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

Complying with the Unique Device Identification timeframes for medical devices

Timeframes for supplying UDI compliant medical devices in Australia

Version 2.0, May 2026

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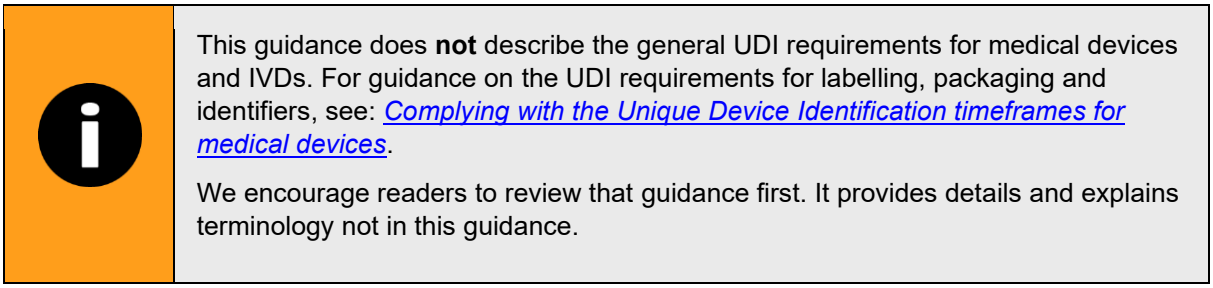
Purpose of this guidance

We developed this guidance to help sponsors and manufacturers understand and comply with Australia's Unique Device Identification (UDI) requirements. It explains UDI compliance dates and provides practical examples for understanding the phased approach and transitional arrangements.

Structure of this guidance

- Introduction: Explains the purpose of UDI and how the phased implementation approach works.
- UDI compliance dates summary: Summarises UDI compliance dates, including transitional dates.
- UDI compliance start dates: Explains the standard UDI compliance dates.
- Transitional arrangement for existing devices: Explains transitional arrangements for devices manufactured and labelled before compliance dates.
- EU MDD and EU IVDD transitional arrangements: Details transitional arrangements for certain devices.
- Consent to supply: Provides information on applying for Consent to Supply.
- Preparing for UDI compliance: Details suggested steps in preparing for UDI compliance.
- Resources: Lists additional resources for meeting UDI requirements.



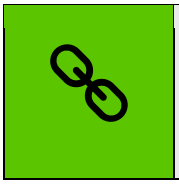
This guidance does **not** describe the general UDI requirements for medical devices and IVDs. For guidance on the UDI requirements for labelling, packaging and identifiers, see: *Complying with the Unique Device Identification timeframes for medical devices*.

We encourage readers to review that guidance first. It provides details and explains terminology not in this guidance.

Terminology used in this guidance

- **we** refers to the Therapeutic Goods Administration (TGA)
- **you** refers to sponsors or manufacturers of medical devices or in vitro diagnostic (IVD) devices
- **UDI record** means a UDI-Device Identifier (UDI-DI) and related data published in the Australian UDI Database (AusUDID)
- **UDI compliance start date** refers to the date in which you must comply with UDI requirements for your device(s)
- **existing devices** are devices that were manufactured and labelled prior to the UDI compliance start date
- **EU certificate** refers to an overseas regulator conformity assessment document issued under either of the following (as in force from time to time):
    - *Council Directive 93/42/EEC of the Council of the European Communities (EU MDD)*
    - *Directive 98/79/EC of the European Parliament and the Council of the European Union (EU IVDD).*

- **devices in scope of UDI requirements** are those that must meet UDI requirements based on their risk classification, for example Class III medical devices
- **devices not in scope of UDI requirements** are those that are not required to meet UDI requirements based on their risk classification, for example Class I non-measuring, non-sterile medical devices
- **as a manufacturer** refers to organisations with the role of the manufacturer. Organisations in this role have obligations under UDI requirements that differ from those of the sponsor
- **as a sponsor** refers to organisations with the role of the sponsor. Organisations in this role have obligations under UDI requirements that differ from those of the manufacturer.



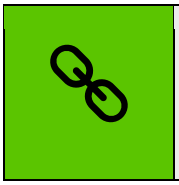
For a full list of acronyms, terms and descriptions, see UDI acronyms and glossary | Therapeutic Goods Administration (TGA).

Symbols used in this guidance

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

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

The exclamation mark indicates important information.



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

Legislation

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

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

Introduction

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

The UDI system supports accurate 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.

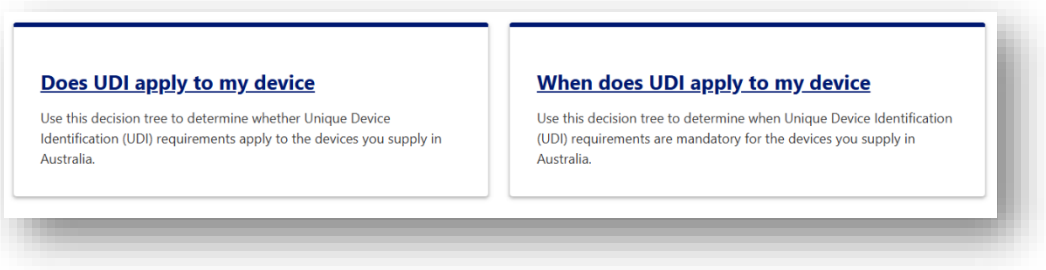
The inability to effectively and efficiently track and trace medical devices that have been supplied to or implanted into patients has constrained timely clinical and regulatory action in a number of medical device safety crises. This includes hip implants, urogynaecological mesh and breast implants.

Australia is implementing UDI in phases over a 5 year period. The phases will apply by device risk classification, starting with high-risk devices, followed by lower risk devices over later years. This staged approach helps sponsors and manufacturers prepare progressively.

UDI timing decision tree

We developed a decision tree to help sponsors and manufacturers determine when UDI requirements apply to their devices. You can access this tool here: When does UDI apply to my device | Therapeutic Goods Administration (TGA).

Figure 1: UDI decision trees



Use the decision tree together with this guidance to clarify compliance timelines, transitional provisions, and key obligations.

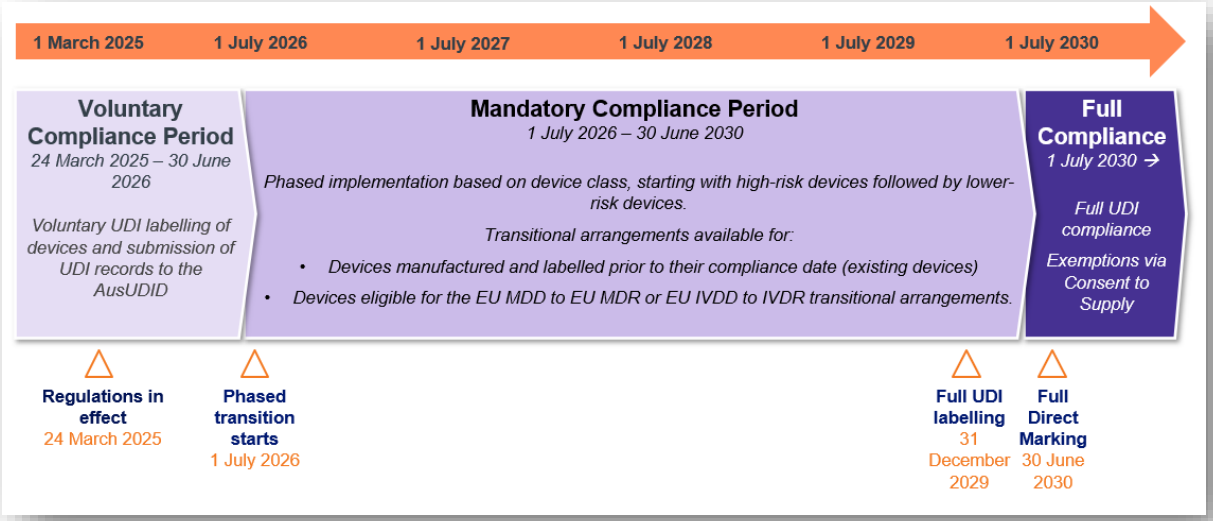
We have also created a decision tree to help sponsors and manufacturers understand if UDI applies to their devices. You can access this tool here: Does UDI apply to my device | Therapeutic Goods Administration (TGA).

