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

UDI Roadshow 2025

Questions and answers

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Contents

Introduction

To support the official launch of the Unique Device Identification (UDI) regulatory framework and the amendments to the *Therapeutic Goods (Medical Devices) Regulations 2002*, the Therapeutic Goods Administration (TGA) hosted 2 workshops: in Sydney on September 30, 2025, and Melbourne on October 9, 2025. These sessions were designed to assist medical device sponsors in understanding the UDI requirements and preparing for compliance.

Purpose of this document

During the workshops, participants submitted questions through an online Q&A platform. Many were addressed during the sessions, while others were noted for follow-up.

This document provides responses to all questions submitted during both UDI Roadshow workshops, including those addressed during the live sessions.

Content in this document is correct at the time of publication. It will not be updated. Current information can always be found on the UDI Hub.

Contact information

For further enquiries, please contact the UDI Support Team at UDI@health.gov.au.

Identifiers

Obtaining a UDI

Do we contact GS1 to get a UDI?

It is the manufacturer's responsibility to determine which Issuing Agency best suits their operational and commercial needs. The TGA recognises 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

Multiple UDI-DIs for the same device

Is it possible that a device has multiple UDIs for the same product because they are made in different countries, and can we add those to the AusUDID?

A model of device may have multiple UDI-DIs depending on factors such as country of manufacture or supply chain differences in packaging and language variations in labelling or instructions for use.

Where a model of device has multiple UDI-DIs, you may add all these UDI-DIs to the AusUDID. To help manage your data management workload, we recommend you submit only the UDI-DIs that are applicable for Australia, however, the AusUDID will support you recording all the UDI-DIs.

Can a manufacturer choose to allocate multiple UDI-DIs for the same device based on differences in label information (like different language)?

Yes. A manufacturer may choose to assign multiple UDI-DIs to the same device if there are differences in label content, such as language variations. We anticipate these differences may arise due to different jurisdictional requirements for devices or UDI-DI allocation and supply chain management rules of the Issuing Agency.

Sponsor and manufacturer responsibilities

Data submission

Who has the final responsibility to enter and update UDI records in the AusUDID?

Sponsors are legally responsible for ensuring the accuracy and completeness of UDI records submitted to the AusUDID. While sponsors may choose to delegate data entry to a manufacturer, agent or third party data provider, they retain accountability for the data submitted.

Does the sponsor always have to be the one to publish UDI records to the AusUDID? Can the publishing step be delegated to another user to maintain data, such as an agent or a third party data provider?

While sponsors may choose to delegate data entry, including publishing of a UDI record, to a manufacturer, an agent or a third party data provider some data entry restrictions will apply depending on the user's role and the data submission method. Sponsors always retain accountability for the data submitted and are legally responsible for ensuring the accuracy and completeness of UDI records.

For more information on using the AusUDID, please visit the UDI Hub.

Are UDI records required for distributors?

The responsibility to submit UDI records lies with the sponsor. However, distributors must ensure that devices they supply are compliant with Australian medical device regulations.

If I am a sponsor and my manufacturer is in the US, do they submit and keep the data updated, or do I?

The AusUDID will support both a manufacturer and a sponsor submitting the AusUDID data, noting some limitations do apply depending on the privileges assigned to the manufacturer and the data submission method used. For example, a manufacturer cannot change a sponsor's ARTG that is linked to a UDI record. The legal responsibility for submitting and maintaining those UDI records always remains with the sponsor. Sponsors must ensure that all data entered into the AusUDID is accurate, complete, and compliant with regulatory requirements, regardless of who performs the submission.

For more information on using the AusUDID, please visit the UDI Hub.

Agreements and procedures

Is there any UDI-relevant requirement that is recommended by TGA to be added to the sponsor agreement?

The TGA does not have any specific UDI-related clauses for sponsor agreements. We advise sponsors to work directly with their manufacturers and update their commercial agreements to ensure responsibilities for meeting UDI requirements are clear.

Sponsors may wish to have their agreement with a manufacturer consider the following responsibilities (noting this information is indicative only and the sponsor is fully responsible for determining the scope and terms of all agreements with their manufacturers):

- The manufacturer's approach to obtaining and assigning UDI-DIs and the inclusion of the UDI on device labels and packaging
- Assignment of direct marking identifiers and placement on devices, if applicable
- The manufacturer's approach for including the production information in the UDI-PI
- Creating the UDI data required for Australia and the approach and timeline for keeping the UDI data up to date, including notifying the sponsor when new UDI-DIs are created for devices supplied in Australia
- The division of responsibilities and approach for the manufacturer and/or sponsor submitting data to the AusUDID
- The division of responsibilities and approach for the manufacturer and sponsor when responding to TGA reporting such as market actions and device incident reporting
- The manufacturer's approach for advising the sponsor of changes to UDI-DI that arise from other jurisdictions
- The manufacturer including information supporting their UDI related decisions in their quality management system
- Updating the sponsor on any issues that impact the sponsor's ability to meet the TGA's UDI requirements and supporting device identification in Australia.

If an agreement between manufacturer and sponsor states that the manufacturer will provide correct UDI information and keep it updated (signed by manufacturer), would this be sufficient for the sponsor?

The sponsor must make this determination. While manufacturers can submit and maintain UDI records, the legal responsibility remains with the sponsor. Sponsors must ensure that all UDI records submitted to the AusUDID are accurate and kept up to date.

What kind of internal procedures do you expect sponsors or manufacturers to establish for Australian UDI implementation?

Sponsors and manufacturers should establish internal procedures that support consistent and compliant UDI implementation. These should include:

- UDI allocation procedures to ensure correct assignment of UDI-DIs and UDI-PIs
- Effective change procedures to ensure data in the sponsor's and manufacturer's product information system / ERP and the AusUDID are aligned and up to date, and new UDI-DIs are appropriately assigned in UDI Trigger scenarios
- Practices and responsibilities for UDI record submission and data maintenance for timely and accurate updates to the AusUDID
- UDI recording on device incident reports and market action notices such as recalls and corrections.

To assist with this, we have developed the *Preparing for UDI and AusUDID Checklist*. This checklist outlines key steps and considerations.

Please note that internal procedures are the responsibility of the sponsor and related stakeholders. Each organisation is responsible for designing and implementing its own processes.

UDI allocation

If the UDI-DI is obtained by the sponsor instead of the US or EU legal manufacturer, does the legal manufacturer need to include UDI-DI in their technical file?

Obtaining the UDI from the Issuing Agency is an element in the manufacturing process and consequently the responsibility of the manufacturer. A sponsor could do this on behalf of the manufacturer, although we recommend the manufacturer obtains the UDI-DI, as this step is best integrated into the manufacturing process. If the sponsor obtains the UDI-DI on the manufacturer's behalf, the manufacturer should include it in all the relevant manufacturer documentation.

How does TGA expect sponsors to control supply from overseas manufacturers/distribution centres if the product is already registered and approved (e.g. already UDI-labelled but not yet implemented in Australia)?

Sponsors remain legally responsible for ensuring that all devices supplied in Australia meet the Essential Principles, which include the UDI requirements. This is regardless of where the product is manufactured or labelled. If a device is already UDI-labelled for another jurisdiction (e.g. US or EU), the sponsor must confirm that:

- The UDI Carrier format is appropriate for the Australian market and expected use
- The UDI-DI has been issued by one of 3 TGA recognised Issuing Agencies
- The UDI-DI and related data are submitted to the AusUDID in accordance with Australian requirements
- The device complies with all relevant Essential Principles.

Sponsors will work with manufacturers to manage UDI labelling and data submission, but sponsors retain full responsibility for compliance. This includes verifying that the manufacturer has met their obligations, and that the device is only supplied in Australia when the UDI requirements are fulfilled.

Is it mandatory for sponsors to track the complete UDI-PI or will tracking batch number, expiry and other details meet the requirements?

The Medical Device Regulations do not require the Sponsor to track the UDI-PI. Sponsors may wish to track the complete UDI-PI as part their product and distribution management practices, especially when responding to enquiries from healthcare organisations or TGA market actions.

Identifier allocation rules

Does a new lot number of a product require a new UDI?

No, provided the UDI-DI for the model of device has not changed. The UDI-PI is dynamic and changes in the production specific information such as the lot or batch number, expiry date or manufacturing date are reflected in the UDI-PI.

If the model of device remains unchanged, the UDI-DI will remain the same. As the UDI-PI is not recorded in the AusUDID, in this scenario there is no requirement to update the AusUDID.

Is it possible to have the same UDI for 2 device models (SOPP) that are in separate ARTGs?

It is possible for 2 SOPPs to include the same component or device model that shares the same UDI. Each SOPP will also have its own UDI-DI. A single SOPP can be linked to more than one ARTG inclusion, however, if the components of the SOPPs are different, they will have different UDI-DIs.

Unit of Use

Is the Unit of Use DI the UDI that is assigned on the primary package?

No. 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 DI is to associate the use of a device with a patient when the 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.

For more information, see Complying with the Unique Device Identification requirements for medical devices.

UDI labelling

Human Readable Interpretation (HRI) and Automatic Identification Data Capture (AIDC)

What is the difference between non-HRI, AIDC and other machine readable Carriers?

Human Readable Interpretation (HRI) refers to the legible text version of the data encoded in the UDI Carrier. It is typically printed next to or below the AIDC form and includes all relevant identifiers in a format that humans can read.

