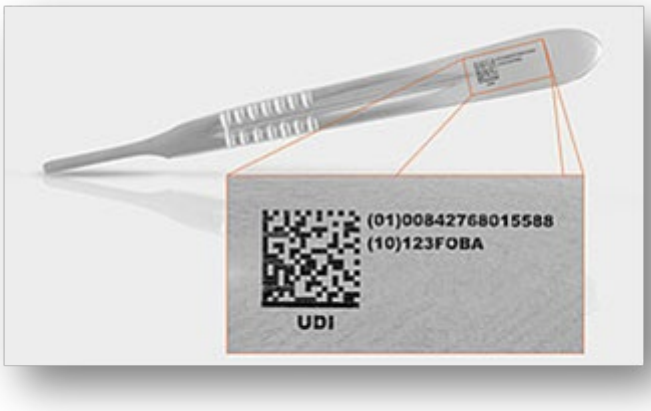


Figure 12: Example of a medical device that a manufacturer has directly marked with a UDI

Unit of Use (UoU)

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

- you supply more than one device in a base package, making the device count in the base package greater than one, and
- you have not labelled or directly marked the individual devices inside 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 device.

The Unit of Use DI is not considered the Primary DI, as it does not replace the UDI-DI for the base package. The base package remains the lowest trade level even when UoU is required. The UoU DI does not replace the Primary DI. 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 may be necessary.

Each device within the base package shares the same Unit of Use DI. You are not required to allocate a different UoU DI to each individual item within the base package.

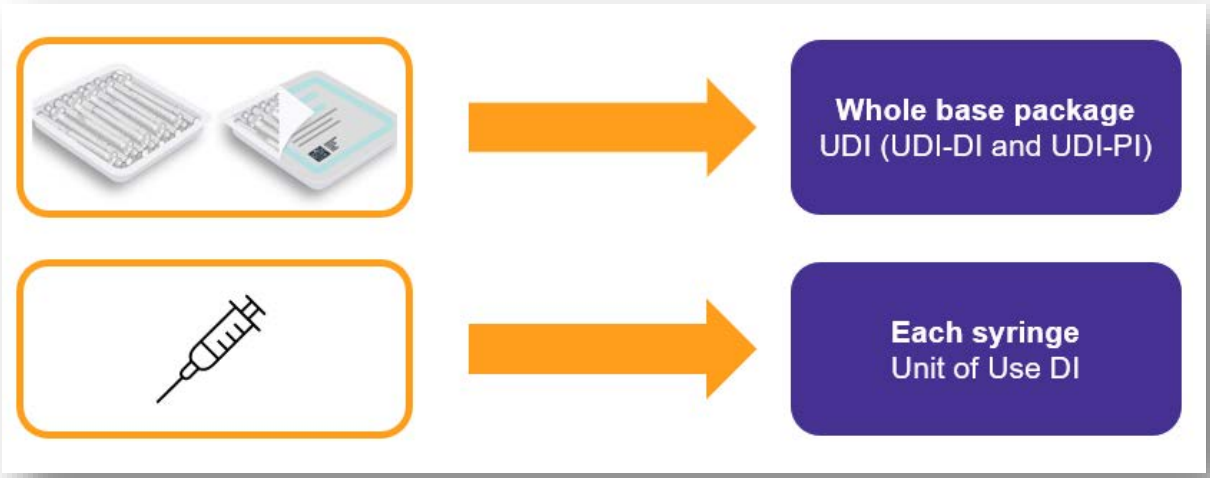


Figure 13: Example of relationship between UDI and Unit of Use DI

Though the UoU DI is used to identify devices below the lowest trade level, the UoU DI is a 'Virtual UDI'. You do not need to label your devices or device packaging with the UoU DI. However, you must supply the UoU DI to the AusUDID. The UoU 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 example

Sam the manufacturer and sponsor

Sam manufacturers a tray of 25 syringes (Figure 14). The tray is the base package. Sam applies the UDI Carrier to the tray. This UDI contains the UDI-DI and UDI-PI. The UDI-DI of the UDI Carrier applied to the tray is the Primary DI.

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

When Sam submits his UDI record for the tray of syringes, Sam supplies the UoU DI. This is in addition to the Primary DI and all other mandatory data.

The Device Count data element reflects the number of devices in the base package (the tray). For Sam's tray, the Device Count is 25.

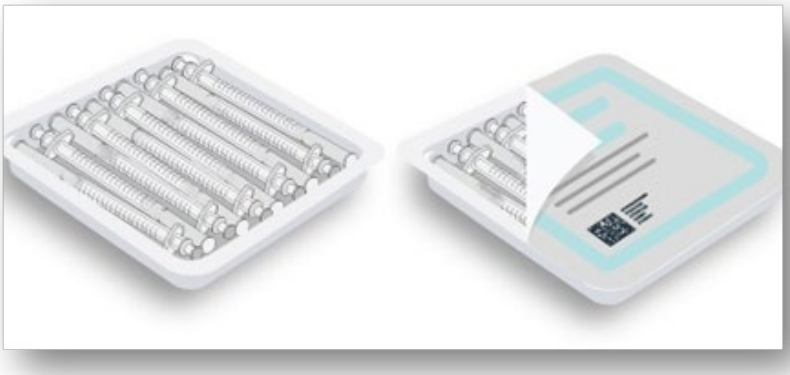


Figure 14: Example of device package that requires Unit of Use DI

Mary the sponsor and manufacturer

Mary manufactures a box of 5 scalpels. The box is 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 meet UoU requirements.

If Mary directly marked her devices with the Primary DI (same as the base package), Mary does not need to supply it a second time in the AusUDID. Mary does however need to select 'no for the data element 'Direct Marking DI Different from Primary DI?'

If Mary has chosen to distinguish the individual scalpels from the base package level and provide a specific Direct Marked DI, Mary must select 'yes' and provide the Direct Marked DI to the AusUDID.

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

You do **not** need to allocate a UoU DI or Device Count to procedure packs or kits. You also do not need to provide a device count for each item, as the kit is considered a single device. Individual devices that already require a Unit of Use DI will inherit this requirement.

Because of their use, Unit of Use is not suitable for IVD kits.

UDI Triggers

The overarching determinant in a UDI Trigger scenario is whether the device must be identified as different from previous iterations of the device.

Certain changes to medical devices or their UDI data elements mean that the device can no longer be identified by its existing UDI, as it is considered a new model of medical device. Because of this, when these changes occur the device requires a new UDI-DI and UDI record.

Changes to devices that are considered a UDI Trigger

Changes to a device that mean that the device requires a new UDI-DI and UDI record include:

- changes to the safety of a device
- changes to the performance of a device
- changes to the intended purpose of a device
- changes to indications for use of the device
- changes to a UDI Trigger data element.

Changes to UDI Trigger data elements

Some changes to characteristics of the device are considered UDI Triggers, even where the change is not to the physical device itself.

For example, a change to the brand name of a medical device is a UDI Trigger. If you change the value for brand name, you must create a new UDI record with a new UDI-DI. This is because this device is considered a new model of medical device and must be identified as different from previous models.

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

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
- 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.

UDI requirements for specific medical device types

Some specific medical device types have their own UDI requirements or are not required to meet all UDI requirements due to the nature of the device. It is important to understand if the devices that you supply are required to meet UDI requirements.

Reusable devices

If you design or intend for your device to be reprocessed for reuse, your device is a reusable device. Reusable devices are intended to:

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

Single use only devices are not reusable devices.

A manufacturer's determination on whether a device is reusable will be considered as part of the application for inclusion submitted to us. You should reflect this in the instructions for use with any relevant information on appropriate processes for allowing reuse.