UDI compliance phases

UDI is being introduced in phases, starting with voluntary compliance and moving to mandatory compliance. Mandatory compliance starts with high-risk devices followed by lower-risk devices in later years.

All devices must comply by **1 July 2030** unless exempt or granted a Consent to Supply.

Figure 2: Summary of compliance phases



Voluntary compliance period

The voluntary compliance period is from 24 March 2025 until the UDI compliance start date for each device class.

As a manufacturer, you should use this time to:

- understand UDI requirements for the devices you manufacture
- prepare your organisation, including educating staff and nominating subject matter experts
- update your labels and packaging.

As a sponsor, you should use this time to:

- ensure your manufacturer is meeting their UDI obligations
- prepare your data for UDI record submission
- choose and test methods for submitting UDI records to the AusUDID.

Compliance is optional during the voluntary compliance period, however we recommend preparing early, especially if you manage a large number of devices.

We have developed a checklist to help sponsors and manufacturers prepare for their UDI compliance: Preparing for UDI and AusUDID checklist | Therapeutic Goods Administration (TGA).

Mandatory compliance period

Once your device reaches its UDI compliance start date, you must meet all UDI requirements or apply for Consent to Supply.

Transitional arrangements

Certain devices qualify for transitional arrangements which extend the voluntary compliance period, including:

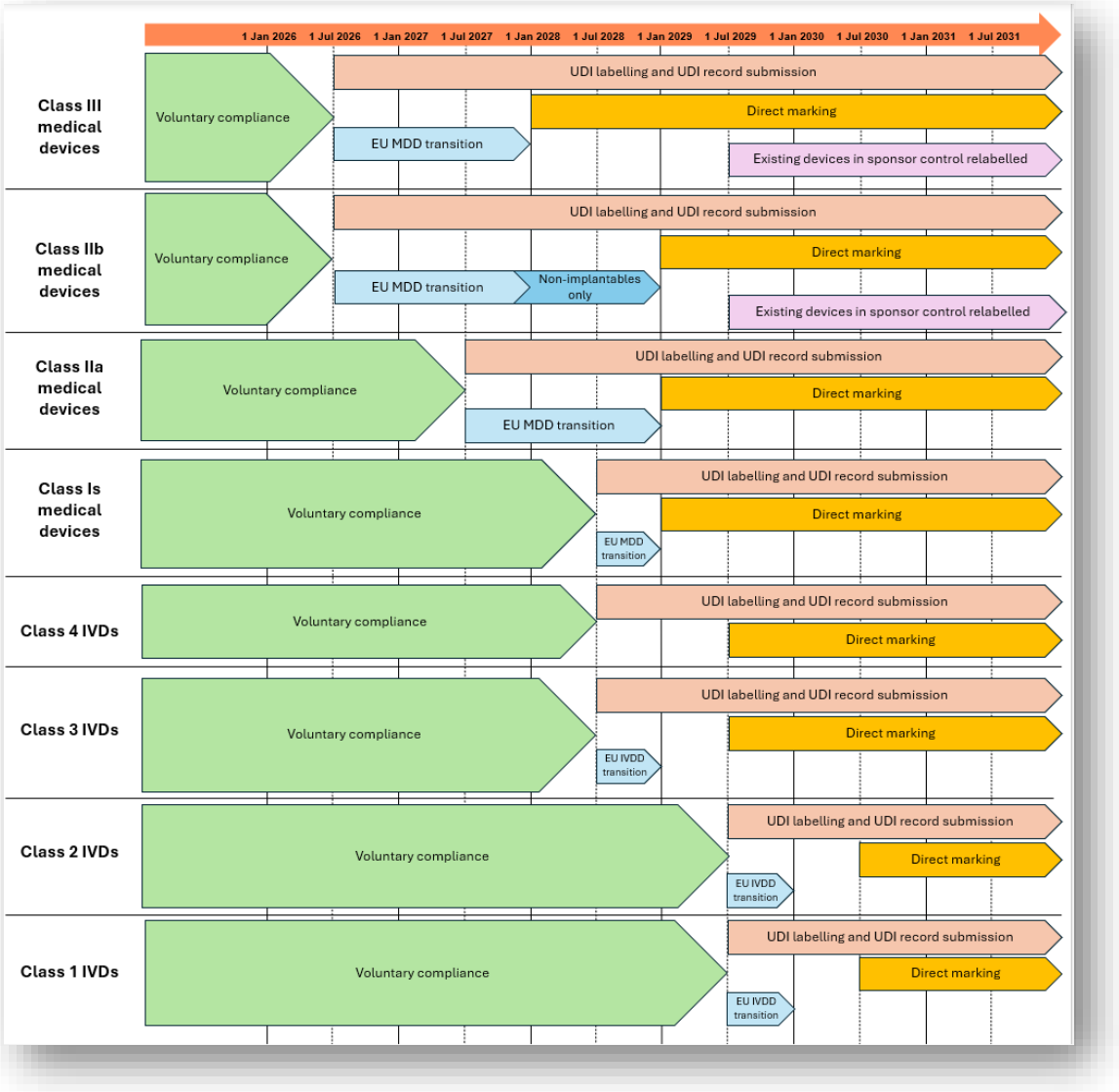
- devices manufactured and labelled before compliance dates (existing devices)
- devices supplied in Australia under an EU MDD or EU IVDD certificate.

Not all devices qualify for transitional arrangements. You must confirm your UDI compliance date to ensure compliance with the Essential Principles.

UDI compliance dates summary

The image below provides a summary of the UDI compliance timeline for all device classes in scope of UDI requirements.

Figure 3: UDI compliance timetable overview



In the image:

- voluntary compliance shows when a device may optionally meet UDI requirements
- UDI labelling and UDI record submission indicates when a device must bear UDI-compliant labelling and have UDI records submitted to the Australian UDI Database (AusUDID)
- direct marking shows when direct marking requirements become mandatory for the applicable device class
- EU MDD transition indicates the additional period for devices transitioning from EU MDD to EU MDR certification
- EU IVDD transition indicates the additional period for devices transitioning from EU IVDD to EU IVDR certification

- existing devices in sponsor control relabelled marks the end of the transitional arrangement, when some existing devices must be relabelled to meet UDI requirements.