Non-HRI refers to plain text that is human-readable but does not follow the structured format of HRI. It may lack data delimiters or application identifiers.

Automatic Identification Data Capture (AIDC) includes all machine readable forms used to encode UDI data. This covers technology such as:

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

Is there a priority for the UDI marking components, for example, barcode versus human readable?

If significant constraints prevent the use of both AIDC and HRI on the label, the AIDC form is preferred. AIDC supports automated data capture and is critical for supply chain and clinical workflows.

However, in certain environments such as home care or low tech settings, HRI may be more appropriate to ensure usability.

Manufacturers are responsible for assessing whether constraints justify omitting one format. These decisions should be recorded as the TGA may review these decisions to ensure compliance with labelling requirements.

Is there a requirement for the UDI-PI to be in machine-readable form if the UDI-DI is submitted as machine readable to the AusUDID?

Data submitted to the AusUDID does not include a machine-readable version of the UDI-DI.

The **full UDI**, including both the UDI-DI and the UDI-PI, must be presented in both HRI and AIDC formats on the label or the device, unless otherwise exempt or significant space limitations prevent the use of both.

Labelling requirements are independent of the data submission.

If you want to use a GS1 DataMatrix, do you also need to use serialisation as well?

TGO 106 requires a GS1 data matrix encoding the GTIN, batch, expiry and serial number to be present on the pack. Further information about medicine serialisation is available here: Understanding serialisation and data matrix codes on medicines | Therapeutic Goods Administration (TGA).

However, the data matrix for the medicine component is separate to the UDI, as the UDI relates specifically to the device whereas the medicine serialisation relates specifically to the medicine. You cannot have a single serialisation to represent both, as the GTIN for the medical device should be different to the GTIN for the medicine, and the 2 products will have different expiry dates, serial numbers or other production identifiers.

If this device currently includes medicine serialisation, we recommend you use the ISO UDI symbol to clearly distinguish the UDI data matrix.

Barcodes and QR codes

How does the sponsor confirm that the barcode works? If it is incorrect or faulty, will we need to recall the product because the barcode is not legible?

Sponsors and manufacturers are responsible for ensuring barcode quality and readability. To confirm that a barcode works, we recommend using barcode verification tools to test both digital and physical samples. You should liaise with your chosen Issuing Agency to see if this is a service they offer.

If a barcode is unreadable or compromises device traceability, a market action may be required. Depending on the severity and risk, this could include a product alert, correction or recall.

Do we need to use a specific barcode scanner to be able to read barcodes from a specific Issuing Agency?

Most modern barcode scanners can read barcodes issued by any TGA recognised Issuing Agencies. However, scanners may need to be configured to correctly interpret the data structures used by different Issuing Agencies. This includes recognising application identifiers and parsing the encoded UDI-DI and UDI-PI.

Can packaging include a second QR code that takes a consumer to the products website?

You may include a QR code on packaging that directs consumers to the product's website. To avoid confusion, especially for end users such as consumers, you should clearly label each QR code to indicate its purpose.

Recommended labelling includes:

- Using the UDI graphical symbol defined in ISO 15223-1 (Symbol 5.7.10, 2021) to identify the UDI
- Labelling the second QR code as 'Website' or 'Product information' to distinguish it from the UDI.

Space constraints

Are there any exceptions for base packages that are too small? For those, are we allowed to not include the UDI on the base package but still generate a UDI and enter it into the AusUDID?

Yes. If there are space constraints that prevent placing the UDI on the base package, you may apply the UDI to the next higher level of packaging.

Manufacturers are responsible for assessing whether space constraints justify omitting the UDI from the base package. The TGA may review these decisions to ensure compliance with labelling requirements.

Other labelling obligations

Is sponsor labelling still required? When UDI is rolled out, will the requirement for sponsor label on the device become redundant? Does this UDI requirement override the need to show compliance to regulation 10.2?

UDI requirements are **in addition to**, and do not replace, any existing labelling obligations including those under regulation 10.2, which outlines general labelling requirements. The labelling obligations under the *Therapeutic Goods Act 1989* or the *Therapeutic Goods (Medical Devices) Regulations 2002*, including information about the sponsor on the label is still required.

Packaging

Can you provide more clarification around UDI-PI for supply packages?

The UDI-PI contains any production specific information that applies to the production run of the device being supplied. This can include the batch, lot, manufacturing date or expiry date associated with the production of the device. It can also include specific information pertaining to a specific device such as serial number or software version.

The UDI-PI must be included on every packaging level, except logistics units or shipping levels. This ensures traceability throughout the supply chain.

Certain requirements can apply to some data in the UDI-PI. For detailed information, refer to the UDI-PI section in the UDI Guidance for more information: Complying with the Unique Device Identification requirements for medical devices | Therapeutic Goods Administration (TGA).

Your selected Issuing Agency can also provide specific instructions on correctly applying UDI-PIs to device packaging, including guidance on formatting, placement, and the use of data delimiters or application identifiers.

If there are multiple individually packaged devices within the box, are they the base packaging?

It depends on whether the individual devices are the same model of device or not.

If each device in the box is the same model of device, individually packaged and able to bear a UDI Carrier, then each individual unit can be the base package.

However, if an individual device cannot accommodate a UDI Carrier – due to being unpackaged, unlabelled, having space constraints, or the packaging type – then the next higher level packaging is considered the base package.

If the devices are not the same model, it may be considered a SOPP or a kit, in which case other requirements apply.

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

Can you explain the different levels of packaging requiring a UDI Carrier?

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

Packaging levels above the base package can be referred to as ‘Secondary’ and ‘Tertiary’ packages. Secondary packages contain a set number of base packages. Tertiary packages contain a set number of secondary packages. Additional packaging levels are any above tertiary.

The UDI-DI on the base package is the Primary DI in the AusUDID.

Each higher level of packaging above the base package must also bear a UDI, unless it is exempt. The UDI-DI on each higher level of packaging is called the Package DI. The Package DI is different to the UDI-DI and each Package DI must be recorded in the AusUDID, which will enable identification of the device using package information. This will support healthcare organisations manage market actions (such as recalls) and easily identify the packages containing impacted devices without having to open every package to verify what is inside.

Logistics units or shipping containers do not require a UDI as they are created for inventory control and logistics purposes such as supporting picking, packing, shipping and receiving a device; not for sale to the end user. Examples include: a shipped carton containing multiple sale units, a caddy of devices supplied to a hospital, a pallet with multiple cartons shrink-wrapped together.

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

What happens when the UDI is on a pack of multiple items that is split apart by a hospital distribution centre?

When a hospital distribution centre splits a pack of devices, the hospital becomes responsible for ensuring that device traceability is maintained throughout distribution.

Sponsors and manufacturers are not responsible for the downstream repackaging or redistribution activities. However, they should consider their packaging and labelling to support traceability if such splitting is likely to occur.

If we supply a primary packaged device in a carton with an ancillary component, do we need to have UDI-DIs for both primary and secondary packaged individually?

This information is provided on the basis that the individual items and the co-packed item are single use devices.

The requirements for the device will vary depending on how the carton is supplied and used.

Carton sold as a co-packaged kit

If the ancillary component and the primary device are packaged together into a carton and the carton is supplied commercially, the carton is a co-packaged device / kit and must have its own a UDI-DI. The UDI-DI on the carton must be different to the UDI-DI of the primary packaged item.

If the ancillary component in the carton is only supplied in the carton, it does not require its own UDI-DI. If, in addition to being in the carton, the ancillary item is supplied as a separate product, it must have a UDI-DI when supplied separately.

Individual devices in the carton do not require a UDI-DI on the label or packaging when they are co-packaged in the carton. If the manufacturer prefers to include the UDI-DI on the label or packaging of the individual items in the carton, that is permitted.

Carton is a logistics unit

If the carton is simply used to facilitate packing, shipping or receiving of the devices (e.g. the carton is a shipper or logistics unit) and is not supplied commercially, each individual device in the carton must meet the UDI-DI requirements. In this scenario, the carton does not require a UDI-DI.

Private labelling

Can a sponsor make use of their own UDI especially for private labelled products as agreed with the Manufacturer?

The responsibility for meeting the UDI allocation and labelling requirements always lie with the manufacturer, including own brand or private labelled medical devices.

The sponsor can attach a UDI-DI Carrier to their privately labelled devices, however, this must be on behalf of the manufacturer. Responsibility for obtaining the UDI and including on the labelling remains with the manufacturer. If the sponsor is relabelling the product, they will be considered the manufacturer of the device, and all the manufacturer's regulatory responsibilities will apply.

Direct marking

Exemptions

For single use or consumable products which are small in size, does each product require the UDI to be direct marked on each product, or can it be supplied on the outer or retail carton only?

UDI Direct Marking requirements do not apply for single-use devices. Direct Marking requirements only apply to reusable devices.

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

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

Space limitations

We manufacture reusable hearing aid products. For the Direct Marking requirements, it would be infeasible to include the UDI on hearing aids due to limited space. Do we need to directly mark these devices?

We allow exemptions from Direct Marking where it is not technically feasible or where marking would interfere with the safety or performance of the device.

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

The manufacturer may be required to give their reasoning for not meeting the direct marking requirements, when requested by the TGA.