As a manufacturer, if you design or intend for your device to be a reusable device you must meet direct marking requirements.

Direct marking requirements specify that the manufacturer must ensure that the UDI of reusable devices is:

- directly marked on the device itself (unless exempt)
- 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 the UDI.

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

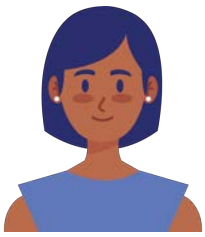
Capital equipment

Capital equipment is not required to be directly marked. However, you must label these devices with a UDI.

Examples of capital equipment that will require a UDI label, but is not directly marked, include:

- MRI machines
- IV pumps
- IVD bench top instruments.

You are required to label capital equipment with a UDI (unless otherwise exempt); however, we do not use the term ‘direct marking’. Equipment that contains labelling on the device itself or has a UDI printed directly on the device as part of labelling is UDI compliant, however this is referred to as UDI labelled. You may choose to directly mark these devices.



Catherine the manufacturer

Catherine manufactures MRI machines. As Catherine’s MRI machines are capital equipment, Catherine does not need to directly mark these devices. However, her MRI machines are in scope of UDI requirements and must still bear a UDI. Catherine chooses to apply a metal plate to the MRI machine that bears the UDI, making her MRI machine UDI labelled and UDI compliant.

Single use devices

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

You must meet UDI requirements for single use devices, where the devices are in scope of devices required to meet UDI requirements.

Placement of UDI for single use devices

Single use devices packaged individually

If the device is intended for individual commercial distribution, you must meet UDI requirements for the individual device.

Single use devices packaged together

If you supply single use devices packaged together in a base package, and these devices are intended to be stored in the base package until removed for use, you are only required to apply the UDI to the base package. You are not required to apply the UDI to each individual internal packaging level, if any exist.

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

All other levels of packaging must bear a Package DI, except logistics units.

Josh the manufacturer

Josh manufactures condoms. Josh supplies his condoms in a box of 100.

Josh’s condoms are single use; however, they are intended to stay in the package until use. Josh is not required to apply a UDI to each individual condom package within the box, but Josh is required to apply the UDI to the base package – in this case, the box.

In this scenario, Josh must also assign a Unit of Use DI to his devices.

Personalised medical devices (PMDs)

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

We use 3 specific terms to describe personalised medical devices:

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

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

Patient-matched medical devices (PMMDs)

As a sponsor or manufacturer, you must meet UDI requirements for patient-matched medical devices (PMMDs) if:

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

Adaptable medical devices

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

Custom-made medical devices

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

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

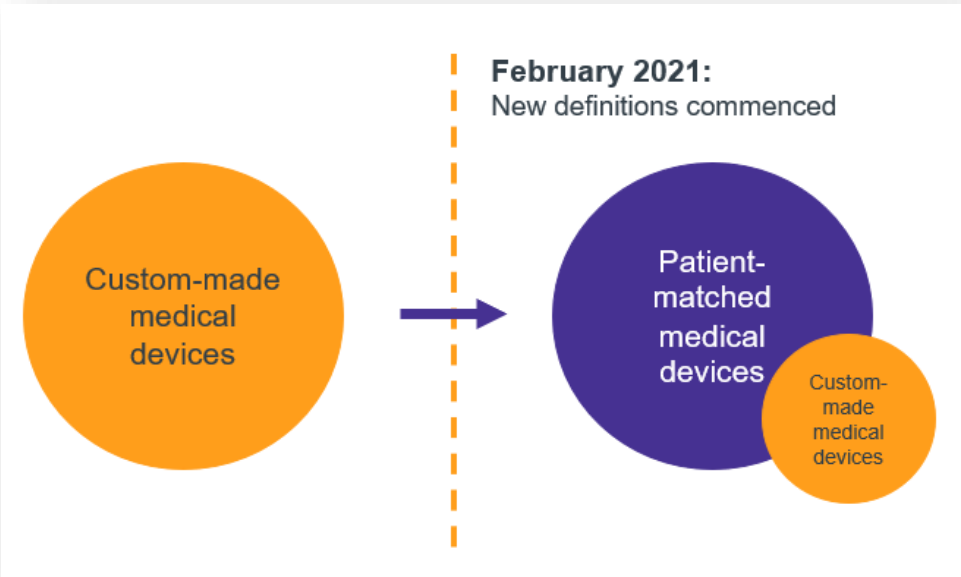


Figure 15: Illustration of relationship between custom-made medical devices and patient-matched medical devices after new definitions commenced

Dental sponsors and manufacturers

You must meet UDI requirements for any dental devices that:

- are in scope of devices required to meet UDI requirements
- are required to be included in the ARTG.

Dental practitioners

As a registered dental practitioner, you have responsibilities to act in accordance with The Dental Board of Australia's standards, codes, and guidelines.

You must be aware of and comply with other laws and regulations, including 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.

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

You are required to meet UDI requirements for medical devices and IVDs that are software or incorporate software unless they are exempt.

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

Type	Requires UDI?	Requirements for submitting data to the AusUDID
Software as a Medical Device	Yes, if in scope of devices required to meet UDI requirements	Include in AusUDID as 'Software as a medical device'.
Medical device incorporating software	Yes, if in scope of devices required to meet UDI requirements	Include in AusUDID as 'Medical device incorporating software'.
Software incorporated into a medical device	No, if it is not a medical device in its own right and is not commercially available on its own.	Does not need an individual UDI record if it is not a medical device in its own right and is not commercially available on its own.

Software specific UDI labelling and data provision requirements depend on factors such as:

- the type of software
- whether it is a physical product
- whether you supply the software packaged or unpackaged.

Medical devices incorporating software

You must meet UDI requirements for medical devices incorporating software, unless otherwise exempt.

If you supply the software as a medical device separately to the medical device incorporating software, you are required to meet UDI requirements for the software itself if it is:

- a medical device in its own right
- in scope of devices required to meet UDI requirements.

UDI assignment

Software as a medical device (SaMD)

As the manufacturer, you must assign the UDI at the system level of the SaMD. The version number of your SaMD is the manufacturing control mechanism and you must include it in the UDI-PI with the application identifier recommended by your Issuing Agency.

If your SaMD changes in the following way, you must assign a new UDI-DI to your device:

- major SaMD revision where a complex or significant change affects:
    - 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.

If your software change requires you to assign a new UDI-DI, you must also supply the new UDI-DI and related information to the AusUDID.

If your SaMD changes in the following way, you must assign a new UDI-PI (but not a new UDI-DI):

- minor SaMD revisions, including but not limited to:
    - 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 QMS. Note that minor changes to software do not need to be recorded in the AusUDID.

UDI placement

If you supply your SaMD in a physical medium, for example a DVD, each package level must have the UDI in HRI and AIDC readable formats.

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 assigned to the system level SaMD.

You should also provide the UDI on a readily accessible screen by the user in an easily readable plain-text formatting. For example, an 'About' file or box included in the startup screen.

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

You only need to provide the HRI portion of the UDI in electronic displays of the SaMD. You do not need to include the AIDC marking in the electronic displays.

You must 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 but later perform an upgrade in which your device requires 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.

Devices principally sold in retail

If you principally sell your device in retail, you have reduced labelling requirements for these devices.

The determination for whether a device is principally sold in retail is the responsibility of the manufacturer. You may be required to justify this upon request.

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.

UDI-DI and UDI-PI requirements for devices principally sold in retail

As a manufacturer, you must allocate and apply a UDI-DI to your devices in both machine readable and human readable forms. The UDI-DI can be applied in any non-HRI form recommended by your chosen Issuing Agency.