UDI compliance start dates

Each device class has 2 compliance milestones:

1. UDI labelling and UDI record submission milestone.
2. Direct marking milestone.

UDI labelling and UDI record submission milestone

This milestone has obligations for the manufacturer and the sponsor.

UDI assignment and labelling

As a manufacturer you must meet the first compliance milestone by:

- allocating a UDI-DI from a TGA recognised Issuing Agency to the device
- using the Issuing Agency's coding standard to allocate the UDI-PI to the device
- applying UDI-compliant labelling to the device's label and all applicable higher levels of packaging
- meeting any additional requirements, such as allocating a Unit of Use DI or directly marking the device
- including the UDI on Patient Implant Cards (PICs) for implantable devices.

UDI record submission

As a sponsor you must:

- submit UDI record(s) to the AusUDID Production environment, either directly or via your manufacturer or a third party data provider
- link your UDI record(s) to your relevant Australian Register of Therapeutic Goods (ARTG) inclusion(s) and ensure all data is accurate and up to date.

The UDI record must be submitted to the AusUDID within 30 days of supply of the device in Australia.

	**Callum the sponsor** Callum supplies a Class III medical device. The standard UDI compliance for his device is 1 July 2026. His manufacturer allocates and applies a UDI to the device label and packaging. Callum submits a UDI record to the AusUDID Production environment within 30 days of next supply in Australia. He supplies the device in Australia on 1 July 2026, so he must submit the UDI record by 31 July 2026. Callum submits the UDI record on 1 July 2026 and is compliant. If Callum did not supply the device in Australia until 1 August 2026, he must submit the UDI record within 30 days. This means he may submit the UDI record by 31 August 2026.

Early submission is encouraged; however, some scenarios make this impractical. For example, sponsors cannot submit a UDI record for a new ARTG application before the application is approved and an ARTG ID is issued. As linking the UDI record to the ARTG inclusion is mandatory for compliance, the ARTG will need to be approved first.

Callum the sponsor

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

His manufacturer allocates and applies a UDI to the device label and packaging but is not able to directly mark the UDI on the device until a later date.

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

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

Although Callum's device is reusable, it is not required to be directly marked until direct marking is mandatory for Class IIb medical devices – 1 January 2028. He may choose to directly mark the device and add the data earlier; however, this is optional.

Direct marking milestone

Direct marking applies to devices that are:

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

If your device does not require direct marking, this milestone does not apply.

To meet this milestone:

- as a manufacturer, you must directly mark applicable devices with the UDI
- as a sponsor, you must include the direct marking information on new UDI records and update any previously submitted UDI record to include direct marking information.

Meeting the direct marking milestone

When submitting the initial UDI record, select '**Yes**' in the field '*Is the device subject to Direct Marking (DM), but exempt?*' This indicates that the device is subject to direct marking but exempt until the requirement becomes mandatory. At the direct marking milestone, update this field to '**No**' to show the exemption no longer applies.

At this time, you must either:

- provide the Direct Marking DI if it differs from the Primary DI, or
- select '**No**' in the field 'Is the Direct Marking DI different from Primary DI?'

Once the device is directly marked and the UDI record is updated, the device is fully UDI compliant.

For more information on meeting direct marking requirements, see Complying with the Unique Device Identification requirements for medical devices | Therapeutic Goods Administration (TGA).

Callum the sponsor

Callum met requirements for his Class III reusable surgical device at the first milestone, including UDI labelling and UDI record submission.

As his device is reusable and reprocessed for use on multiple patients, it must meet direct marking requirements by 1 January 2028.

His manufacturer directly marks the device with a UDI, and Callum updates his UDI record to include the direct marking information by 1 January 2028.

He has met both milestones for his device.

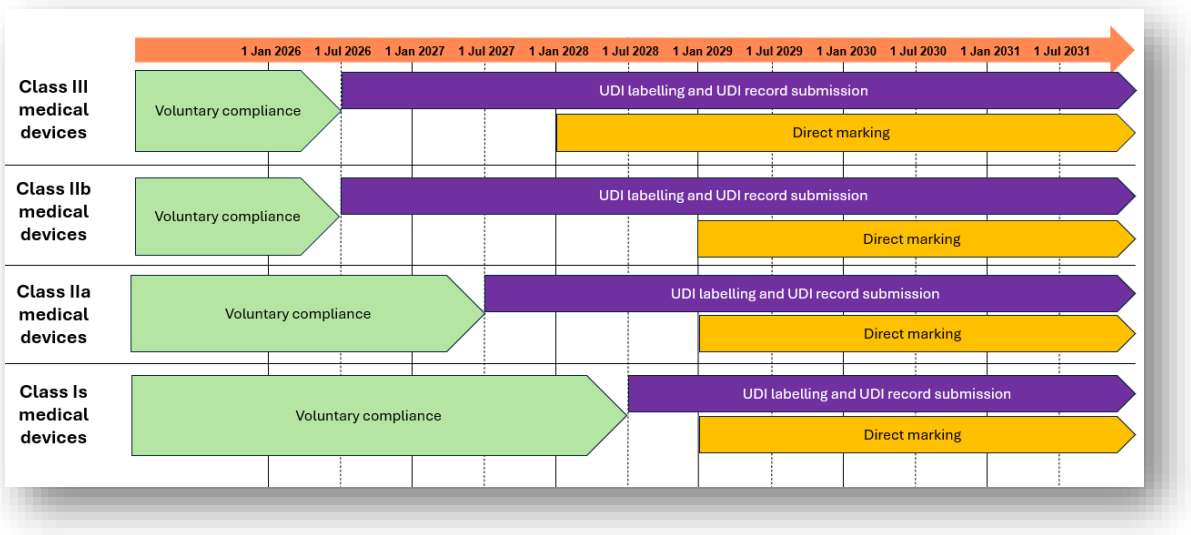
UDI compliance start dates for medical devices

The UDI compliance start dates for each medical device risk classification are outlined in the table below. These dates include both UDI compliance milestones.

Requirement	Class III	Class IIb	Class IIa	Class Is
UDI labelling and UDI record submission	1 July 2026	1 July 2026	1 July 2027	1 July 2028
Direct Marking and adding Direct Marking information to the UDI record	1 Jan 2028	1 Jan 2029* Not applicable for implantable medical devices.	1 Jan 2029	1 Jan 2029

The image below demonstrates these dates in the UDI implementation timeline:

Figure 4: Medical device UDI implementation timeline



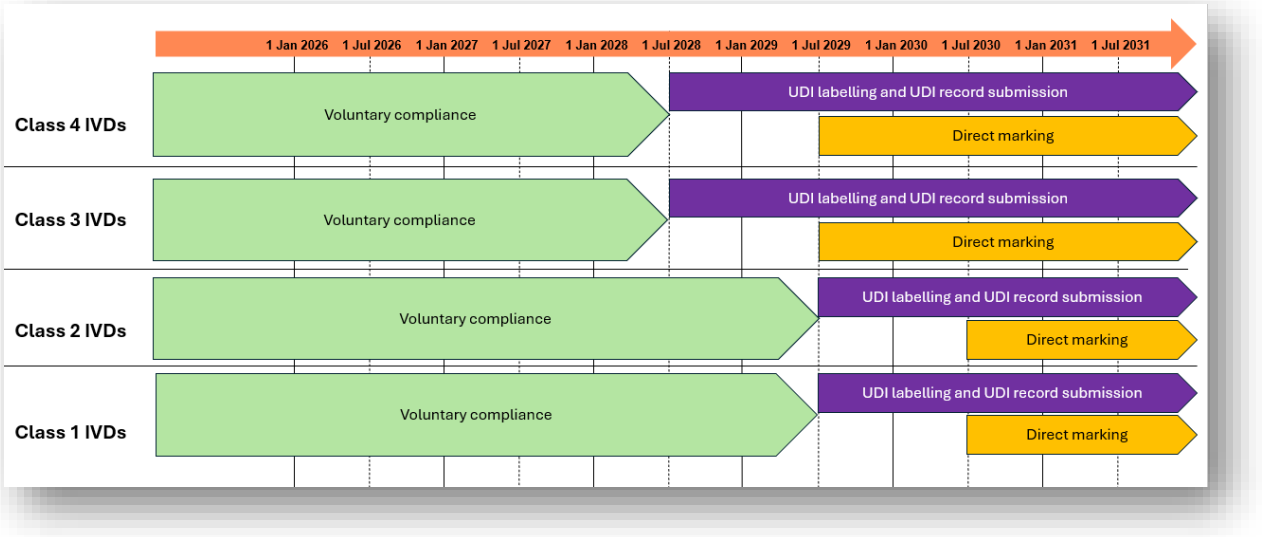
UDI compliance start dates for IVDs

The UDI compliance start dates for each IVD device class are outlined in the table below.

Requirement	Class 4 IVD	Class 3 IVD	Class 2 IVD	Class 1 IVD
UDI labelling and UDI record submission	1 July 2028	1 July 2028	1 July 2029	1 July 2029
Direct Marking and adding Direct Marking information to the UDI record	1 July 2029	1 July 2029	1 July 2030	1 July 2030

The image below demonstrates these dates in the UDI compliance timeline:

Figure 5: IVD UDI implementation timeline



Jeff the sponsor

Jeff supplies a Class 2 single use IVD. His device:

- must meet UDI labelling and UDI record submission requirements by 1 July 2029
- meet direct marking requirements, including adding direct marking information to the UDI record, by 1 July 2030.

To be compliant, Jeff ensures:

- UDI labelling is completed by 1 July 2029
- he submits a UDI record within 30 days of first supply of the device after 1 July 2029.

As his device is single use, direct marking does not apply.

Transitional arrangement for existing devices

Devices manufactured and labelled before their compliance date are considered **existing devices**.

We provide a transitional arrangement for existing devices.

Where a device is eligible for the EU MDD to EU MDR or EU IVDD to EU IVDR transitional arrangement, devices manufactured and labelled before the device transitions to EU MDR or EU IVDR are also considered existing devices.

Existing devices that are Class III or Class IIb must be relabelled by 1 July 2029 if in sponsor control. All existing devices of other device classes, including in vitro diagnostic (IVD) devices, are exempt from relabelling requirements for the lifetime of the device.

The transitional arrangement for existing devices ends on **1 July 2029**. From that date, **Class III and Class IIb medical devices must be relabelled**.

Where a device qualifies for both:

- the **EU MDD to EU MDR** or **EU IVDD to EU IVDR** transitional arrangements, and
- the **existing devices** transitional arrangement,

these arrangements apply **in parallel**. They do not extend beyond their respective end dates.

For example, a Class III medical device may qualify for the EU MDD to EU MDR transitional arrangement. If the device is manufactured and labelled before transition, it is also considered an existing device. However, this does not provide additional time beyond **1 July 2029**, even where the EU transitional arrangement has a later mandatory compliance date.

Where a Class III device is manufactured after transition to the MDR, it must be UDI-compliant at the time of manufacture. Where it is an existing device, it must be relabelled by **1 July 2029**.

If you cannot meet UDI requirements after the end of the applicable transitional arrangement or arrangements, you must apply for **Consent to Supply**.

Requirements at the end of the existing devices transitional arrangement

Devices that qualify for the existing devices transitional arrangement have different requirements at the end of the transitional period, depending on:

- the device class
- whether the device remains in sponsor control.

Class III and Class IIb devices that are in sponsor control **must be relabelled** to meet UDI requirements by 1 July 2029. If these devices are returned to sponsor control after 1 July 2029, they must be relabelled before resupply.

All other device classes are **exempt** from relabelling requirements.

All existing devices are exempt from direct marking requirements for the lifetime of the device, regardless of whether they are returned to sponsor control.

Where a device is no longer in sponsor control and not returned to sponsor control, that device is exempt for the lifetime of the device. Note that this applies to the specific device or batches or device, and not to the model of device.

Sponsor control

Sponsor control refers to devices that have left the manufacturer but are not distributed or supplied to end users. This includes:

- devices stored in a sponsor's warehouse but not yet supplied to hospitals or healthcare providers
- devices returned to a sponsor, such as consignment devices.

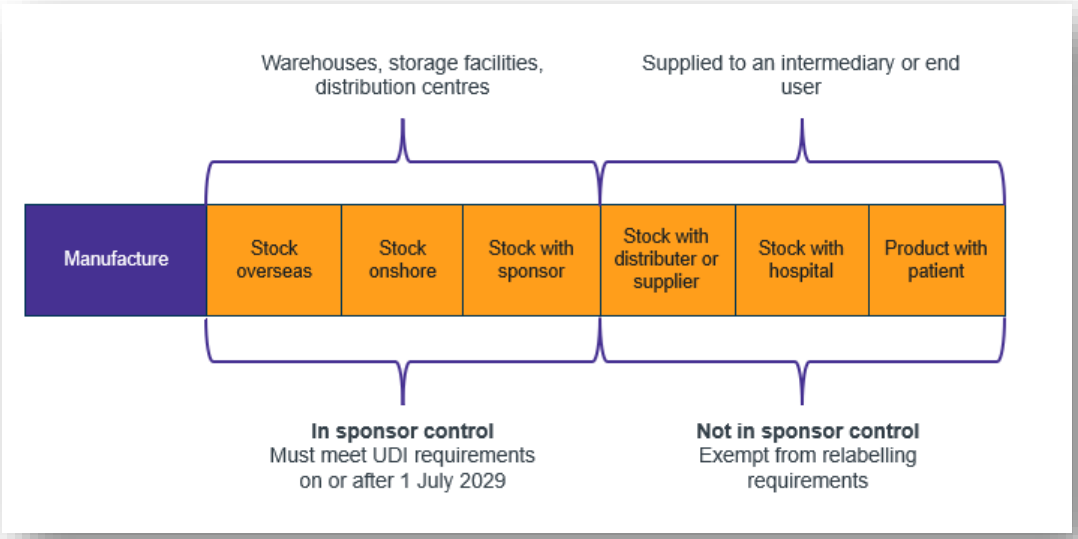
Determining whether a device is in sponsor control

The image below outlines typical points in the supply chain where a device may or may not be considered in sponsor control. These examples are not exhaustive, as supply processes can vary.

As a general principle, if a device has left the manufacturer and is awaiting distribution, or has been returned to the sponsor, it is considered in sponsor control.

Note that if a device is returned to the sponsor solely for repair (rather than redistribution, resupply or refurbishment), it is not considered in sponsor control.