Configurable devices

Is direct marking required on single components for devices that are comprised of multiple detachable parts?

No. Direct marking is not required on every individual component. However, you should apply the UDI Carrier to the part that is least likely to get exchanged during the lifetime of the device.

Manufacturers are responsible for assessing which component is most appropriate for direct marking. The TGA may review these decisions to confirm the direct marking practices support traceability and meet regulatory requirements.

Direct marking DI submission

What is meant by supplying a Direct Marking DI to the AusUDID?

If your device is subject to the Direct Marking requirements, you must enter a valid Direct Marking UDI into the *Direct Marked DI* data field in the AusUDID, with the *Primary DI* of this AusUDID record matching the Primary UDI-DI of the device.

As we are introducing UDI compliance in phases, you can create the AusUDID record first and enter the Direct Marking UDI-DI once the Direct Marking compliance date is reached.

Requirements for specific device types

Clinical trial devices and investigational devices

Does UDI apply to medical devices included in clinical trials?

No. UDI requirements do not apply to medical devices included in clinical trials.

Does UDI apply to investigational medical devices?

No. UDI requirements do not apply to investigational medical devices.

Although medical devices supplied under the CTN scheme are exempt from UDI, do you anticipate that sponsors will comply with the requirements as part of pivotal studies to support TGA submissions?

Although medical devices supplied under the CTN scheme are exempt from UDI requirements, manufacturers and sponsors may choose to have a UDI assigned to the device and realise the benefits that the UDI provides in relation to device identification and tracking.

Please note that while the data for these devices could be entered into the AusUDID. as they do not have an ARTG Inclusion, the device(s) cannot be linked to an ARTG, and they will not be visible to any other AusUDID user other than sponsors.

Reclassified devices

For products subject to reclassification reforms, will a new UDI-DI be required after the reclassification?

If a device is reclassified and it moves from being out of scope of the UDI requirements to being in scope of UDI requirements, it must comply with UDI requirements once it is reclassified. For example, if a Class I device is reclassified to Class IIa, it must meet UDI requirements once included in the ARTG as a Class IIa device.

If the device already has a UDI-DI assigned, the UDI-DI does not need to change when the device is reclassified. You may need to link the UDI record to a new or different ARTG Inclusion, if a new ARTG Inclusion is created by the reclassification.

If a device will be up classified in the future under the reclassification reform with the deadline of 2029, does the current classification apply for the UDI compliance timelines?

Yes. The current classification of the device determines the applicable UDI compliance timeframes.

If the current classification means the device must meet UDI requirements and the device will be reclassified to risk class where the UDI requirements do not apply (for example being reclassified as an exempt device), the device must meet the UDI requirements from the compliance date of the current classification. You may apply for Consent to Supply, to cover the period from when the device must meet the UDI requirements through to when the device is reclassified and UDI will not apply.

If a device is currently out of scope of UDI, you do not need to meet UDI requirements until it is reclassified and included in the ARTG with a risk class that is in scope of UDI.

If the device is up-classified before the UDI compliance date of its current classification, you must meet the UDI requirements of the new device classification from the date the device is up-classified.

Class I medical devices

Do reusable Class I medical devices that are sterilised after each procedure need to meet UDI Direct Marking requirements?

Class I non-sterile non-measuring medical devices are exempt from UDI requirements. This includes being exempt from direct marking.

You may choose to meet the UDI requirements for these devices; however, this is optional. If you do add data for these devices to the AusUDID, the TGA asks that you keep this data up to date.

Do Class I medical devices sold across retailers, distributors, and direct to hospitals, and the product is classed as capital equipment need to meet UDI requirements?

Class I non-sterile non-measuring medical devices are exempt from UDI requirements, regardless of where they are supplied or the type of equipment. You may choose to meet the UDI requirements for these devices; however, this is optional. If you do add data for these devices to the AusUDID, the TGA asks that you keep this data up to date.

The TGA notes that hospitals and healthcare organisations are seeking to implement a single scheme for procuring and managing all medical devices they use and therefore may request a UDI-DI be provided for Class I non-sterile non-measuring medical devices.

Do Class I medical devices sold in healthcare settings need meet UDI requirements?

Class I non-sterile non-measuring medical devices are exempt from UDI requirements, regardless of where they are supplied. You may choose to meet the UDI requirements for these devices; however, this is optional. If you do add data for these devices to the AusUDID, the TGA asks that you keep this data up to date.

The TGA notes that hospitals and healthcare organisations are seeking to implement a single scheme for procuring and managing all medical devices they use and therefore may request a UDI-DI be provided for Class I non-sterile non-measuring medical devices.

For Class I devices that are shared with the European Union, if these devices are supplied in Australia and have the UDI on the packaging due to EU requirements, does a UDI record need to be submitted to the AusUDID?

No. Class I non-sterile non-measuring medical devices are exempt from Australian UDI requirements.

However, if these devices carry a UDI on the packaging due to EU requirements, we support submitting a UDI record to the AusUDID to help reduce confusion for end users such as consumers and healthcare professionals. This is optional, however, if you do add data for these devices to the AusUDID, the TGA asks that you keep this data up to date.

The TGA notes that hospitals and healthcare organisations are seeking to implement a single scheme for procuring and managing all medical devices they use and therefore may request a UDI-DI be provided for Class I non-sterile non-measuring medical devices.

Do Class I reusable surgical instruments need to meet UDI requirements, including direct marking?

Class I non-sterile non-measuring medical devices are exempt from UDI requirements, regardless of whether they are reusable or not.

You may choose to meet the UDI requirements for these devices; however, this is optional. If you do add data for these devices to the AusUDID, the TGA asks that you keep this data up to date.

The TGA notes that hospitals and healthcare organisations are seeking to implement a single scheme for procuring and managing all medical devices they use and therefore may request a UDI-DI be provided for Class I non-sterile non-measuring medical devices.

Please note that Class Is (supplied sterile) devices are in scope of UDI requirements.

Do Class I medical devices that require a prescription from a general practitioner need to meet UDI requirements?

Class I non-sterile non-measuring medical devices are exempt from UDI requirements, regardless of whether they are prescription devices or not.

You may choose to meet the UDI requirements for these devices; however, this is optional. If you do add data for these devices to the AusUDID, the TGA asks that you keep this data up to date.

The TGA notes that hospitals and healthcare organisations are seeking to implement a single scheme for procuring and managing all medical devices they use and therefore may request a UDI-DI be provided for Class I non-sterile non-measuring medical devices.

Retail devices

Could you give us an example of a machine readable UDI Carrier other than AIDC for devices principally sold in retail?

All machine-readable formats fall under the definition of Automatic Identification and Data Capture (AIDC).

For devices principally sold in retail settings, retail-friendly UDI Carriers may include:

- Linear barcodes commonly used in retail environments
- 2D DataMatrix or QR code for compact packaging
- RFID tags, though less common in retail, are also acceptable.

Devices principally sold in retail require the UDI-DI to be encoded in the device's barcode; the UDI-PI does not need to be present in the AIDC for these devices.

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

Are medical devices that are principally supplied to retail exempt from UDI requirements? If a small portion are supplied directly to hospitals, are these still considered exempt?

Medical devices principally sold in retail premises are **not** exempt from UDI requirements; they are eligible for **reduced** labelling.

What responsibilities, if any, will retailers have regarding UDI compliance? Is there a way to verify the accuracy of the data submitted by sponsors?

Retailers are not responsible for UDI compliance.

The TGA will work with the Issuing Agencies and retailers to check the quality of the UDI data. Retailers can also search the AusUDID using the UDI-DI to compare the information in the UDI record against the information they have for the device.

Surgical loan kits (SLKs)

How can UDI requirements be met for Surgical Loan Kits (SLKs)? For example, implantable devices within the loan kit that do not have individual packaging?

Guidance on meeting UDI requirements for SLKs is available here: Complying with the Unique Device Identification requirements for medical devices | Therapeutic Goods Administration (TGA).

UDI requirements have also been incorporated into the SLK guidance, available here: Manufacturing and supplying surgical loan kits to Australian hospitals | Therapeutic Goods Administration (TGA).

Regarding the proposed amendments for Surgical Loan Kits, will you define 'small' for implantable devices or that will be determined by the SLK manufacturer?

The TGA does not prescribe a definition of 'small' but allows flexibility for manufacturers to assess whether components of an SLK are too small to bear a UDI.

Manufacturers must record details of this as this may be reviewed during audits and other regulatory activities.

Existing devices

Will the TGA expect relabelling of existing stock once the UDI system becomes mandatory, or will previously labelled products be allowed to deplete under grandfathering provisions?

Class III and IIb devices manufactured and labelled before 1 July 2026 are considered existing devices. If they remain under sponsor control on or after 1 July 2029, these devices must be relabelled to meet UDI requirements.

Devices in all other device classes manufactured and labelled before their respective UDI compliance dates are exempt from UDI requirements for the lifetime of the device.

Additionally, all devices that must be direct marked and are manufactured and labelled before their direct marking compliance date, are exempt from Direct Marking requirements for their lifetime.

For more information, see Complying with the Unique Device Identification timeframes for medical devices.

What is the purpose of relabelling instead of having the cut-off date based on the date of manufacture?

Accurate identification and tracking of high risk Class III and IIb medical devices is a key driver of the Australian government's decision to implement UDI in Australia. Class III and IIb medical devices still under sponsor control on or after 1 July 2029 will help realise the government's goals.