Devices principally sold in retail premises are exempt from using HRI and AIDC forms. You are not required to use HRI or AIDC forms. However, these devices must still meet reduced UDI labelling requirements.

You only need to apply the UDI-PI in non-HRI form. You may choose to apply the UDI-PI in machine readable form; however, this is on a voluntary basis.

The below table 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
AIDC	Optional	Optional
Machine readable (other than AIDC)	Required	Optional

You must meet all UDI requirements for all other applicable levels of packaging. You are not required to meet UDI requirements for logistics units. This includes Shelf Ready Packaging (SRP) as advertising material.

You must also meet all other UDI requirements, including submitting UDI records for these devices to the AusUDID.

Aidan the manufacturer and sponsor

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

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

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

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 or not 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

As a manufacturer of IVDs, you must assign a UDI to each model of IVD unless exempt. 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 IVD kits where they are in scope of devices required to meet UDI requirements.

You must also meet UDI requirements for components of the kit, if the component is:

- regulated as a medical device, and
- commercially available on its own.

If your IVD kit does not include any components that you must meet UDI requirements for, you only need to assign and apply the UDI to the IVD kit itself, where applicable.

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
- the single use medical devices are Class I non-measuring non-sterile or Class Im (measuring).

However, you should provide a UDI for replacement parts of the IVD kit, regardless of whether they are single use or not.

*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)

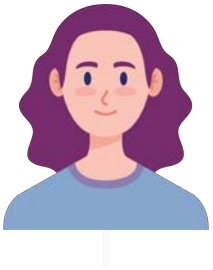
Surgical loan kits (SLKs) are supplied on loan to Australian hospitals for use in a particular surgical procedure and generally comprise collections of reusable surgical instruments. They may also include implantable medical devices and other medical devices. All goods in a SLK are medical devices and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

SLKs are exempt from requiring a UDI at the kit-level. The item for transporting the devices in the kit (tray, tub or case) is considered a logistics unit which does not need a Package DI.

While the SLK is exempt at the kit level, your SLK components may require a UDI if in scope of devices that must meet UDI requirements.

If the component must meet UDI requirements, the UDI (UDI-DI and UDI-PI) for each component must be easily accessible at the point of care. This will allow the linking of the medical devices to their implantation or use on patients.

We acknowledge the global challenges to assigning UDI identification to devices in surgical loan kits, as typical UDI labelling methods are often not feasible. To reduce these challenges, we are not prescribing the method you use to provide the UDI. We aim to be consistent with the flexibility offered by other international regulators. This includes allowing provision methods such as stickers, tags, inventory sheets and data carrier strips.



Meg the manufacturer

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

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

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

System or Procedure Packs (SOPP)

You must assign a system or procedure pack (SOPP) a UDI if it contains one or more medical device in scope of the UDI requirements.

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

- medical devices that are Class I – with a measuring function, or
- medical devices that are Class I non-sterile.

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

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

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

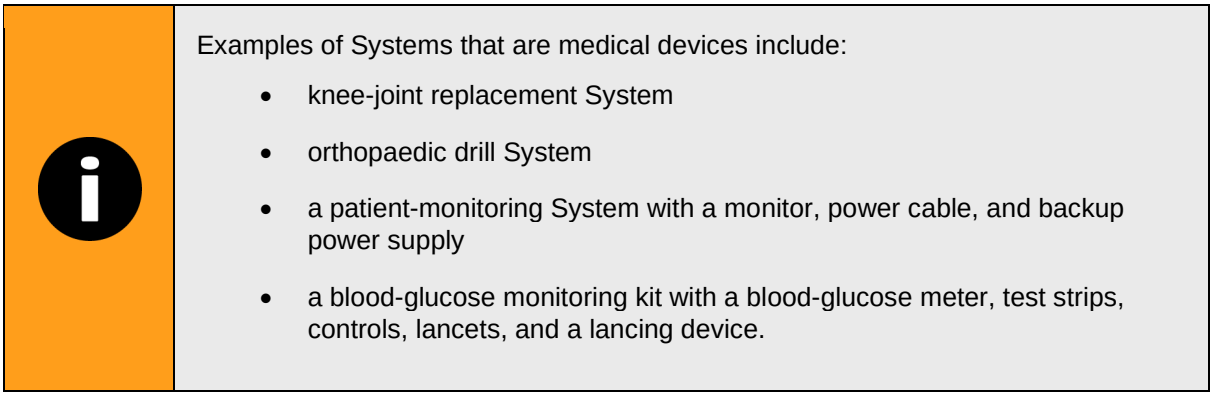
Medical device components that you supply separately from the SOPP must be included in the ARTG and comply with UDI requirements, unless exempt.

Systems that are medical devices

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

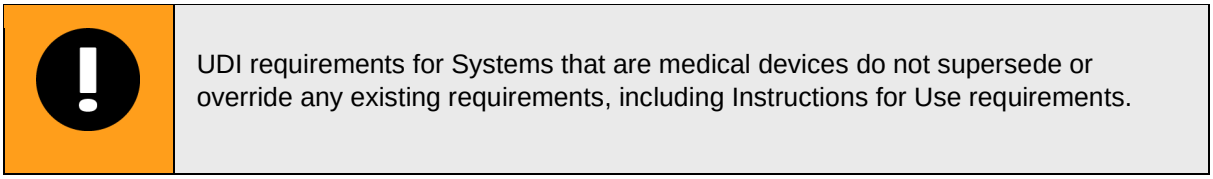
A System is **not**:

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



As a manufacturer, you must allocate a UDI to the System that is a medical device in the same way as other medical devices.

As a sponsor, you must supply the UDI-DI and related data for the System to the AusUDID in the same way as other devices.



Systems that are configurable

For Systems that can be configured, as a manufacturer you must allocate a UDI to the entire configurable System. The UDI for the entire system is known as the System UDI, however this is not an additional identifier but rather a distinction made to understand system configurations.

As a manufacturer, you must allocate a UDI-DI to defined groups of configurations the same way you would allocate a UDI-DI to defined models of medical devices. The UDI-DI is known as the System UDI-DI; however, this is not an additional identifier, but again to make a distinction.

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

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 UDI-PI of the System.

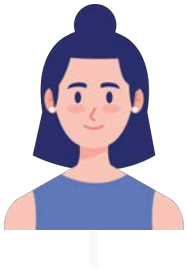
The concept of System UDI, System UDI-DI and System UDI-PI is to help define configurations of systems. You are not required to provide an additional identifier, nor are you required to enter an additional identifier into the AusUDID. The System UDI-DI is the Primary DI for configurable systems.

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

As a manufacturer you must ensure that each component, sub-System or accessory has a separate UDI if:

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

Example: Upgrade to system which impacts safety or performance



Claire the manufacturer

MRI system

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

Example: Component change which impacts safety or performance

Alice the manufacturer

X-ray system

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

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

Bella the manufacturer

Cardiac ultrasound system

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

Examples of changes where the UDI-DI remains unchanged

As a manufacturer, you do not need to allocate a new UDI-DI where a changed device does not require the device to be specifically identified from the original device.

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

Indigo the manufacturer

CT system

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

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

Olivia the manufacturer

CT system

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

Example: Addition of an accessory for an installed device

Matilda the manufacturer

System used with accessories

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

Components or accessories supplied separately from the system

As a manufacturer, you must allocate a UDI to each component of the System that is a medical device (for example, accessories and consumables), if the component is:

- supplied separately (commercially available on its own)
- included in devices required to meet UDI requirements.