Figure 6: Sponsor control diagram



Compliance implications

- In sponsor control:
  - Class III and IIb existing devices in these stages must meet UDI requirements by 1 July 2029
  - this includes relabelling with UDI-compliant labels and submitting UDI records to AusUDID if not already done.
- Not in sponsor control:
  - devices supplied to hospitals, distributors, suppliers, or patients that are not returned to sponsors control are exempt from UDI requirements for their lifetime
  - sponsors do not need to relabel or submit UDI records for these devices.

Geordie the sponsor

Geordie supplies Class III medical devices in Australia.

By 1 July 2026, his manufacturer labels newly manufactured devices with UDI compliant labels and Geordie has submitted UDI records to the AusUDID.

Geordie has 1,000 devices in his warehouse and 1,000 devices already supplied to a hospital.

If the 1,000 devices remain in his warehouse on 1 July 2029, Geordie must:

- relabel these devices with the UDI

	• submit UDI records to the AusUDID, if the data differs from previous submissions. The devices he supplied to the hospital are exempt for the lifetime of the device. All the devices that Geordie supplies that are manufactured after 1 July 2026 must meet UDI requirements.

	**Geordie the sponsor** Geordie also supplies Class Is medical devices in Australia. Only Class III and IIb existing devices must be relabelled if still in sponsor control on 1 July 2029. Because of this: • any of Geordie's Class Is devices manufactured and labelled prior to 1 July 2028 are exempt for the lifetime of the device. • all of Geordie's Class Is devices manufactured or labelled after 1 July 2028 must meet UDI requirements. Geordie can continue to supply both batches of devices until the existing devices are exhausted.

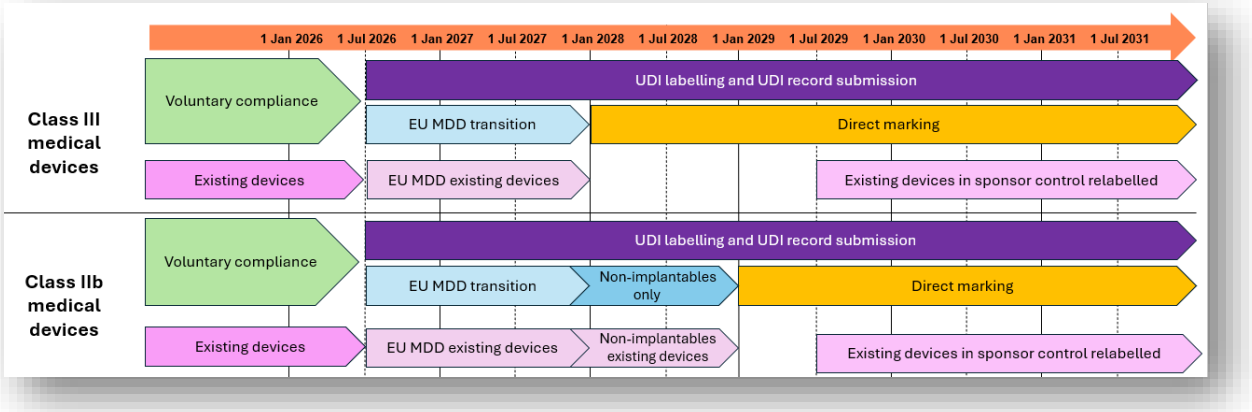
Relabelling at the end of the existing devices transitional arrangement

Where an existing device is in sponsor control:

- existing Class III and IIb devices must be relabelled by 1 July 2029
- existing Class Is, IIa, and all IVD devices are exempt from UDI requirements for the lifetime of the device, even if the device is in sponsor control on or after 1 July 2029.

The image below shows when existing Class III and IIb devices must be relabelled, if in sponsor control.

Figure 7: Existing devices relabelling timeline



When Class III and IIb medical devices are relabelled to become UDI compliant, a UDI record for these devices must also be submitted to the AusUDID, if not previously submitted.

If you relabel a device that is eligible for the existing device transitional arrangement and the relabelling is after the applicable UDI compliance start date passes, you must meet all the UDI requirements for this newly labelled device. This includes submitting UDI data to the AusUDID.

Relabelling your device after the UDI compliance start date does not impact the exemption from Direct Marking requirements. Your device remains exempt from Direct Marking requirements for the lifetime of the device.

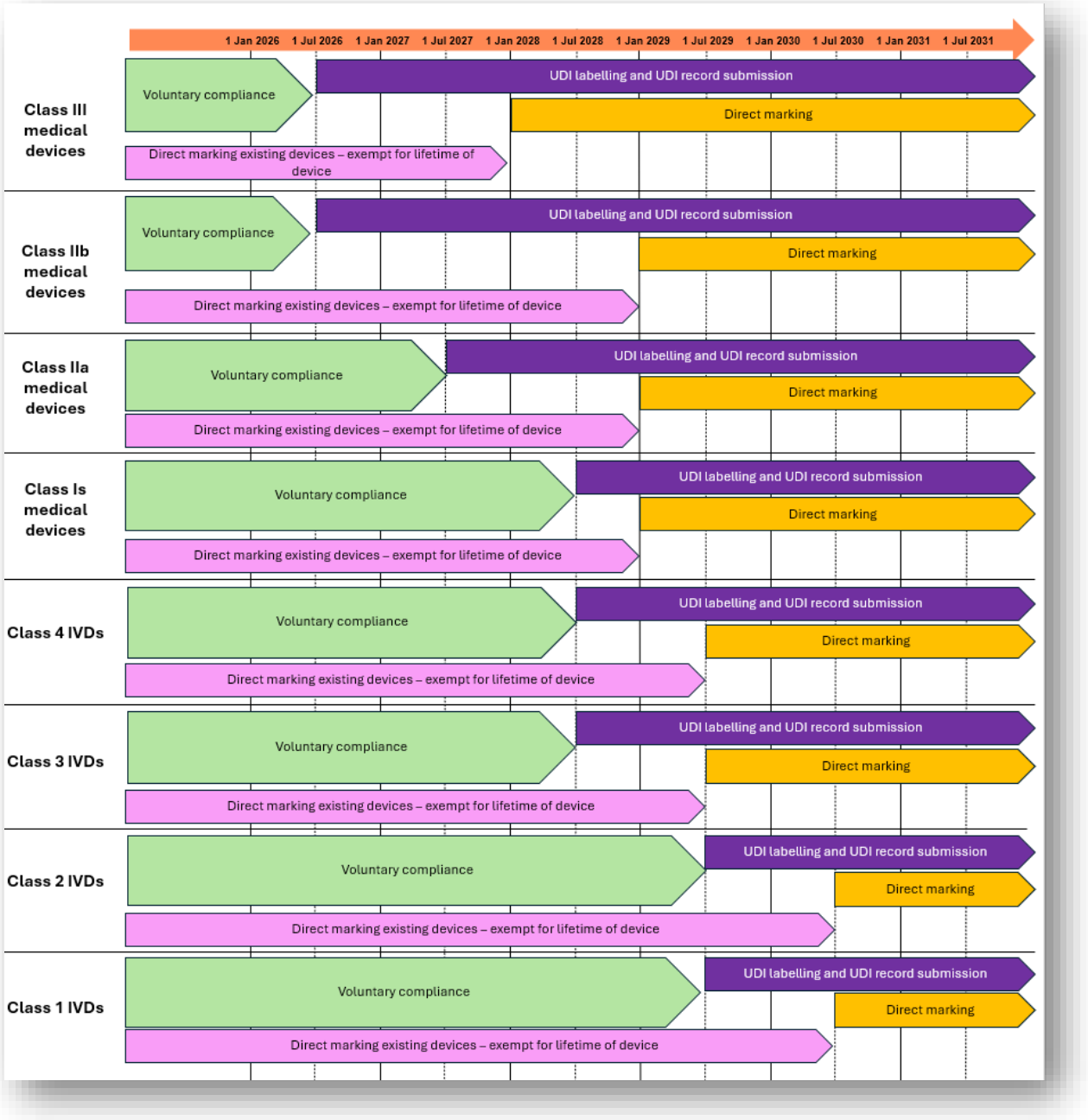
Direct marking at the end of the existing devices transitional arrangement

All existing devices are exempt from direct marking requirements for the lifetime of the device.