In the context of existing devices, what if the device goes back to sponsor control after a PMS action such as product defect correction? Does this need to meet UDI requirements?

If the device has been supplied before the mandatory compliance date it does not need to meet the UDI labelling requirements. This includes if the device is returned to the sponsor to repairs. However, if the device is refurbished, remanufactured or resupplied, then the device is to be relabelled.

Can stock in hospital consignment be considered as stock under sponsor's control or will it be considered as supplied stock?

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.

Are devices supplied on loan and held by a hospital still considered in sponsor control?

See above.

Samples

What do you mean by 'samples' in the context of UDI?

When a medical device is a supplied as a sample, other medical regulatory requirements apply before the UDI requirements. Whether the sample requires a UDI will depend on whether the sample is made available to members of the public or to healthcare professionals.

A sponsor must not offer a sample unless:

- the goods are included in Annexure 2 of the Code and the conditions for the item (if any) are met
- the goods do not contain substances included in Schedule 2, 3, 4 or 8 of the Poison Standard
- the goods can be lawfully advertised to the public.

For more information see What can and cannot be advertised to the general public.

If the goods are included in the ARTG, the sample must only be supplied in the approved container or packaging as entered in the ARTG (for example, do not remove foil sachets from their box). In addition, the sample must be compliant with all other aspects of the Code.

However, under section 42AA of the Therapeutic Goods Act 1989, samples offered by healthcare professionals to their patients during a consultation or course of treatment do not have to comply with these requirements.

Therefore, where the sample is made available to members of the public, it will require a UDI on the device or its base packaging as it must only be supplied in the approved container or packaging as entered in the ARTG. Where the sample is made available to healthcare professionals, as the device can be supplied without its base packaging, it will not require a UDI. Medicines

Will the TGA be looking to implement a similar system for medicines?

This is outside the scope of the UDI Project.

Capital equipment

Is there a definition of capital equipment?

The Medical Device Regulations do not define capital equipment. Typically, industry has referred to capital equipment as large, durable medical devices that are used repeatedly over time. For example, items such as MRI machines or CT scanners.

This classification is more aligned with operational perspectives than with specific regulatory terminology. For regulatory purposes, such equipment is still assessed under the general definition of a medical device in the *Therapeutic Goods Act 1989*.

Export only devices

Is a UDI record required if a product is supplied outside of Australia by an Australian sponsor?

Export only products are exempt from Australian UDI requirements, including being exempt from requiring data in the AusUDID. A sponsor or manufacturer can optionally add data in the AusUDID, however, it will not be available to external users unless the record is linked to an ARTG inclusion.

System or procedure packs

How are procedure packs impacted by the changes?

UDI requirements apply to a procedure packs the same way they apply to other medical devices.

For additional information, see Complying with the Unique Device Identification timeframes for medical devices.

For a component in a SOPP, a UDI is not required if its 'not intended for individual use outside the SOPP'. Does this intention need to be formalised somewhere to meet criteria?

Sponsors should record this within their internal quality management systems.

Software as a Medical Device (SaMD)

The UDI regulations require UDI to be in machine-readable form. How does this work for software when it is supplied non-physically?

When SaMD is supplied non-physically, you only need to provide the HRI portion of the UDI in the electronic display. The AIDC form is not required in electronic displays.

If your SaMD does not have a user interface, it must be capable of transmitting the UDI through an Application Programming Interface (API) or similar method.

What are the acceptable production identifiers for software apart from software version?

In addition to software version, acceptable production identifiers for SaMD may include:

- lot number
- serial number
- manufacturing date.

We are a SaMD sponsor. Can you provide examples of how the regulations will apply to a Class IIa device?

UDI requirements apply to a Class IIa SaMD medical device the same way they apply to other medical devices.

For additional details, see Complying with the Unique Device Identification requirements for medical devices.

UDI triggers for software changes

How will the TGA classify software updates for Software as a Medical Device (SaMD) such as security patches, minor user interface changes or new algorithms/claims regarding UDI Triggers?

You must assign a new UDI-DI to your device if your SaMD changes due to a 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 add the new UDI-DI and related information to the AusUDID.

If your SaMD changes due to minor SaMD revisions, you assign a new UDI-PI (a new UDI-DI is not required). These changes can include but not be 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.

Minor changes to software do not need to be recorded in the AusUDID.

We recommend that you record changes and how changes are communicated to users of the SaMD in your QMS.

Software version

Does the TGA only require for major versions to be included on the AusUDID?

Major software versions require a new UDI-DI. Minor revisions do not require a new UDI-DI and do not need to be recorded in the AusUDID.

Do we have to include the software version number in the AusUDID? If so, multiple software version numbers may come under one UDI-DI – does the TGA expect sponsors to list all?

You are not required to list each software version number in the AusUDID. The software version is treated as a production identifier, which is not required in the UDI record.

Only major version changes that result in a new UDI-DI must be recorded in the AusUDID.

Firmware and software definitions

Does the software definition include firmware?

If a device contains firmware, or the software is in the medical device, the UDI requirements are essentially the same as software as a medical device.

That is, major changes to the firmware require the device to be issued with a new UDI-DI. A complex or significant change will affect:

- the original performance and effectiveness

- the safety or intended use of the device.

Firmware changes that will require a new UDI-DI include, but are not limited to:

- new or modified algorithms
- extended features and functions
- operating platform
- new channels for interoperability.

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

International alignment

Is there any alignment between TGA and Medsafe to use the AusUDID for New Zealand?

There is no formal alignment between the TGA and Medsafe to use the AusUDID for New Zealand.

Can I send a product compliant with Australian UDI requirements to Europe without any changes?

A product that complies with Australian UDI requirements may also meet European requirements.

It is the sponsor's responsibility to ensure the device complies with the specific regulatory requirements of the jurisdiction it is being supplied into. The TGA notes that the EU's UDI requirements are part of the EU's Medical Device Regulations or IVD Regulations, which places additional requirements on manufacturers.

From a global perspective, how will the TGA and the AusUDID capture the same device with different brand names, considering that some manufacturers have different brand names and product specifications by market?

Sponsors must submit UDI records to the AusUDID for devices in scope of UDI requirements that they supply in Australia. This includes ensuring the brand name listed reflects the device as supplied locally.

As all international UDI systems categorise Brand Name is a UDI Trigger field, the same model of device supplied under different brand names will have a different UDI-DI for each Branch Name.

What are the different exceptions? What types of products are excepted in the EU and US but not Australia?

It is not within the scope of the Australian UDI Project to provide direction on exceptions in other jurisdictions.

Sponsors are responsible for understanding and complying with the specific requirements and exemptions in each market where their devices are supplied.

Other UDI systems have a risk-based approach for implementation. Is TGA considering this approach in Australia to link UDI with PMS annual reports for example?

Australia's UDI requirements are part of the Medical Device Regulations. Any future considerations to the Medical Device Regulations may impact UDI requirements.

UDI triggers

Is the change in indication a trigger?

Typically, a change in an indication is a change in the clinical characteristics of the device, which often requires a change to the device data in the UDI database. If this change in indication affects a UDI Trigger Data Element, then a new UDI-DI will need to be issued, and a new record added to the AusUDID. If the data change does not impact a UDI Trigger Data Element, a new UDI-DI is not required.

Changes to the following attributes of a medical device will require a new UDI-DI to be issued for the device and be entered into the AusUDID:

- Brand name
- Device version or model, including software version (major SaMD revisions)
- Quantity of devices provided in a package (Device count)
- Labelled as single use
- Critical warnings or contraindications:
  - Contains latex
  - Contains DEHP
  - MRI safety status
- Packaged sterile
- Need for sterilisation before use
- Clinical size (including Volume, Length, Gauge, Diameter)
- A reduction in the recommended number of reuses

In cases where the change is not a UDI Trigger, other regulatory actions, such as an ARTG variation or change, may still be required.

Even if the data change is not a UDI Trigger, if the manufacturer wishes to record the change in device data as a separate entry in the UDI databased, they are able to do so with a new UDI-DI for the device.

Are all of the UDI Trigger data elements for Australia covered under European Union (EU) and United States (US) UDI Trigger data elements? Are there any that are specific to Australia?

Generally, all Australian UDI Trigger data elements align with the EU and US systems.

The exception to this is the Australian UDI Trigger data element ‘Restricted number of reuses.’ This data element aligns closely with the EU data element ‘Maximum number of reuses’; however, they are not perfectly aligned. The US does not have this data element.

You should note that the EU and US have UDI Trigger Data Elements that are not reflected in Australian requirements. Where a UDI-DI changes for a device based on a UDI Trigger in another jurisdiction, and this device is supplied in Australia with the new UDI-DI, it will require a new UDI record in the AusUDID.

When a UDI record is updated in the AusUDID due to a change in the UDI Trigger data, does that UDI record need to be relinked to its ARTG inclusion?

If the update changes a UDI Trigger Data Element (e.g. a change in the device’s brand name or clinical characteristics) and the data is not being corrected, a new UDI-DI must be allocated, and a new UDI record must be created in the AusUDID. In this case, the ARTG ID must be linked to this new UDI record. To help uses create new records in these circumstances, the AusUDID provides the ability for users to copy a new UDI record, which includes copying the related ARTG inclusions.