For example, you must include an Automated External Defibrillator (AED) that you supply with electrodes and batteries in the AusUDID as a System. You must include replacement batteries and electrodes in the AusUDID separately if they have separate ARTG IDs.

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

Maddie the sponsor

System used with accessories that are sold separately

Maddie is a sponsor who supplies a System that customers can use with accessories. Maddie also supplies the accessories separately (commercially available on their own). Maddie has an ARTG inclusion for the accessories different ARTG to the system. However, the System and accessories are covered by what is originally specified for the defined groups of configurations.

	In this circumstance, Maddie links the UDI record for the accessory to both the ARTG for the System and the ARTG for the accessory.

In vitro diagnostic 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

An accessory is something that the manufacturer specifically intends to be used with a device. The accessory allows or helps the device to be used, in a way that the manufacturer of the device intended.

As a manufacturer, you must meet UDI requirements for accessories if your accessory (including components and sub-systems):

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

You do not need to meet UDI requirements if your accessory:

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

Spare or replacement parts

Replacement consumables

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

Spare parts

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

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

- is considered a medical device in its own right
- is commercially available
- has its own ARTG inclusion, and

- is in scope of devices required to meet UDI requirements.

Managing UDIs for spare or replacement parts

If you exchange a component of a device that is a device itself and has a UDI, you must continue to meet UDI requirements for the component, even when it is a replacement.

The Australian UDI Database (AusUDID)

We have established the AusUDID as the repository for UDI-DIs and related data in Australia.

We have designed the AusUDID to store UDI-DIs and related data about a model of medical device. This can help to improve tracking and traceability of medical devices supplied in Australia. When providing data to the AusUDID, you should consider information that will help the end user to distinguish the device from other models. This will help them to use current product information.

As a sponsor, you or your approved third party can submit and maintain UDI records in the AusUDID. You must keep UDI records up to date while your device(s) remains in supply in Australia. Once your device is no longer in supply, the UDI record(s) must remain indefinitely in the AusUDID.

Patients, consumers, clinical quality registries and health professionals will be able to view and download this medical device information, at no cost.

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

The AusUDID does not store any patient information.

AusUDID and the Australian Register of Therapeutic Goods (ARTG)

You must link your relevant medical device inclusion(s) in the ARTG to your UDI records. The purpose of this is to allow validation of certain data fields, such as manufacturer information and to associate your device(s) with the approval to supply.

To be compliant with UDI requirements your UDI records must be linked to an ARTG record.

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

UDI records in the AusUDID

A UDI record is made up of a UDI-DI and related data. This data includes information about the device as well as the supply of the device, such as:

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

The UDI-PI is not included in a UDI record.

Sponsors, manufacturers and third party data providers can submit UDI records to the AusUDID. We have published resources on using the AusUDID on the UDI Hub.

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

The UDI record must not be deleted, even if the device is no longer in supply. When a medical device is no longer in commercial distribution, the sponsor must update the Sponsor Commercial Distribution End Date in the UDI record to reflect this.

AusUDID data elements and rules

The Australian UDI Data Dictionary includes a list of the fields in the database, including:

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

You can find the Australian UDI Data Dictionary on the UDI Hub.

UDI Trigger data elements

There are generally 2 kinds of data elements in the AusUDID:

- UDI Trigger data elements
- Non-UDI Trigger data elements.

UDI Trigger data elements

UDI Trigger data elements are the fields that cannot be changed without requiring a new UDI-DI or UDI record.

The Australian UDI Data Dictionary describes which data elements are UDI Triggers.

Non-UDI Trigger data elements

Non-UDI Trigger data elements are the fields that can be edited at any time without requiring a new UDI-DI or new UDI record.

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

Data entry rules

Successful entry and updates of a UDI record are subject to the data passing the data validation requirements set out in the AusUDID Data Dictionary.

These rules include whether the field is mandatory, conditionally mandatory or optional, which may vary depending on the type of device.

We have provided a List of Values (LOV) in the Australian UDI Data Dictionary that specifies the permitted values in certain fields.

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

Correcting and updating UDI records

We recognise there are many scenarios in which device data will change over time. These include:

- correcting data errors
- applying clinically relevant changes to the device
- changes to Issuing Agency requirements
- where you supply a single device to multiple countries with different UDI requirements.

To accommodate this, we allow both corrections and updates to data in the AusUDID.

Whether a change to a UDI record is an update or a correction depends on the purpose of the change.

Update a UDI record

Updates are changes to a UDI record due to the device or the devices characteristics changing. Updates are only permitted for non-UDI Trigger data elements. Updates to UDI Trigger data elements are not permitted, as the device requires a new UDI-DI and UDI record.

As a sponsor, it is your responsibility to keep your UDI record(s) up to date. You must update your UDI record within 30 days of the changes to the device if the changes do not trigger a new UDI-DI.

Correct a UDI record

Corrections are changes to a UDI record due to the data being incorrect. This may be because of a data entry error or technical error.

If you have supplied incorrect data to the AusUDID, you can correct your data error in the AusUDID. The AusUDID keeps an audit trail of the changes made, who made them and when.

The method for correcting data errors varies based on whether the UDI record is in the ‘Grace Period’.

Grace Period

The Grace Period is a set time frame that begins once you have published your initial version of the UDI record. During this time frame, you can make any needed changes to any data element. The purpose of the Grace Period is to allow you fix errors in the UDI record due to data entry errors or technical issues. The Grace Period allows these changes without triggering the need for a new UDI-DI.

The length of the Grace Period is subject to change as we introduce UDI and the AusUDID. You can find the current length of the Grace Period on the UDI Hub, or when updating or correcting a UDI record.

Changing UDI data in the Grace Period

You can update or correct any data field during the Grace Period. UDI Trigger rules do not apply during the Grace Period.

Changing UDI data outside the Grace Period

You can correct any errors outside the Grace Period by specifying that you are undertaking a Correction. You can correct UDI Trigger data elements, if the existing data is incorrect and you are fixing it. You must give your reasoning for why the change is needed. We may review corrections to data errors.

You can update any non-UDI Trigger data elements outside the Grace Period, as UDI Trigger rules do not apply to these fields.

You cannot update UDI Trigger data elements outside the Grace Period, except when using the corrections function. Updates to a UDI Trigger data element outside of the Grace Period will require a new UDI record.

Corrections or updates by third party data providers

You must action any corrections or updates to data under the authority of the sponsor. An agent or third party data provider that is appointed to submit data under the authority of the sponsor can action corrections or updates.

We have published resources for correcting or updating data on the UDI Hub.

Multiple sponsors of the same device

Because of the nature of therapeutic good regulation in Australia, it is possible that multiple sponsors supply the same medical device with the same UDI-DI. We have designed the AusUDID to cater for these scenarios.

As a sponsor, you are responsible for submitting your UDI-DI(s) and related data. This remains your responsibility, even if another sponsor supplies the same medical device with the same UDI-DI as you.

If another sponsor has already submitted the UDI-DI(s) and related data, you only need to add your sponsor specific data to the existing UDI record. You will be compliant with UDI requirements for submitting data, as long as you have added your sponsor specific data to the existing record. You do not need to resubmit or duplicate the existing UDI record.

Data element types for multiple sponsors of the same device

Generally, there are 2 data element types:

- UDI Trigger data elements
- Non-UDI Trigger data elements.

However, when there are multiple sponsors of the same device who are both linked to a UDI record, further distinction is required. UDI data elements are separated into 2 categories when more than one sponsor is linked to a UDI record:

- Common data elements
- Sponsor data elements.