Due to the 2 UDI compliance milestones, some devices will only be considered ‘direct marking existing devices’ while still requiring UDI labelling and UDI record submission. These are the devices that are manufactured and labelled before the direct marking compliance date, but after the UDI labelling compliance date.

The image below illustrates when devices are considered direct marking existing devices.

Figure 8: Direct marking implementation timeline



Direct marking existing devices remain exempt from direct marking requirements for the lifetime of the device, regardless of:

- the device class
- whether it is in sponsor control or not
- whether it is relabelled or not.

Consignment stock

Consignment stock refers to an inventory model where the sponsor or manufacturer retains ownership of the stock until it is used or consumed by the end user, typically within a hospital, clinical or healthcare provider location.

Devices on consignment may be considered under sponsor control depending on how they are stored.

When devices on consignment are kept in hospital storage and can be accessed and used by hospital staff, with the hospital then being charged for use, these devices are considered **not** under sponsor control.

When devices are stored in a sponsor-controlled inventory location, such as a warehouse managed by the sponsor or their representative and not accessible to hospital staff, these devices **are considered** under sponsor control.

Relabelling consignment stock

When devices on consignment are returned to the sponsor because they were not used, they are considered **back under sponsor control**. General existing device requirements apply at this point.

If devices on consignment remain under sponsor control - for example, in a sponsor-controlled inventory store – the general existing device requirements also apply. It is the sponsor's responsibility to determine how best to relabel these devices at the end of the transition period. If the sponsor cannot relabel these devices, they will need to apply for Consent to Supply if they wish to continue supplying this batch of devices.

General existing devices requirements refers to:

- **Class III and Class IIb existing devices** must be relabelled by 1 July 2029 to meet UDI requirements
- **all other existing devices** remain exempt from relabelling for the lifetime of the device
- **all existing devices** remain exempt from direct marking requirements for the lifetime of the device.

Existing devices in Surgical Loan Kits (SLKs)

Existing Class IIa and Is devices that are returned in the SLK remain exempt from the UDI requirements. No existing devices are required to be directly marked; however, you may choose to do so.

If existing Class III or Class IIb devices remain in an SLK that is returned to the loan kit assembler or manufacturer, and that entity is **not** also the sponsor of those devices, these devices are **not** considered in sponsor control.

If existing Class III or Class IIb devices remain in an SLK that is returned to the SLK manufacturer or component manufacturer, **and that entity is also the sponsor of the devices in the SLK**, these devices are considered in sponsor control. Therefore, these devices must be relabelled to meet UDI requirements when in sponsor control or after 1 July 2029, and before the SLK is next supplied after 1 July 2029.

The devices in a SLK may be relabelled using alternative methods such as inventory sheets, stickers, or tags. Small non-sterile devices retain their reduced UDI requirements.

If a UDI record has not been submitted to the AusUDID for these devices previously, a UDI record for each UDI-DI must be submitted within 30 days of the device being relabelled.

For more information on UDI requirements for SLKs, see: Complying with the Unique Device Identification requirements for medical devices | Therapeutic Goods Administration (TGA).

Refurbished existing 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.

Refurbished devices are **not** considered existing devices, regardless of whether you were the original manufacturer.

Refurbishing a device originally manufactured by a different manufacturer

If you refurbish a device that was originally manufactured by different manufacturer, you are considered the manufacturer of the refurbished device. These devices are **not** considered existing devices and must meet UDI requirements at the relevant UDI compliance start date.

Angus the refurbisher

Angus refurbished a Class Is medical device that another manufacturer originally manufactured. 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. Since he did these activities, Angus became the manufacturer of the device.

His device is not considered an existing device. Standard UDI compliance start dates apply, and he must meet all applicable UDI requirements for his 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, 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, this is considered a new device. It is **not** considered an existing device. You must meet UDI requirements at the relevant UDI compliance start date, including obtaining and assigning a new UDI-DI for the refurbished 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. It is **not** considered an existing device. You must meet UDI requirements at the relevant UDI compliance start date, including obtaining and assigning a new UDI-DI for the refurbished device.

If you refurbish a device that you originally manufactured and this device does not yet have a UDI-DI allocated, you must meet UDI requirements by the UDI compliance start date. For example, if the device was not previously required to meet requirements, and the device then meets the scope of UDI requirements at the time of refurbishment, you must meet UDI requirements for this device. This includes meeting the Direct Marking requirements, if applicable. Refurbished devices are not exempt from Direct Marking.

Angus the refurbisher

Angus refurbished a Class Is medical device that he originally manufactured 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 retains the legal liability for the quality, safety and performance of the device. Since he did these activities, Angus remains the manufacturer of the device. This device did not change intended purpose and is considered the same model of device.

Angus refurbished these devices after 1 July 2028 so Angus must now meet UDI requirements, as this device is no longer considered an existing device. This includes Angus allocating and applying the UDI to the device.

As Angus is also the sponsor of the device, he must meet the obligations of a sponsor. These include submitting the UDI record to the AusUDID and linking the relevant ARTG to the UDI record within 30 days of supply of the device.

EU MDD and EU IVDD transitional arrangements

We provide transitional arrangements for devices that have an extension to their EU MDD or IVDD certificate.

These arrangements apply **only** to devices supplied in Australia that:

- are supplied under:
  - Council Directive 93/42/EEC of the Council of the European Communities, or
  - Directive 98/79/EC of the European Parliament and the Council of the European Union, and
- have an extended validity under EU transitional arrangements, and
- have not yet transitioned to UDI.

These arrangements do not apply to devices supplied under EU MDR, EU IVDR, or any other overseas regulator's conformity assessment certificate.

For the purposes of UDI, a device is considered to have transitioned to EU MDR or EU IVDR once all of the following occur:

- a Notified Body has issued an EU MDR or EU IVDR certificate, and
- the labelling and packaging is UDI compliant:

  - a UDI has been issued by a TGA recognised Issuing Agency
  - the labelling for the device and associated packaging includes a UDI Carrier on the labels, and
- the UDI-DI and associated device data has been provided to EUDAMED.

Once a device has transitioned, the transitional arrangements no longer applies and the device must comply with UDI requirements in Australia.

Devices supplied in Australia under an EU MDR or IVDR certificate must meet the Australian UDI compliance start dates.