If the change is a correction due to a data entry error (e.g. typing mistake when originally entered), the change can be submitted as a 'Correction'. This will not require a new UDI-DI, a new UDI record, or relinking to the ARTG.

In these circumstances, the original UDI record for the previous version of the device remains unchanged and stays in the AusUDID.

If a device is impacted by an EU UDI Trigger but not by an Australian UDI Trigger, does that mean in the EU it results in a new UDI and does that require us to update the AusUDID with the updated EU UDI?

If the new EU UDI-DI is on the label of any devices supplied into Australia, you must add the new UDI-DI into the AusUDID and link it to the applicable ARTG inclusion.

If changes need to be made to UDI Trigger data elements, will the TGA ask sponsor to input the date the change occurred?

The AusUDID automatically records the date that the new record was entered into the database and user responsible for the change. This information will be saved in the AusUDID audit trail and can be viewed in the device's history.

Is there alignment between the UDI Triggers and medical device change management processes? For example, do non-substantial not require a new UDI, and significant changes do?

The UDI Trigger rules specify a new UDI-DI must be created when device changes can vary a medical device's safety and/or performance, lead to misidentification of the medical device and/or create ambiguity in its traceability. In essence, these requirements relate to substantial changes to a device.

The current UDI Trigger rules stipulate that changes to key attributes of a medical device require a new UDI-DI to be issued for the device and this UDI-DI is entered into the AusUDID. These fields are:

- Brand name
- Device version or model, including software version (major SaMD revisions)
- Quantity of devices provided in a package (Device count)
- Labelled as single use
- Critical warnings or contraindications:
  - Contains latex
  - Contains DEHP
  - MRI safety status
- Packaged sterile
- Need for sterilisation before use
- Clinical size (including Volume, Length, Gauge, Diameter)
- A reduction in the recommended number of reuses.

Does the TGA have suggestions on how to ensure manufacturers notify sponsors of changes to their devices that are UDI Trigger fields?

The TGA expects sponsors to be aware of any changes to the devices they supply in Australia, including changes to UDI-DIs for the device. At a minimum, manufacturers should notify sponsors if

their device labelling changes. The TGA anticipates this will be communicated via existing communication methods between the sponsor and the manufacturer.

Implementation and compliance timeframes

Australian vs international timelines

Is the TGA aware of the new delay for mandatory implementation of the UDI module in EUDAMED to November 2026? If so, are there plans to allow for a new extension on implementation timelines in Australia?

The TGA is aware of the delay to mandatory use of the UDI module in EUDAMED. The TGA has no current plans to extend the UDI compliance timelines.

Why is UDI implementation in Australia much later than other jurisdictions?

Each jurisdiction started their UDI implementation at different stages, and many jurisdictions are still to finalise their UDI implementations.

Australia's implementation reflects a deliberate, phased approach designed to give medical device manufacturers and sponsors adequate time to prepare and align with international systems and requirements, where possible. This timeline was informed by extensive consultation, during which industry highlighted administrative burden would result from an earlier rollout.

EU MDR

Post July 2026, when submitting a new application for a Class IIb product supplied using clause 7.5 but subcomponents are EU MDD – what would be the implementation for that scenario?

If the device is newly included in the ARTG after 1 July 2026, and falls within the Class IIb category, it must comply with Australia's UDI requirements, regardless of whether subcomponents are certified under the EU MDD.

If the subcomponents are unchanged and already compliant under MDD, they may be referenced in technical documentation, but the final assembled device must meet Australian UDI requirements.

If the device is following the MDR transition period, does it still need to be relabelled if under our control at July 2026?

If a Class III and IIb device is MDR compliant (i.e. has a UDI-DI assigned and on the device label and the device data is in EUDAMED) it must be UDI compliant from 1 July 2026. If a Class III and IIb device is transitioning from EU MDD to MDR, the device has until 1 January 2028 to be UDI compliant.

Patient implant cards

Why does the TGA require a barcode on Patient Implant Cards (PICs) when the US FDA does not? This adds global burden for devices aligned with USFDA UDI rules.

The TGA conducted extensive consultation during the development of Australia's UDI requirements, including whether to include UDI on Patient Implant Cards (PICs). Stakeholder feedback strongly supported alignment with the European Union, which requires inclusion of the UDI in AIDC format on PICs. As a result, the TGA adopted the EU approach. This is also consistent with the TGA's alignment with the EU's medical device regulatory framework.

As the UDI-PI is assigned per production run, how do we add this to an electronic version of the PIC available on a company website?

The amendments made on 29 October 2021 to the *Therapeutic Goods (Medical Devices) Regulations 2002* allow patient information materials for implantable and active implantable devices to be supplied in more flexible (principally electronic) formats if they **contain all required information and are made available in a way that is readily accessible by the patient concerned**.

Since the batch code, lot number, or serial number are already mandatory, sponsors must ensure these details are included, regardless of UDI requirements. If the electronic PIC cannot reliably present the UDI-PI, sponsors should consider supplying physical PICs to meet compliance.

Does the full UDI need to be on the PIC, or just the UDI-DI?

The full UDI must be included on the PIC in AIDC format. Only the UDI-DI is required in HRI format.

Additionally, it is an existing requirement that PICs include the batch code, lot number, or serial number.

Australian UDI Database (AusUDID)

AusUDID access

Will TGA provide a separate account for manufacturers or third parties if they want to maintain data on behalf of the sponsor?

Accounts to access TGA systems such as AusUDID are managed through the TGA Business Services (TBS) portal and the AusUDID access is governed by the access options in the TBS.

Manufacturers for devices listed on ARTG inclusions will have a basic TBS entry for their organisation. If a manufacturer wishes to access the AusUDID, in addition to their basic organisation entry, they must also have a TBS user account that is linked to their organisation entry. To request a user account, manufacturers should contact the TBS Helpdesk at ebs@health.gov.au.

Third party data providers cannot have a TBS organisation nor a user account and are unable to access the AusUDID with their own account.

If your manufacturer is overseas and you are the sponsor, do they have access to AusUDID?

Overseas manufacturers can access the AusUDID in the same way as local manufacturers. To do so, the manufacturer must have a user account linked to their organisation in TBS. To request a user account, manufacturers should contact the TBS Helpdesk at ebs@health.gov.au.

How do manufacturers get access to the AusUDID Pre-Production environment?

Once a manufacturer has a TBS user account linked to their organisation, they can access both the AusUDID Production and Pre-Production environments by following the steps outlined in this guide: Logging into the AusUDID Pre-Production and Production environments.

How many sponsor accesses can one sponsor have to manage UDI records in the AusUDID?

There is no limit to how many users can be created within a Sponsor TBS account. Users are maintained within the TBS Portal by the TBS Organisation Administrator, which is usually an administrator in the user organisation. Each user is required to have their own login credentials.

Could we have information on the 'key' that sponsors can provide to manufacturers so that manufacturers can submit UDI records to the AusUDID?

The AusUDID has different access methods and user privileges.

For access via the online portal, there is no key assigned; access is controlled solely by the privileges assigned to the user and their organisation, which are in TBS.

In this situation, a manufacturer can obtain their own organisation account and create individual users. The AusUDID will limit what functions these users can perform and the data they can update. For example, a user from a manufacturer cannot link a UDI record to an ARTG inclusion and make the UDI data publicly available; this is restricted to users from the sponsor organisation.

Sponsors can choose to give manufacturers access to their organisation account and extend the manufacturer user's privileges by creating a user account under the sponsor's organisation in TBS. In this arrangement:

- The sponsor's Administrator creates the user account for the manufacturer
- This allows the manufacturer to submit UDI records on behalf of the sponsor using the sponsor organisation's TBS account.

The most appropriate arrangement should be determined by the sponsor and manufacturer, based on their commercial relationship. It is important to note that if a sponsor assigns external users' full privileges to their AusUDID record, this access is also extended to other TBS services including the ARTG. Sponsors should consider what access they would like the manufacturer to access.

User privileges are managed differently when data is managed via the machine to HL7 SPL machine data interface. This method does require a "key" to be generated and assigned to the users. As access via the HI7 SPL requires more technical knowledge, more detailed information can be found here: Machine to Machine (M2M) HL7 SPL | Therapeutic Goods Administration (TGA).

For users who maintain data for a sponsor, can a user be linked to or edit data for multiple sponsors?

The TGA Business Services (TBS) allows for a user to be assigned an Agent role that allows them to maintain data for multiple organisations. An Agent user can only access and edit data for the sponsor or manufacturer organisations they are formally linked to via their TBS account and can only log into one account at a time. The AusUDID allows for Agent users to easily switch organisations.

AusUDID functionality

Will scanning the UDI Carrier on the label open the UDI record in the AusUDID?

The AusUDID does not currently support direct access via barcode scanning of a UDI Carrier.

To view a UDI record, users should enter the UDI-DI from the HRI component on the label or search the database using the brand name, UDI-DI, ARTG ID or other relevant keywords.

Can you scan UDIs directly into the AusUDID?

You cannot scan UDIs directly into the AusUDID. The UDI record must be submitted using one of the 4 available submission methods.

The AusUDID does not currently support direct access of the data via barcode scanning of a UDI Carrier. To view a UDI record, users should enter the UDI-DI from the HRI component on the label or search the database using the brand name, UDI-DI, ARTG ID or other relevant keywords.