Common data elements are the data elements that are common between sponsors, as these are determined by the manufacturer.

Sponsor data elements are the data elements that are specific to each sponsor and can only be edited by the sponsor they relate to.

UDI Trigger data elements remain as UDI Triggers.

Data entry rules for multiple sponsors of the same device

If you make any changes to a UDI record that has additional sponsor(s) linked, you must do this as a Correction. You must also give a reason for the change. This is to ensure consistency and accuracy in the data and minimise changes to shared data.

Change to a UDI record are recorded in the history tab of the UDI record. We may contact sponsors if we believe a change has been made incorrectly.

You are only responsible for the data that you provide. If another sponsor changes data to be incorrect, you are not liable for the incorrect change.

If you believe a change has been made incorrectly, you can contact us at UDI@health.gov.au.

UDI and TGA processes

Market actions including recalls, alerts and corrections

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

- recalls
- market action customer letters.

When submitting a new market action notification through the TBS portal, you should 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.

Patient Implant Cards

Manufacturers must provide Patient Implant Cards (PICs) and Patient Information Leaflets (PILs) for their implantable medical devices.

You are required to include the following information on a PIC:

- name of the device
- model of the device
- batch code, lot number or serial number of the device

- manufacturer's name, address, and website.

If available, you must also supply the UDI on the PIC for all implantable devices, including:

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

This UDI information is in addition to the information already supplied on the PIC.

You should display the UDI-PI either as a single field or split into the above data elements, per the current PIC requirements.

An example of a PIC with a UDI:

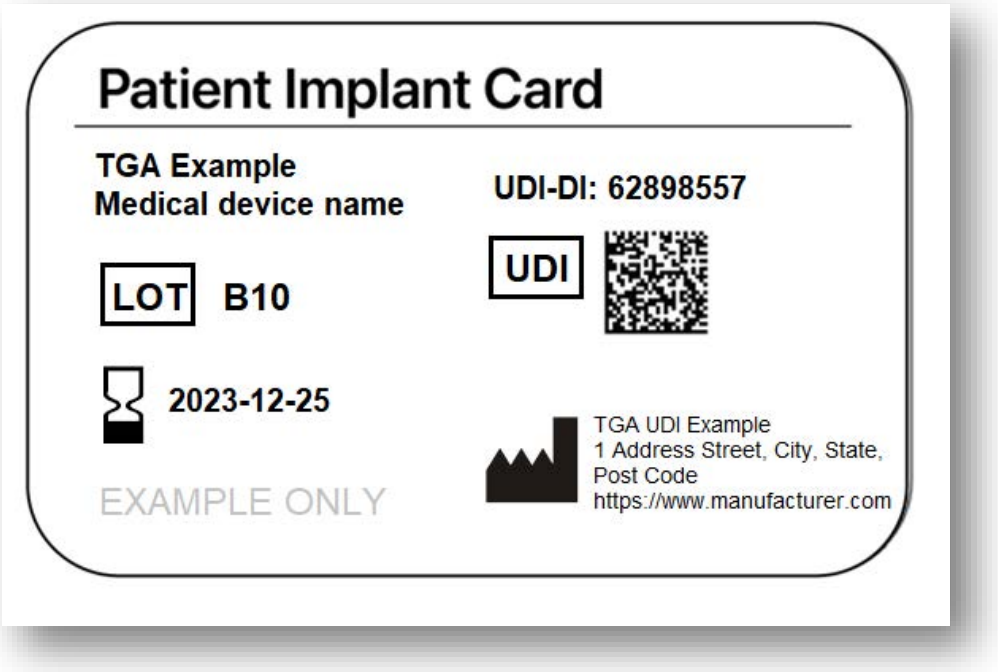


Figure 16: Example of a Patient Implant Card with a UDI

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

Patient Information Leaflets

There are no requirements for you to include UDIs on Patient Information Leaflets (PILs).

As a sponsor, you can choose to submit PILs to the AusUDID for your devices as a URL or a PDF attachment.

As a sponsor, you are responsible for ensuring the PIL is up to date if submitted to AusUDID.

Instructions for Use

You do not need to supply the UDI on Instructions for Use (IFU) or electronic Instructions for use (eIFU), although as a manufacturer, you may choose to do so.

Certifications and audits

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 amending other supporting documents.

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, including:

- dates
- batch/lot numbers
- product expiry dates
- volume information such as:
    - records of receipt and shipment from manufacturing sites, including records of shipping and storage conditions where required
    - records of storage and warehousing conditions where required
    - records of distribution to customers, retail outlets, hospitals, suppliers and distributors (including export countries).

We expect you to keep records for 10 years for:

- Class 4 IVDs
- Class III medical devices
- Class IIb implantable medical devices.

For all other classifications, we expect you to keep records for 5 years after you distribute the last product.

We expect that you include the UDI in your records and keep your records for the applicable time frame based on the device's classification.

UDI specific record keeping requirements

As a sponsor, you are responsible for maintaining records showing all UDIs used to identify devices that must bear a UDI on their label.

Your records should indicate whether a device was directly marked, and whether the Direct Mark DI is the same or different to the Primary DI. You should update your records when you make changes to the Production Identifiers (PIs), to reflect all PIs currently associated with each DI.

Your records should also refer to:

- the location of the DI for the model of device*
- the associated types of PIs in the UDIs for that model of the device such as lot number, batch number, manufacturing date.

*This is part of what you should agree with your chosen Issuing Agency.

Fees and charges

No fees are applicable for submitting or updating your UDI records in the AusUDID. We have included ongoing management and maintenance of the AusUDID in annual charges.

Additional resources

UDI Hub

We have published a range of resources to support you in implementing UDI and using the AusUDID. These are available on the UDI Hub.

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 a UDI Carrier on device labels