Devices supplied in Australia under any other overseas regulator conformity assessment certificate must meet the standard UDI compliance start dates.

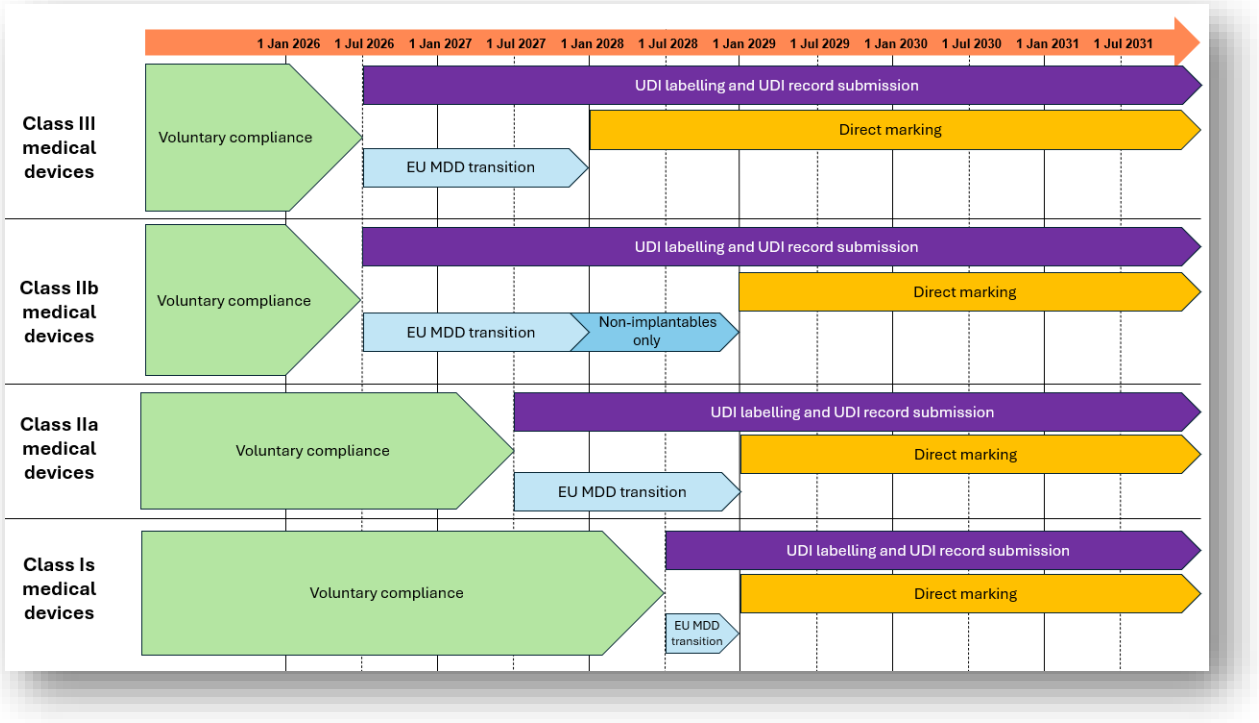
EU MDD to EU MDR transitional arrangement dates

The table below summarises the transitional dates for UDI compliance for devices you supply in Australia under a Council Directive 93/42/EEC of the Council of the European Communities certificate.

Requirement	Class III	Class IIb implantables	Class IIb non-implantables	Class IIa	Class Is
UDI labelling and UDI record submission	1 January 2028	1 January 2028	1 January 2029	1 January 2029	1 January 2029
Direct Marking and adding Direct Marking information to the UDI record	1 January 2028	Not applicable (Direct Marking is not required for implantables)	1 January 2029	1 January 2029	1 January 2029

The image below illustrates how transitional compliance dates align with the overall UDI implementation timeline.

Figure 9: EU MDD to EU MDR transitional timeline



Charlotte the sponsor

Charlotte supplies a Class III medical device in Europe. These devices are supplied in Europe under an MDD certificate.

Charlotte also supplies these devices in Australia under an MDD certificate. Charlotte's devices require transitional arrangements and are not UDI compliant.

Under UDI compliance start dates, Class III devices must be compliant by 1 July 2026. However, with the transitional dates for devices supplied under an EU MDD certificate, Charlotte has an extension until 1 January 2028 before being required to meet the UDI requirements.

Charlotte does not need Consent to Supply for her Class III devices during this time.

If Charlotte cannot meet UDI requirements by 1 January 2028, she must apply for Consent to Supply.

If her devices transition to MDR before 1 January 2028, Charlotte must meet UDI requirements in Australia from the time the device is MDR compliant.

Her devices are considered transitioned once:

- they have an EU MDR certificate
- they bear UDI-compliant labelling
- the UDI-DI and associated data has been submitted to EUDAMED.

	**Vivian the sponsor** Vivian supplies a Class III medical device in Australia under an MDR certificate. Under UDI compliance start dates, Class III devices must be compliant by 1 July 2026. Vivian's devices are not eligible for the EU MDD to EU MDR transitional arrangement, as they are EU MDR compliant and supplied in Australia under an EU MDR certificate. If Charlotte cannot meet UDI requirements in Australia by 1 July 2026, she must apply for Consent to Supply.

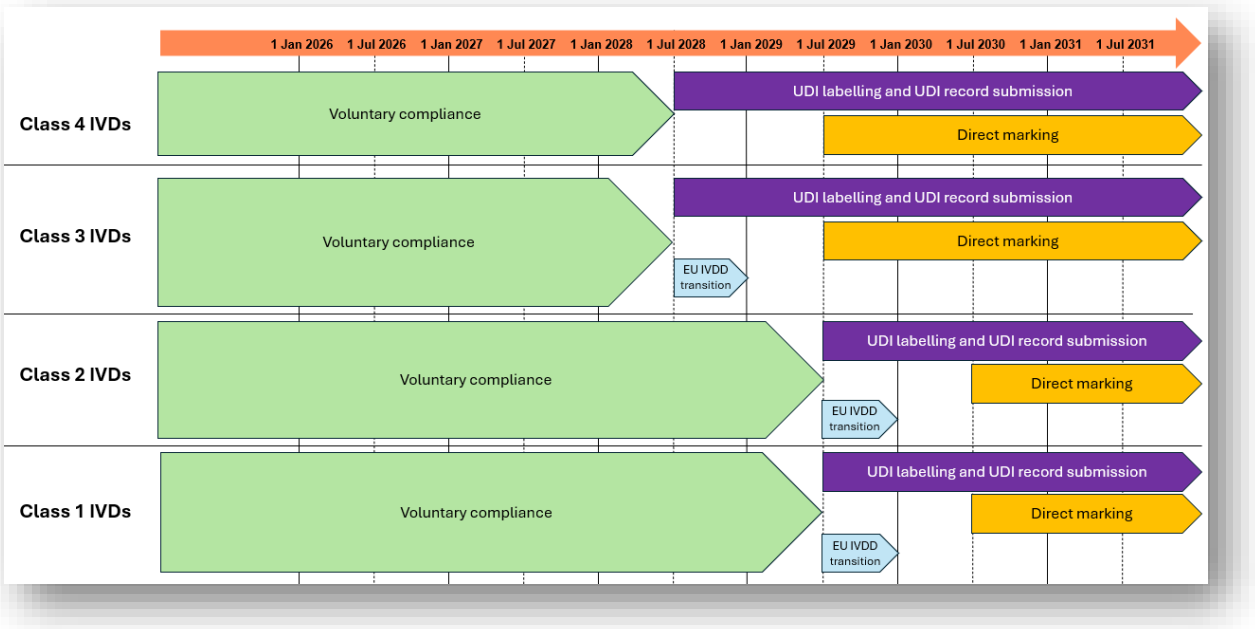
EU IVDD to EU IVDR transitional arrangement dates

The tables below summarise the transitional dates for UDI compliance for devices you supply in Australia under a Directive 98/79/EC of the European Parliament and the Council of the European Union certificate.