Can a second sponsor duplicate an existing UDI record? As the UDI-DI may be the same except for some fields such as the ARTG and sponsor.

To ensure integrity in the UDI data, the AusUDID does not permit more than one record with the same UDI-DI to be in the database.

Where more than one sponsor supplies the same device with the same UDI-DI and that UDI-DI is already in the AusUDID, they add their own sponsor-specific details such as ARTG ID and Catalogue number to the existing UDI record and this will associate the device with their inclusion(s).

Is there any existing ability or will there be future ability to extract data out of the TGA Business Services (TBS) portal? Such as all Manufacturer IDs, all ARTG IDs and their associated linked manufacturer evidences?

Currently, there is no bulk export function for all Manufacturer IDs or ARTG IDs with linked evidence.

Sponsors who require specific data sets or exports can submit a request directly to the TGA.

The TGA has noted this feedback and may consider enhanced data access features in future system updates.

When adding manufacturer details to AusUDID records via the online portal, the AusUDID provides users with the ability to search for the organisation via a name search.

Integration

Will the AusUDID be integrated with GS1 or will it be its own portal?

The AusUDID is a standalone system administered by the TGA. Sponsors have the ability to create and update UDI records with data sent from via GS1's National Product Catalogue (NPC), if they wish to use the NPC as their source system.

Other UDI databases

We already have UDI in EU/US. Do we still need to submit UDI records to the AusUDID? And is there a streamlined process if we have UDI elsewhere?

The AusUDID is a standalone system administered by the TGA and is separate to the UDI systems in the EU and US.

While the TGA has strived to simplify the data submission for organisations that have UDI data in other jurisdictions' UDI databases, with aligned data elements and rules, different regulatory environments and rules for each jurisdiction means separate databases. If your device has a UDI in the EU or US and has submitted data to other UDI databases, you must still submit a UDI record in the AusUDID for all in scope devices supplied in Australia.

If we have manufacturers in other countries, can we use their published data to meet UDI requirements for Australia?

The TGA has strived to have the Australian UDI data aligned with the EU and US UDI data and you may be able to use UDI data used for compliance with EU MDR or USFDA requirements. However, it's important to note that:

- Some data elements and definitions differ between jurisdictions
- You must ensure the data is accurate, complete, and aligned with the specific requirements of the Australian UDI framework
- The UDI-DI must be issued by a TGA recognised Issuing Agency (GS1, HIBCC, or ICCBBA)
- The UDI record must be linked to the relevant ARTG inclusion(s).

Sponsors are responsible for verifying that the data reflects the actual device supplied in Australia and meets all AusUDID submission requirements.

Is there a mechanism in EUDAMED that flags the corresponding entry in Australia?

EUDAMED and the AusUDID are not linked. Each system operates independently, and there is no automatic cross-referencing between entries.

Data quality

How will the TGA ensure that poor data entry does not make the AusUDID irrelevant? If multiple sponsors submit differing data, it could erode trust in the system.

The TGA will conduct reviews of UDI records submitted to the AusUDID and integrate UDI into existing audit processes.

When multiple sponsors submit data for the same device, we recommend that each sponsor use the manufacturer's data to ensure consistency and alignment with the manufacturer's quality management system.

Additional capabilities are being considered for the AusUDID to identify and manage data for devices with more than one sponsor.

Who maintains the AusUDID, and how do you ensure that the information stored there is secure and trustworthy?

The data in the AusUDID is the responsibility of the sponsor. While the TGA maintains the database, sponsors and manufacturers are responsible for ensuring the accuracy of the data they submit.

The AusUDID is managed in line with the Australian Government Data Governance Framework, which promotes secure, accurate and accountable data handling.

The TGA will conduct reviews of UDI records submitted to the AusUDID and integrate UDI into existing audit processes. In addition, the TGA is also investigating methods for validation of the device data with other stakeholders such as hospitals, healthcare organisations and other government agencies.

Pre-Production

How long will the AusUDID Pre-Production environment be accessible?

The AusUDID Pre-Production environment will remain indefinitely to support ongoing testing and training activities.

Does AusUDID Pre-Production connect to AusUDID Production? Can you approve data sets to push through from AusUDID Pre-Production to AusUDID Production, or do you need to duplicate the loads?

Apart from sharing user accounts and linking to Production ARTG inclusions, the AusUDID Production and Pre-Production environments are separate. UDI data submitted to AusUDID Pre-Production cannot be transferred to Production.

The AusUDID Pre-Production environment is intended solely for testing and training, meaning data entered in there can be test data. Any data submitted there is not considered as part of UDI compliance.

To be compliant with UDI requirements, your UDI records must be published in AusUDID Production.

Change history and UDI record management

Is the AusUDID able to manage changes in UDI to maintain the entire history of the device?

The AusUDID maintains a version history of UDI records, allowing users to view changes over time.

Is there any template and procedure or guidance to help sponsors maintain the UDI data?

While we are developing support materials to assist users with using the AusUDID, we don't currently provide templates or procedures for maintaining UDI data. Because data maintenance practices vary across organisations, we recommend that sponsors establish internal procedures tailored to their own systems and workflows.

Is the UDI record change history public information?

The AusUDID allows all users to view the history of changes made to UDI records over time.

Australian UDI bulk upload template

Can the UDI be linked with the ARTG automatically through the *Australian UDI Bulk Upload Template* or through Machine to Machine (M2M)?

Both the *Australian UDI Bulk Upload Template* and the 2 M2M methods (HL7 SPL and NPC submission) support linking ARTG IDs to UDI records.

The *Australian UDI Bulk Upload Template* states that you can add supporting information such as Patient Information Leaflets (PILs) and Instructions for Use (IFUs). If the UDI is only required on PICs, do we need to include all the supporting documents?

You are not required to submit PILs or IFUs to the AusUDID. This is optional additional data that you may choose to provide.

Is TGA planning on increasing the number of UDI records that can be submitted per spreadsheet using the *Australian UDI Bulk Upload Template?*

At this time, the TGA is not planning to increase the number of UDI records that can be submitted per template. This limitation is in place due to system performance constraints when processing data sets over 200 records.

Is it possible that the *Australian UDI Bulk Upload Template* will be updated to allow it to be used to update UDI records in future?

This functionality is not currently supported, but future updates are under consideration and may include the ability to update existing UDI records.

When information in the existing UDI records is being changed, can I use the bulk upload approach to update multiple records at the same time?

The bulk upload does not currently support the updating of existing UDI records. Future updates are under consideration and may include this.

Can you only publish one record at a time, or can you do more than one?

You do not have to publish one UDI record at a time. You can publish multiple UDI records simultaneously the *Australian UDI Bulk Upload Template* or the Machine to Machine submission methods.

Will there be an API or bulk upload option for sponsors managing a large portfolio of devices?

Sponsors managing a large portfolio of devices have the following AusUDID submission methods to choose from:

- Australian UDI Bulk Upload Template
- Machine-to-Machine via HL7 SPL
- Machine-to-Machine via National method, both of which support bulk data uploads.

For more information, see The Australian UDI Database for sponsors and manufacturers | Therapeutic Goods Administration (TGA).

After submitting the bulk upload template, do you then have to publish each UDI individually manually? Or is there a way to publish multiple UDI records from draft?

All UDI records submitted using the *Australian UDI Bulk Upload Template* are immediately published. These are not submitted as drafts, and you do not need to individually manually submit each UDI record after submitting the template.

After bulk uploading, the data becomes live. If an error is identified, is there a way to edit just one entry?

You can edit single UDI records via the AusUDID portal.

Machine to machine HL7 SPL

Does TGA maintain a list of suppliers who are UDI compliant?

The TGA does not maintain or publish a list of UDI-compliant suppliers. The Australian Government does not endorse or promote specific commercial entities. It is the responsibility of sponsors to ensure that any third party data providers they engage can meet UDI requirements.

Do you have an update on when the Machine to Machine submission method will be available?

The Machine-to-Machine (M2M) HL7 SPL submission method is available for use in the AusUDID Pre-Production environment. Pre-Production is used to test submissions and validate data before data can be submitted to the Production environment.

If a third party or manufacturer submits UDI records to the AusUDID via M2M for a portion of the sponsors entries, will they have access to change or upload any of that sponsor's UDI records, or is it restricted to a subset?

When a sponsor grants access to a third party or manufacturer, they provide the ability to add and update all their UDI records via the M2M methods.

If the manufacturer has loaded the data by M2M, how does the record appear for the sponsor to add the ARTG? Can it be done by bulk upload?

All UDI records published by manufacturers are visible to sponsors once they are logged into the AusUDID. Sponsors can link their ARTG ID to these UDI records in one of 2 ways:

- Manually, by selecting and linking each UDI record individually
- In bulk, using the *Australian UDI Bulk ARTG to UDI Link template*.
- Using a HL7 SPL submission with the sponsor's data (noting this method must also include the manufacturer data that was previously submitted).

Data submission and timing

How did the TGA select the 30 day timeframe for updating the AusUDID?

The TGA selected the 30-day timeframe for updating the AusUDID based industry consultation, including consultation papers, position statements, and technical working groups.

This timeframe reflects a balance between regulatory oversight and operational feasibility. It ensures sponsors have sufficient time to submit or update UDI records after a device is next supplied in Australia, while maintaining timely and accurate data in the AusUDID.