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

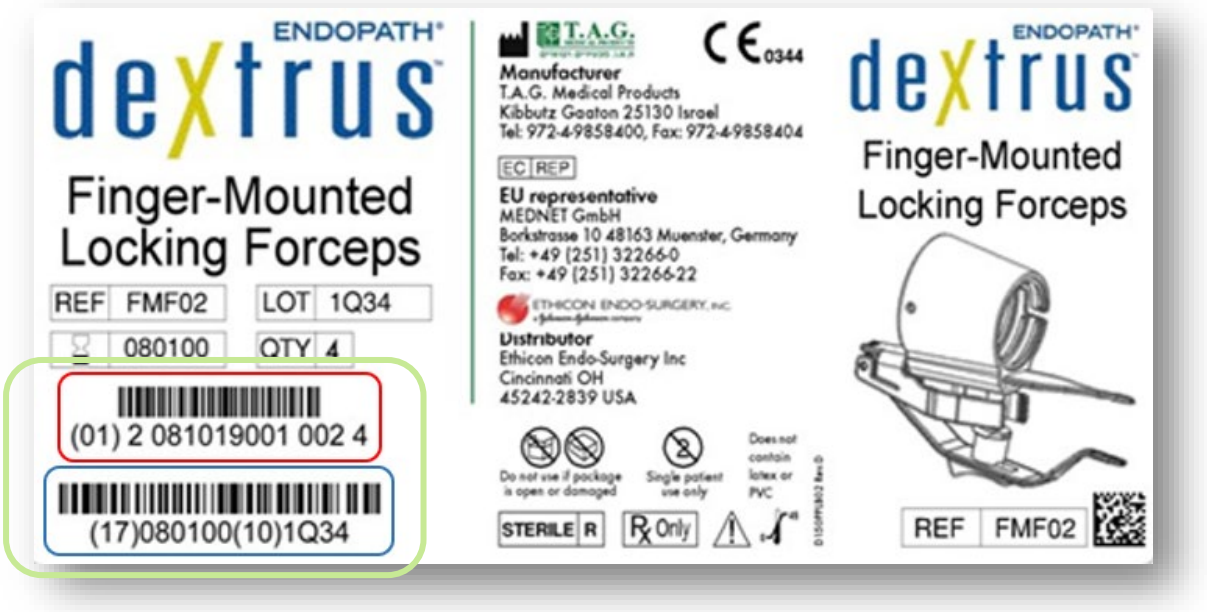


Figure 17: Example of a GS1 label with UDI Carrier

HIBCC UDI Carrier example

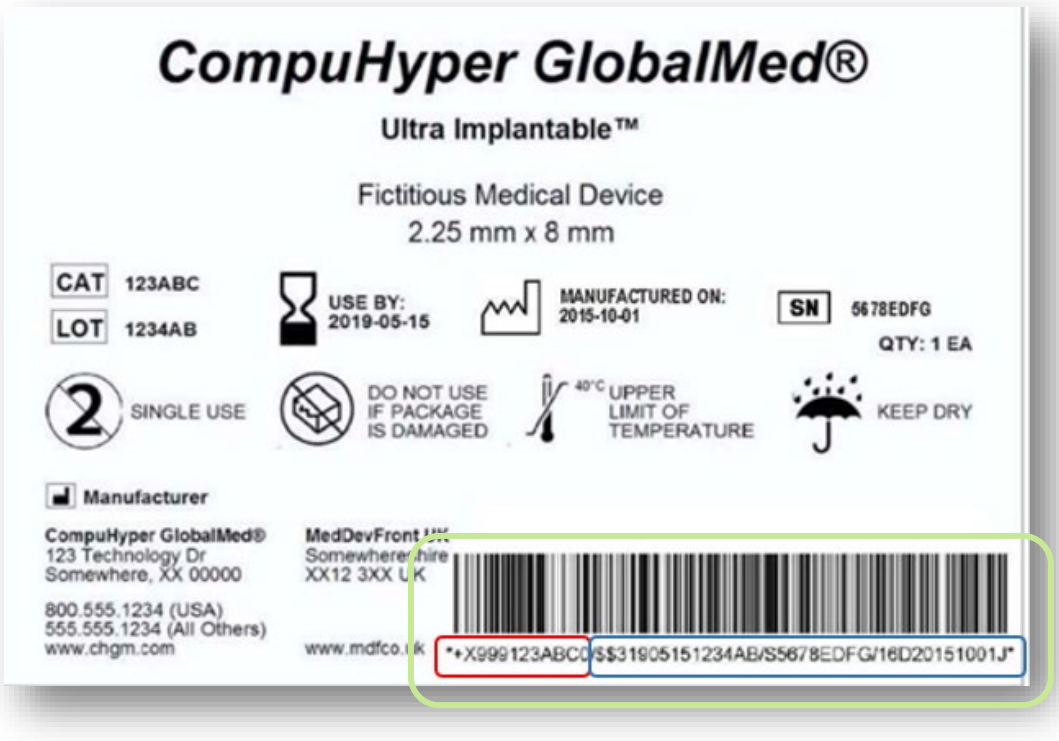


Figure 18: Example of a HIBCC label with UDI Carrier

ICCBBA UDI Carrier example

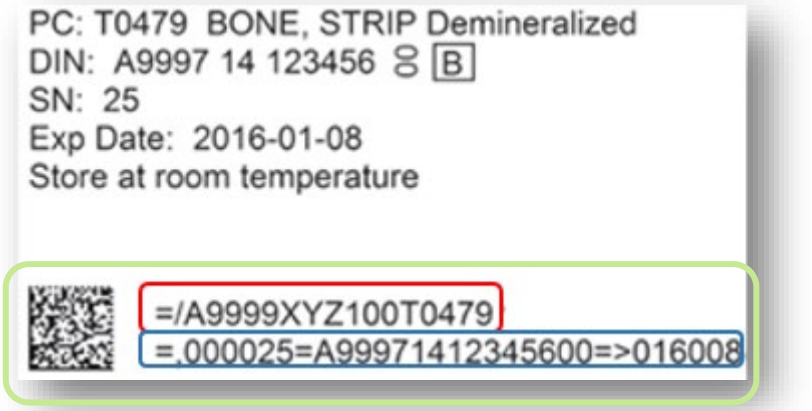


Figure 19: Example of an ICCBBA label with UDI Carrier

Appendix B: UDI HRI formats

GS1 standards

Issuing Agency	Data Delimiter/Application Identifier	Identifier	Data type	Human Readable Field Size	Database Field Size
GS1	(01)	Device Identifier	Numeric	16	14
GS1	(11)	Manufacturing / Production Date	numeric [YYMMDD]	8	6
GS1	(17)	Expiration Date	numeric [YYMMDD]	8	6
GS1	(10)	Batch/Lot Number	alphanumeric	22 (max)	20 (max)
GS1	(21)	Serial Number	alphanumeric	22 (max)	20 (max)
GS1	(8012)	Software Version	Alphanumeric	24 (max)	20 (max)
GS1		***Maximum Base UDI***	***alphanumeric***	***76***	***66***
ex: (01)09506000117843(11)141231(17)201231(10)1234AB(21)5678CD					

HIBCC standards

Issuing Agency	Data Delimiter/Application Identifier	Identifier	Data type	Human Readable Field Size	Database Field size
HIBCC	+	Device Identifier	Alphanumeric	7 to 24	6 to 23
HIBCC	$	Lot Number Only	Alphanumeric	19	18
HIBCC	$$7	Lot Number Only (alternative option)	Alphanumeric	21	18
HIBCC	$$	Expiration Date followed by Lot Number	Exp. Date: numeric [MMYY]	6	4
			Lot Number: alphanumeric	18	18
HIBCC	$$2	Expiration Date followed	Exp. Date: numeric [MMDDYY]	9	6

Issuing Agency	Data Delimiter/Application Identifier	Identifier	Data type	Human Readable Field Size	Database Field size
		by Lot Number	Lot Number: alphanumeric	18	18
HIBCC	$$3	Expiration Date followed by Lot Number	Exp. Date: numeric [YYMMDD]	9	6
			Lot Number: alphanumeric	18	18
HIBCC	$$4	Expiration Date followed by Lot Number	Exp. Date: numeric [YYMMDDHH]	11	8
			Lot Number: alphanumeric	18	18
HIBCC	$$5	Expiration Date followed by Lot Number	Exp. Date: numeric [YYJJJ] – Julian Date format	8	5
			Lot Number: alphanumeric	18	18
HIBCC	$$6	Expiration Date followed by Lot Number	Exp. Date: numeric [YYJJJHH] – Julian Date format with Hour option	10	7
			Lot Number: alphanumeric	18	18
HIBCC	$+	Serial Number only	Alphanumeric	20	18
HIBCC	$$+7	Serial Number only (alternative option)	Alphanumeric	22	18
HIBCC	$$+	Expiration Date followed by Serial Number	Exp. Date: numeric [MMYY]	7	4
			Serial Number: alphanumeric	18	18
HIBCC	$$+2	Expiration Date followed by Serial Number	Exp. Date: numeric [MMDDYY]	10	6
			Serial Number: alphanumeric	18	18