Requirement	Class 4	Class 3	Class 2	Class 1
UDI labelling and UDI record submission	1 July 2028	1 January 2029	1 January 2030	1 January 2030
Direct Marking and adding Direct Marking information to the UDI record	1 July 2029	1 January 2029	1 July 2030	1 July 2030

The image below illustrates how transitional compliance dates align with the overall UDI implementation timeline.

Figure 10: EU IVDD to EU IVDR transitional timeline



Devices transitioned before the end of transitional dates

The EU MDD to EU MDR and EU IVDD to EU IVDR transitional arrangements only apply while a device cannot reasonably meet UDI requirements in Australia due to EU MDD or EU IVDD extensions. These arrangements exist to reduce the administrative burden of managing EU transitions while implementing UDI across multiple jurisdictions.

These transitional arrangements only apply to devices that are:

- are supplied in Australia under:
    - *Council Directive 93/42/EEC of the Council of the European Communities, or*
    - *Directive 98/79/EC of the European Parliament and the Council of the European Union, and*
- cannot meet UDI requirements due to the EU MDD and EU IVDD extensions.

If a device becomes EU MDR or EU IVDR compliant before the transitional arrangement ends:

- the device must meet Australian UDI requirements, and
- the transitional arrangement no longer applies.

This applies even if the sponsor continues to supply the device in Australia under an EU MDD or EU IVDD certificate.

If your device has transitioned to EU MDR or EU IVDR but is not yet UDI compliant in Australia because your organisation's internal processes are still being updated and implemented, you must still meet UDI requirements in Australia. If you cannot meet these requirements, you must apply for Consent to Supply.

New applications under an EU MDD certificate

For new Applications for Inclusion that rely on an EU MDD certificate submitted after the certificate's expiry date, you must provide evidence that the manufacturer is eligible for extended validity under the EU MDR. This evidence will form part of the Application for Inclusion process.

Devices supplied under this new ARTG inclusion will be eligible for the EU MDD to EU MDR transitional arrangement.

Lucy the sponsor

Lucy supplies a Class IIa medical device in Europe. These devices are supplied in Europe under a MDD certificate and are 'legacy' devices. Because of this, Lucy has an extension until 31 December 2028 to meet UDI requirements for this Class IIa device in the EU.

Lucy applies to the TGA to supply these devices in Australia.

To minimise burden on sponsors and ensure quality data is provided to the AusUDID, the TGA will recognise the extension provided in the EU. For Lucy, this means her Class IIa legacy device has until 1 January 2029 to be UDI compliant in Australia.

When Lucy's device becomes MDR compliant, and Lucy supplies the MDR compliant devices in Australia, Lucy must meet Australian UDI requirements by the UDI compliance start date for MDR compliant devices. For Class IIa devices, this is 1 July 2027.

If Lucy's device is not UDI compliant by the UDI compliance start date, Lucy can apply for Consent to Supply.

Devices supplied under an EU MDR certificate

You must meet UDI requirements for any device supported by an EU MDR certificate from the standard UDI compliance start date for the device's risk class. This includes new and existing applications.

EU MDD to EU MDR transitional arrangements do not apply to devices supplied under an EU MDR certificate.

For more information on EU MDD to EU MDR transitions, see EU MDR transition extension | Therapeutic Goods Administration (TGA).

Hailey the sponsor

Hailey supplies a Class Is medical device in Europe and Australia. These devices are supplied in Europe and Australia under MDR certification. These devices do not require transitional arrangements and are UDI compliant.

As the devices are MDR compliant, Hailey must meet Australian UDI requirements for the Class Is devices by the Australian UDI compliance start date for MDR compliant Class Is devices, which is 1 July 2028.

This includes Hailey's devices requiring a UDI on the label and Hailey supplying the UDI and related data to the AusUDID.

Hailey may also choose to meet UDI requirements prior to 1 July 2028.

Devices supplied under another certificate

For devices supplied under any other comparable overseas regulatory approval, the devices must comply with UDI requirements according to the **standard UDI compliance dates** for their risk class. These dates apply regardless of the certificate type or jurisdiction.

This means that if your device is supported by an EU MDR certificate, a U.S. FDA certificate, or any other certificate, you must meet UDI obligations by the standard UDI compliance start date for your device class.

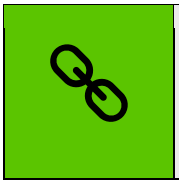
Transitional arrangements do not apply for any other certificate type.

Example: A Class IIa device supported by a U.S. FDA certificate must comply with UDI labelling and record submission by 1 July 2027, and direct marking by 1 January 2029. It is not eligible for transitional arrangements.

Consent to supply

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



For more information on consent to supply for UDI-related Essential Principles, please see: Unique Device Identification Consent to Supply process | Therapeutic Goods Administration (TGA).

Non-compliance

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

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

See the TGA website for compliance actions and outcomes.

Preparing for UDI compliance

We recommend that you begin preparing for UDI compliance early, especially if you manage large volumes of devices.

Preparing for UDI compliance can be complex. It may involve:

- establishing new internal processes for labelling, data management, and UDI record submission
- cleaning and validating existing device data to meet UDI requirements
- training staff and nominating subject matter experts to oversee compliance activities

- reviewing and updating contracts with manufacturers to ensure UDI responsibilities are clear.

Preparing for UDI and AusUDID checklist

We have developed the Preparing for UDI and AusUDID Checklist to help sponsors and manufacturers plan and implement UDI compliance by outlining key activities, responsibilities, and suggested timeframes.

Key activities include:

- **Understand UDI requirements** for your device type and when they apply.
- **Agree responsibilities** and define responsibilities of the manufacturer and sponsor in meeting Australian UDI requirements.
- **Define standard operating procedures** and create internal procedures for assigning, managing and maintaining UDIs and related data.
- **Organise and validate your data** to ensure your UDI records are accurate, complete, and aligned with Australian regulatory requirements.
- **Test your UDI record submissions** to validate your data, systems and processes for submitting UDI records in the AusUDID Pre-Production environment.
- **Submit and maintain your UDI records** in the AusUDID Production environment.

Resources

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

UDI Hub

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

UDI requirements resources

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

UDI record submission resources

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

UDI Support Team

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

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

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

Contact us at UDI@health.gov.au.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Device Reforms Taskforce	March 2025
V2.0	Updated to: • clarify existing devices • clarify EU MDD to EU MDR and EU IVDD to EU IVDR • added additional timeline graphics • added information on consignment stock • clarified definition of sponsor control • added compliance date summary • added information on existing devices in Surgical Loan Kits (SLKs)	Device Reforms Taskforce	May 2026

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Reference/Publication #