What records does the sponsor need to keep showing the UDI record has been linked within 30 days of first supply?

To demonstrate compliance with the requirement to submit a UDI record within 30 days of first supply in Australia, sponsors should retain internal records that show:

- The date the device was first supplied into Australia after the UDI compliance date

- The date the UDI record was created
- The ARTG ID linkage date, if done separately from the initial submission.

These records may include system logs, submission confirmations, internal tracking spreadsheets, or correspondence with third party data providers or agents.

When does the 30 day period to update a UDI record – when the changed product is first supplied or when notified by the overseas manufacturer?

The 30 day period to update or create a UDI record when there is a change to the data, starts when the product is first supplied in Australia.

However, we recommend updating the UDI record (or submitting a new one, if the change affects a UDI Trigger Data Element) as soon as possible after becoming aware of the change.

If there are 100 variants under the ARTG inclusion but only 10 are actually being supplied in Australia currently, do the remaining 90 variants need to be in the AusUDID?

Only the variants being supplied in Australia require UDI records in the AusUDID. Variants not supplied do not need to be entered into the AusUDID. If they are supplied to the Australian market at a later date, they will need to be added to the AusUDID at that time.

Could you please clarify the requirement for existing ARTG inclusions and the need for UDI records to be provided when the device is next supplied?

For existing ARTG inclusions, sponsors must submit UDI records within 30 days of the device being supplied in Australia after the relevant UDI compliance date. This requirement applies even if the device was included in the ARTG before the UDI regulations came into effect.

Example:
Sponsor A holds ARTG inclusion 12345 for a Class III medical device. If they next supply the device on 1 July 2026, they must submit the UDI record by 31 July 2026. If the first supply occurs later, for example on 1 July 2027, the UDI record must be submitted by 31 July 2027.

Is the 30 days requirement applicable after importing into the country or 30 days after commencement of supply?

The 30 day requirement applies from the date the device is **first supplied** in Australia, not the date of import. In this context, ‘supply’ refers to making the device available for use, sale or distribution.

What is considered point of supply if the sponsor is not the importer and distributor? The sponsor may be a consulting agency not involved in distribution. When would the data need to be submitted?

If the sponsor is not the importer or distributor, for example, a consulting agency, the point of supply is still defined as the moment the device is made available for use, sale, or distribution in Australia. The 30-day requirement for submitting the UDI record begins from that point of supply.

Even if the sponsor is not directly involved in logistics or distribution, they remain responsible for ensuring the UDI record is submitted within 30 days of the device being supplied in Australia. Sponsors should work closely with their supply chain partners to track supply dates and meet this obligation.

Does the commercial end date need to be updated by the sponsor within 30 days?

Yes. UDI records must be kept accurate and up to date. If the commercial distribution end date information changes, it must be updated within 30 days.

Why not incentivise sponsors to submit UDI records early?

The TGA selected the 30-day timeframe for updating the AusUDID based on extensive industry feedback, and the timeframe reflects a balance between regulatory oversight and operational feasibility. It ensures sponsors have sufficient time to submit or update UDI records after a device is next supplied in Australia, while maintaining timely and accurate data in the AusUDID.

While the TGA encourages sponsors to submit their information ahead of deadlines, it remains the sponsor's responsibility to meet their regulatory obligations.

Data elements

Does the UDI record need to be updated for each new batch number?

Production information such as batch or lot number is not stored in the AusUDID.

The AusUDID captures which types of production identifier appear on the label, such as batch number or serial number, but specific batch information is not submitted to AusUDID.

To what extent should we specify the storage and handling requirements in the UDI record? Are we allowed to include only storage information that appears on the label?

You may choose to include only the storage and handling information that appears on the label. However, we recommend providing as much detail as possible to enhance the value of the UDI record for users and encourage other storage and handling information to be entered if it is in the IFU.

Could you please clarify what is expected to be entered for brand? Can the brand name be the name of a kit configuration?

For the brand name, enter the name that identifies the device as it is marketed. This is typically the name recognised by users and healthcare professionals. The brand name may be the name of or reflect a kit configuration, especially if the kit is supplied under a distinct name that appears on the label.

The TGA encourages detailed information about the device and its configuration to also be added to the Device description field.

Can you please clarify the data element 'Model or version'? The model of a device will not change by the version may change more frequently. The manufacturer is most likely to use the model (less change).

For the model, enter the specific model or version number that distinguishes the device from others under the same brand or manufacturer.

What happens if between the time of applying for an ARTG and the UDI entry, the GMDN is made obsolete, and the manufacturer provides a different one associated with the UDI?

The AusUDID will display the GMDN that appears on the ARTG inclusion, regardless of whether the GMDN is active or obsolete.

If the manufacturer provides an additional GMDN, this can be provided in the field 'GMDN (Manufacturer).' This is only visible to the sponsor and the TGA.

Character limits

Are there character limits in the fields within the AusUDID?

Many fields in the AusUDID have defined character limits, these are specified in the *Australian UDI Data Dictionary*.

Can you extend the Device Description character limit in the AusUDID?

The device description field currently supports 2000 characters. The TGA can consider extending this field length in future updates to the AusUDID.

Grace period and corrections functionality

Can you clarify how the correction functionality works to update an incorrect data entry after the Grace Period ends? Will this create a new UDI record?

The Grace Period allows users to edit all fields of a UDI record except for Manufacturer ID and Primary UDI-DI for a set period after the UDI record is first submitted. Currently, this Grace Period is 30 days, however, this is subject to change.

After the Grace Period ends, only non-UDI Trigger data elements can be updated. If you change a UDI Trigger data element, the system will prompt you to create a new UDI record and not accept the change.

However, if the existing UDI record contains an genuine data entry error, you can use the 'Corrections' function to update any data (including UDI Trigger data elements) without creating a new UDI record. You must provide a reason for the correction, and the TGA may audit use of this feature.

Corrections can be made at any time, including once the Grace Period has ended.

Will there always be the ability to make corrections to UDI Trigger data elements within an existing UDI record? Or will there be a point where no changes can be made and a new UDI record would be required within the AusUDID?

Corrections can always be made to a UDI record to fix data entry errors. This functionality will remain available even after Grace Period ends. The TGA may extend or shorten the Grace Period available to sponsors, which may impact whether a correction is required. The AusUDID will identify if the record needs to be corrected.

If a variation is done to a medical device, will the linked UDI record be highlighted to advise that the UDI record needs to be revised or updated?

The AusUDID does not automatically flag ARTG variations. Sponsors are responsible for assessing whether a variation affects any UDI Trigger data elements. If it does, they must update the existing UDI record or create a new one, as appropriate.

If you wanted to add non-mandatory data at a later date, is it considered a correction?

Adding non-mandatory data such as device description or supporting documents is not a correction. This can be done at any time without using the correction function.

For more information on the data elements can be edited and the Grace Period rules refer to the Australian UDI Data Dictionary on the TGA website.

Will a Grace Period of 7 days allow for error corrections also be applicable to UDI records that have been made publicly available?

The Grace Period applies after publication, even if the UDI record is publicly available. During this time, users can edit all data elements.

After the Grace Period ends, corrections can still be made but users must provide a reason for change.

Please note the TGA extended the Grace Period to 30 days on 19 February 2026. The TGA expects it will remain at 30 days until most of UDI data has been supplied by sponsors and manufacturers.

Multiple sponsors of the same device/UDI record

In a multiple sponsor scenario, can one sponsor change data in the UDI record without the consent or approval of other sponsors?

In a multiple sponsor scenario, each sponsor can edit the device data without needing consent or approval from other sponsors. However, sponsors cannot modify sponsor-specific data belonging to others such as ARTG ID or catalogue number.

To edit device data, users must use the correction function and provide a reason for the change.

Will changes to device fields being made by one sponsor on the same UDI record be visible to other sponsors of the same UDI record? How do we prevent duplicated efforts?

Changes made by one sponsor to device fields in a shared UDI record are visible to other sponsors through the device record history.

To avoid duplicated efforts and ensure data accuracy, we recommend sponsors coordinate with the manufacturer before making updates.

In a multiple sponsor scenario, do multiple sponsors need to submit the same data fields, and wouldn't this create 2 UDI records? Or can one sponsor omit the common fields and submit the ones relevant to the sponsor?

In a multiple sponsor scenario, only one UDI record is created for a device with a single UDI-DI, even if multiple sponsors supply it.

The first sponsor enters the device data and creates the UDI record. Any subsequent sponsor will be informed that the UDI record already exists and they can and add sponsor-specific information, such as their ARTG ID and catalogue number to the existing record. They do not need to re-enter common device data.

If 2 sponsors supply the same product with the same UDI-DI but their ARTGs have 2 different GMDNs, how will this be managed?

If 2 sponsors supply the same product with the same UDI-DI but have different GMDNs in their ARTG inclusions, the shared UDI record will reflect both. Each sponsor's ARTG details, including their respective GMDN codes, will appear on the ARTG details page. The GMDNs do not need to match.

How does multiple sponsorship work for private labelled products? If branding is a trigger category but the only difference from the manufacturer is the branding, will this require separate UDIs?

Brand name is a UDI Trigger data element. Changes to brand name, including private labelling, require a new UDI-DI.

If the same device is supplied under different brand names by different sponsors, each version is considered a separate device. Therefore, each must have its own UDI-DI.