Issuing Agency	Data Delimiter/Application Identifier	Identifier	Data type	Human Readable Field Size	Database Field size
HIBCC	$$+3	Expiration Date followed by Serial Number	Exp. Date: numeric [YYMMDD]	10	6
			Serial Number: alphanumeric	18	18
HIBCC	$$+4	Expiration Date followed by Serial Number	Exp. Date: numeric [YYMMDDHH]	12	8
			Serial Number: alphanumeric	18	18
HIBCC	$$+5	Expiration Date followed by Serial Number	Exp. Date: numeric [YYJJJ]	9	5
			Serial Number: alphanumeric	18	18
HIBCC	$$+6	Expiration Date followed by Serial Number	Exp. Date: numeric [YYJJJHH]	11	7
			Serial Number: alphanumeric	18	18
HIBCC	/S	Supplemental Serial Number, where lot number also required and included in main secondary data string	Alphanumeric	20	18
HIBCC	/16D	Manufacturing Date (supplemental to secondary barcode)	numeric [YYYYMMDD]	12	8
HIBCC	/14D	Expiration Date (supplemental to secondary barcode as optional format)	numeric [YYYYMMDD]	12	8

Issuing Agency	Data Delimiter/Application Identifier	Identifier	Data type	Human Readable Field Size	Database Field size
HIBCC		***Maximum Base UDI***	***Alphanumeric***	***70 to 87***	***58 to 75***
Ex of Human Readable Barcode: +H123PARTNO1234567890120/$$420020216LOT123456789012345/SXYZ456789012345678/16D20130202C					

ICCBBA standards

Issuing Agency	Data Delimiter/Application Identifier	Identifier	Data type	Human Readable Barcode Field Size	Database Field Size
ICCBBA	=/	Device Identifier	Alphanumeric	18	16
ICCBBA	=,	Serial Number	Alphanumeric	8	6
ICCBBA	=	Donation Identification Number	Alphanumeric	16	15
ICCBBA	=>	Expiration Date	numeric [YYYJJJ]	8	6
ICCBBA	=}	Manufacturing Date	numeric [YYYJJJ]	8	6
ICCBBA	&,1	MPHO Lot Number	Alphanumeric	21	18
ICCBBA		***Maximum Base UDI for HCT/Ps***	***Alphanumeric***	**79**	**67**
Ex of Human Readable Barcode:=/A9999XYZ100T0944=,000025=A99971312345600=>014032=}013032&,1000000000000XYZ123					

Appendix C: Glossary

We use these terms, definitions and acronyms in the regulation of therapeutic goods in Australia in relation to the Unique Device Identification (UDI) system.

We have provided this list is provided as general information only. This list is not exhaustive.

You can find the general Therapeutic Goods Administration glossary here: Acronyms and glossary terms.

Term	Definition
Accessory	Accessory means a thing intended specifically by its manufacturer to be used together with a specific medical device(s) to enable the medical device to be used in accordance with its intended use.
Alphanumeric	Consisting of both letters and numbers and often other symbols (such as punctuation marks and mathematical symbols).
AIDC	Automatic Identification and Data Capture (AIDC) refers to the methods of automatically identifying objects and entering them directly into computer systems without human involvement. AIDC technologies can include bar codes, QR codes, smart cards, biometrics and RFID.
API	Application Programming Interface (API) allows for 2 or more computer programs to communicate with each other. The Australian UDI Database uses an API for the Machine to Machine exchange of data.
APIM Credential	API Management Credentials (APIM Credentials) are the unique login credentials used when accessing the API Management Portal. These credentials are provided by the UDI Support Team upon request to use the Machine to Machine (M2M) method of UDI data submission in the Australian UDI Database (AusUDID).
APIM Portal	The API Management Portal (APIM Portal) which was established by the Department of Health and Aged Care to support Machine to Machine (M2M) data submission. The portal allows creation of API Subscription Keys and allows the user organisation to submit data to the Australian UDI Database (AusUDID) via HL7 SPL.
API Subscription Keys	API Subscription Keys are generated by an organisation within the APIM Portal. These keys can then be provided to another organisation or user registered within the APIM portal, such as a third-party data provider. API Subscription Keys allow a connection to be made between these organisations and enables the third-party data provider or user to utilise the APIM Portal to allow submission of UDI data to the Australian UDI Database (AusUDID).
AusUDID	The Australian Unique Device Identification Database (AusUDID), managed by the Therapeutic Goods Administration, stores UDIs and medical device data supplied by sponsors and manufacturers to identify models of device supplied in Australia.
Base package	The lowest packaging level.
Bulk Upload	A method of data submission to the Australian UDI Database via a Microsoft Excel Spreadsheet.
Configuration	Configuration is a combination of items of equipment, as specified by the manufacturer, that operate together to provide an intended use or purpose as a medical device. The combination of items may be modified, adjusted or customised to meet a customer need.
Data delimiter	Within a UDI, a defined character or set of characters that specifies the boundary between specific data elements. These could also be called application identifiers or qualifying identifiers.
Device Classification	See Classification of medical devices.
Device Identifier (DI)	The term Device Identifier is synonymous with the proper technical term, UDI-DI. The UDI-DI is a unique numeric or alphanumeric code specific to a model

Term	Definition
	of medical device. It is also used as the 'access key' to information stored in the AusUDID.
Direct Marking	Direct marking, for the purposes of UDI requirements, is recording the UDI permanently on the device itself. Reusable devices requiring reprocessing between uses must consider direct marking requirements.
Grace Period	The Grace Period is a set timeframe that begins once a UDI record has been published. During this timeframe, the UDI record can be edited without triggering a new UDI-DI or requiring a correction to be registered.
GDSN	Acronym for GS1 Global Data Synchronisation Network. For more information see Home - GS1 Australia- external site.
GLN	Acronym for GS1 Global Location Number. For more information see Home - GS1 Australia- external site.
GMDN	Global Medical Device Nomenclature (GMDN) is a collection of internationally recognised terms used to describe and catalogue medical devices, in particular, those products used in the diagnosis, prevention, monitoring, treatment or alleviation of disease or injury in humans. For more information see Home New - GMDN (gmdnagency.org)- external site.
GS1	GS1 is one of 3 TGA recognised Issuing Agencies.
GTIN	Global Trade Item Number (GTIN) is the GS1 identification key used to identify trade items. For more information see Home - GS1 Australia- external site.
HIBCC	Health Industry Business Communications Council (HIBCC) is one of 3 TGA recognised Issuing Agencies. For more information see HIBCC – Health Industry Business Communications Council- external site.
HIBC-LIC	Health Industry Bar Code – Labeller Identification Code (HIBC-LIC) allows identification of a registered organisation of Issuing Agency Health Industry Business Communications Council (HIBCC). For more information see HIBCC – Health Industry Business Communications Council- external site.
HIBC-UPN	Health Industry Bar Code – Universal Product Number is the HIBCC product identifier used to uniquely identify medical products. For more information see HIBCC – Health Industry Business Communications Council- external site.
HL7 SPL	Health Level 7 Structured Product Labelling (HL7 SPL) is the format used in the Machine to Machine (M2M) method of data submission to the Australian UDI Database via an API connection. The Structured Product Labelling (SPL) specification is a document markup standard that specifies the structure and semantics of the content of authorised published information that accompanies a medical device licensed by a regulatory authority. HL7 SPL is managed by HL7 International. For more information see Health Level Seven International- external site.
HRI	Human Readable Interpretation (HRI) is characters that can be read by people, e.g. letters and numbers, as opposed to symbol characters within barcode symbols, which are read by machines.
ICCBBA	The International Council for Commonality in Blood Banking Automation (ICCBBA) is one of 3 TGA recognised Issuing Agencies. For more information see ISBT 128 | ICCBBA- external site.
ICCBBA ISBT 128-PPIC	The International Council for Commonality in Blood Banking Automation Information Standard for Blood and Transplant 128 - Processor Product Identification code is the ICCBBA product identifier used to uniquely identify products. For more information see ISBT 128 | ICCBBA- external site.
eIFU	See Electronic Instructions for Use - eIFU.
Implantable device	Any device, including those that are partially or wholly absorbed, which is intended to either:

Term	Definition
	• be totally introduced into the human body • replace an epithelial surface or the surface of the eye by surgical intervention which is intended to remain in place after the procedure. Any device intended to be partially introduced into the human body through surgical intervention and intended to remain in place after the procedure for at least 30 days is also considered an implantable device.
Issuing Agency	An organisation that operates a system for the issuance and ensuring global uniqueness of UDIs.
Kits	Kits are a collection of products, including medical devices, that are packaged together to achieve a common intended use and are being distributed as medical devices. These could also be called procedure packs or convenience kits.
Label	Written, printed, or graphical information either appearing on the medical devices itself, or on the packaging of each unit, or on the packaging of a set or group of devices packaged together.
Mandatory compliance	Mandatory compliance refers to the time in which UDI requirements must be complied with, unless otherwise exempt.
Manufacturer	Corporation or person carrying out one or more of the steps specified in the definition of manufacture. Section 41BG in Part 4-1 Division 2 of the *Therapeutic Goods Act 1989*- external site contains a full definition.
M2M	Machine to Machine (M2M), is a method of data submission to the Australian UDI Database that uses the HL7 SPL format and the National Product Catalogue. M2M is the automated exchange of UDI data between computer systems without the manual intervention of humans.
NPC	National Product Catalogue (NPC) is one of GS1 Australia's data pools in GS1's Global Data Synchronisation Network (GDSN) services. This certified data pool is used to share master data between trading partners. NPC can be utilised within the Australian UDI Database as a method of data submission.
Own brand/private labeller	An Own Brand or Private Labeller relabels a device from a third party with their own name without making any further changes to the device, thereby taking responsibility as the manufacturer.
Packaging	Product to be used for the containment, protection, handling, delivery, storage, transport and presentation of goods, from raw materials to processed goods, from the producer to the user or consumer, including processor, assembler or other intermediary.
Packaging levels	Packaging levels refers to the various levels of device packages that contain a quantity of medical devices, for example a carton or case. Note: for the purpose of UDI, this does not include shipping containers or logistics units.
PIC	Patient Implant Card (PIC). For more information, see Patient implant cards and information leaflets.
PIL	Patient Information Leaflet (PIL). For more information, see Patient implant cards and information leaflets.
Previous DI	Previous Device Identifier (DI) is assigned to a version or model of a medical device prior to the assignment of a new device identifier to a medical device. This is required when a UDI is superseded due to a UDI Trigger.
Primary DI	The UDI-DI on the base package or the device itself is the Primary DI portion of the UDI that is submitted to the AusUDID.
Production Identifier (UDI-PI)	The Production Identifier is a numeric or alphanumeric code that describes the unit of device production.

Term	Definition
RFID	Radio Frequency Identification (RFID) is a technology that uses communication through radio waves to exchange data between a reader and an electronic tag attached to an object, for the purpose of identification.
Secondary DI	The Secondary DI is an optional data element in the UDI record designed to accommodate a DI from an Issuing Agency other than the Primary DI Issuing Agency.
Secondary package	Secondary packages contain a set number of base packages of a device.
Serial Number	A unique sequence of numbers or letter in a series used to identify an individual unit of a medical device.
Shipping units/logistics units	Shipping unit is a unit whereby the traceability is controlled by a process specific to logistics systems.
SaMD	Software as a Medical Device (SaMD) is defined as software intended to be used for one or more medical purposes.
SOPPs	System or Procedure Packs (SOPPs) are medical devices intended to be used in a medical or surgical procedure, containing a combination of 2 or more goods where at least one of the goods is a medical device or in vitro diagnostic device, and all goods are packaged together or are to be interconnected or combined for use.
Sponsor	In relation to therapeutic goods, means: • a person who exports, or arranges the exportation of, the goods from Australia; or a person who imports, or arranges the importation of, the goods into Australia; or a person who, in Australia, manufactures the goods, or arranges for another person to manufacture the goods, for supply (whether in Australia or elsewhere). But does not include: • exports, imports or manufactures the goods; or arranges the exportation, importation or manufacture of the goods, on behalf of another person who, at the time of exportation, importation, manufacture or arrangements, is a resident of, or is carrying on business in, Australia. A full definition is provided in Chapter 1 Section 3 of the *Therapeutic Goods Act 1989*- external site.
Standard	Document, established by consensus and approved by a recognised body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context.
Tertiary package	Tertiary packages contain a set number of secondary packages of a device.
Third-Party	A third party, for the purpose of UDI, is a company or individual other than the sponsor or manufacturer of a device that, based on a contract with that sponsor or manufacturer, is authorised by the sponsor or manufacturer to carry out certain operations on their behalf such as submitting data to the AusUDID or placed the UDI Carrier on the device.
Unit of Use DI	The Unit of Use DI (UoU DI) is a virtual identifier assigned to an individual medical device. It is assigned in the instance when a UDI is not labelled at the level of device unit of use (for example, several units contained in a plastic bag). Its purpose is to associate the use of a device to or on a patient.
Unique Device Identifier (UDI)	A Unique Device Identifier (UDI) is a series of numeric or alphanumeric characters that is created through a globally accepted standard and applied to a specific model of medical device. It is comprised of both the UDI-DI and UDI-PI is applied to the device label and all applicable levels of

Term	Definition
	packaging for the device in both AIDC and HRI. Note: the word 'unique' does not imply serialisation of individual production units.
Unique Device Identification system (UDI system)	A system that is intended to provide globally harmonised positive identification of medical devices through distribution and use. The system requires: • The label of devices to bear a globally unique device identifier (to be conveyed by using AIDC and, if applicable, its HRI) based upon a standard, with the DI and related device data for that unique identifier being also supplied to the AusUDID.
UDI-DI	UDI-Device Identifier (UDI-DI) – identifies the model of medical device. The UDI-DI is used as the 'access key' to information stored in the AusUDID and will be used for device related information such as adverse events and recalls. *Examples of the UDI-DI include a GS1 GTIN (Global Trade Item Number), a HIBC-UPN (Universal Product Number), or an ICCBBA ISBT 128-PPIC (Processor Product Identification Code).*
UDI-PI	UDI-Production Identifier (UDI-PI) – identifies the production specific information such as the production run of the device. This could include a batch number, lot number or expiry date. The UDI-PI is present on the device but not stored in the Australian UDI Database (AusUDID).
UDI Carrier	The UDI Carrier is the means to convey the UDI by using AIDC and HRI. Note: Carriers can include 1D linear bar code, 2D or matrix bar code or RFID.
UDI Triggers	Changes to certain UDI data elements require a new UDI-DI to be allocated as they represent a change to the medical device that could lead to misidentification of the medical device or ambiguity in its traceability. These data elements are called UDI Triggers.
Voluntary compliance	Voluntary compliance refers to the time in which sponsors and manufacturers of medical devices may choose to comply with UDI requirements, prior to mandatory compliance.

Appendix D: 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* Do not trigger a new UDI-DI if the field was blank prior to change.
Direct Marked DI Issuing Agency	Yes* 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* Do not trigger a new UDI-DI if the field was set to ‘Labelling

Data element	Trigger?
	does not contain MRI safety information' prior to the change.
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* 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* 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* 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* 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

Data element	Trigger?
Package DI	No
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

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