If I want to sponsor a product that is already sponsored by another supplier, how do I find out that there is an existing UDI record for that product?

If you want to sponsor a product that's already sponsored by another supplier, you can check whether a UDI record already exists by:

- Talking to the manufacturer of the device.
- Searching the AusUDID using the UDI-DI provided by the manufacturer.
- Consulting with your manufacturer to confirm whether the device is already supplied by another sponsor using the same UDI-DI.

If you attempt to create a new UDI record using an existing UDI-DI, the AusUDID will notify you that a UDI record already exists.

Ending supply of a device

Do we need to mark products that are obsolete or no longer being supplied?

You must update the 'Sponsor commercial distribution end date' when a device is no longer being supplied.

UDI records should never be deleted from the AusUDID, even if the product becomes obsolete. This allows them to be referenced in the case of adverse event reporting and market actions.

If you change the status of your ARTG inclusion, this will be automatically reflected in the AusUDID record.

If we add a commercial distribution end date and then later recommence commercialisation, can that date be changed?

You can remove the Sponsor commercial distribution end date if the device resumes supply. This allows you to reflect the recommencement of commercialisation in the UDI record.

If a sponsor or distributor stops distribution and later decides to reinvoke to resupply it due to demand, does the sponsor have to resubmit the UDI to the AusUDID from scratch or is there a field to update?

If a sponsor stops supplying a device and later decides to recommence distribution, they do not need to resubmit the UDI record from scratch.

Instead, they can update the 'Sponsor commercial distribution end date' field in the existing UDI record to reflect the new supply status. This allows the UDI record to remain active and accurate without duplication or re-entry.

If the redistribution requires a new ARTG inclusion you will need to link the UDI record to the new ARTG ID.

UDI in healthcare settings

Is eHealth also considering that Class I devices are not in scope of UDI requirements as part of their processes?

The TGA is unable to comment on behalf of eHealth NSW regarding their processes or decisions.

Hospital processes

Referring to the video that was shared during the presentation, is it mandatory for healthcare providers to record UDI in patient records?

It is currently not mandatory for healthcare providers to record UDI in patient records. However, the TGA encourages including UDI in patient records, discharge summaries, registries, and inventory systems to support traceability and improve patient safety. The TGA is working with other government agencies to identify where UDI capture could be mandatory.

As hospitals will need to self-report from next year, will UDI be requested to be included in these self-reports?

The UDI is an optional field in the dataset for reporting of adverse events by hospitals. Where available, hospitals are asked to include the UDI.

Are healthcare providers required to use UDI and record UDIs used in hospitals for traceability, considering the AusUDID does not collect production information?

Healthcare providers are not required to record UDIs in hospital systems or patient records. However, the TGA strongly encourages healthcare providers to adopt UDI into their processes.

Healthcare providers are required to provide patients receiving an implantable device with a Patient Implant Card that includes UDI information.

Tenders

Are sponsors expected to notify healthcare facilities of UDI requirements and how they intend to be compliant? For example, we are already receiving questions as part of the tenders process.

The TGA is unable to comment on behalf of healthcare organisations and their tendering processes or decisions.

Is there a UDI entry number or equivalent in the AusUDID, and have there been discussions with tender panels about including UDI entry data into tender response forms?

The TGA is unable to comment on behalf of healthcare organisations and their tendering processes or decisions.

Education

How are customers, users or patients being educated about which products require UDI and which do not?

The TGA has not yet launched educational activities for consumers or patients, as the AusUDID is still in the early stages of data collection. Once the AusUDID contains more comprehensive information and becomes more useful to the public, the TGA will begin targeted education initiatives to raise awareness and understanding of UDI requirements.

Will UDI educate the public by providing more fact check opportunities to the public?

The AusUDID will offer the public improved access to detailed information about medical devices, increasing transparency and visibility.

Consumers

What does the use of UDI look like from the perspective of a customer? How will they use the UDI?

Consumers and their healthcare professionals can use the UDI to search the AusUDID for information about devices used on or implanted in the patient. This gives them greater visibility into the device's clinical characteristics, as well as the sponsor and manufacturer responsible for it.

They can also use the UDI to check whether their device is affected by recall notices or product alerts. In addition, healthcare providers can use the UDI to notify patients in the event of a recall or safety issue.

Australian Register of Therapeutic Goods (ARTG)

For existing ARTG inclusions, does this mean for devices that are currently in the 'excluded' category from the ARTG, do we need to provide UDI information when it is supplied/imported?

No, excluded therapeutic goods are exempt from UDI requirements. There is no obligation to provide UDI information for these products when they are supplied or imported.

Is the expectation to submit UDI records for every device that is covered by an ARTG inclusion, regardless of whether the particular SKUs are supplied or not in the Australian market?

No. UDI records are only required for devices that are supplied in Australia. You do not need to submit UDI records for devices not supplied in Australia.

What happens with ARTG inclusions for devices that are not supplied? Is there a requirement to link UDI data for these?

UDI records are only required for devices that are supplied in Australia. You do not need to submit UDI records for devices not supplied in Australia.

As ARTG cancellation has no impact to UDI tracking, is there any obligation to notify TGA regarding a data update?

Yes. If the device will no longer be supplied in Australia, the sponsor must update the 'Sponsor Commercial Distribution End Date' in the AusUDID to reflect this change. This ensures the database remains accurate and supports traceability, even after ARTG cancellation.

Will adding a UDI to an existing ARTG entry be treated as an administrative change or a variation requiring notification?

No. Adding a UDI to an existing device will not be considered a variation requiring notification.

You will continue to be responsible for advising the TGA is a change or variation is required to the ARTG inclusion.

You do not need to notify the TGA, 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.

ARTG transfers

If there is a sponsor transfer for an ARTG, are there any actions required by the new sponsor on the AusUDID or is it updated automatically?

This depends. There are many different reasons for sponsor changes. The implications of changing sponsors will be based on individual circumstances.

Does transfer or ARTG sponsorship trigger a new UDI-DI?

Sponsor ID is not a UDI Trigger. However, if the UDI-DI uses the sponsor prefix rather than the manufacturer prefix, sponsor changes will require a new UDI-DI.

For ARTG transfers, will the new sponsor have to reupload the same information? Or will the UDI record be transferred? If transferred, will they have an opportunity to access or audit the UDI records?

At present, when the sponsor for an ARTG inclusion is changed, the AusUDID:

- Updates the linked ARTG data on the UDI record to reflect the current ARTG state, including sponsor details
- Updates the sponsor section to change the sponsor from Sponsor A to Sponsor B
- Removes sponsor-specific data previously provided by the previous sponsor, such as *Sponsor Commercial Distribution End Date* and *Catalogue Number.*

When this occurs, the UDI record is removed from the *My UDI Records* screen of Sponsor A and becomes visible to Sponsor B.

Therefore, in a transfer of sponsorship scenario, the UDI records would automatically update to reflect the new sponsor. The new sponsor, or Sponsor B, would **not** need to upload the same UDI data. However, they must:

- Ensure all data is accurate and up to date
- Maintain the UDI record for the lifetime of the device.

However, please note that while this is the way that the AusUDID system functions – this is something that is still being refined and developed further. Once system rules are fully implemented, we will publish guidance regarding transfer of sponsorship and the AusUDID on the TGA website.

If I am the relinquishing sponsor, what do I need to do in the AusUDID after the sponsor transfer takes place?

This depends. There are many different reasons for sponsor changes. The implications of changing sponsors will be based on individual circumstances.

Australian UDI Data Dictionary

Is the Australian UDI Data Dictionary subject to change? Will it expand and what sort of notice would be given for additional fields, if required?

Yes. It is possible that the Australian UDI Data Dictionary will continue to change. Future updates are likely to focus on clarifying existing elements and adding further detail to support data quality and usability.

The TGA is currently exploring options for notifying users about changes. This may include advance notice through official channels or stakeholder communications.

Indications and intended purpose

Can you provide an example of when a change of intended purpose would trigger a new UDI-DI?

Yes. For example, if a Software as a Medical Device originally intended to monitor heart rate is updated to also diagnose arrhythmias, this represents a change both to software functionality and intended purpose. As a result, a new UDI-DI must be allocated.

How will different indications for the same device in different jurisdictions be managed from the perspective of the AusUDID?

Where an indication reflects the device's technical characteristics, devices with different indications are likely to require separate UDI-DIs to ensure accurate identification of distinct device types and their technical differences by healthcare providers.

As many indications relate to clinical attributes of the device (for example, sterility or MRI safety status), where a change to an indication results in a change to information captured in a UDI-DI Trigger data element, the device must be recorded under a different UDI-DI in the AusUDID.

If the intended purpose for Australia is narrower than for example the EU, then does the EU and Australia need 2 separate UDI? Or can we use the same one?

The TGA supports either scenario, provided all UDI-DI's – and the associated data in the AusUDID – correctly reflect the intended purpose of the ARTG Inclusion and the identifiers on the labels of all devices supplied in Australia.

Other TGA regulatory processes

Declaration of conformity

Will UDI be required to be on Australian Declaration of Conformity?

No. The UDI is not required to be included on the Australian Declaration of Conformity. Any future changes to the Australian Declaration of Conformity to include UDI will be communicated via an industry consultation.

Recalls

Does adding the UDI reference in the recall notice mean the hospital must confirm/identify the UDI as well as model and lot/SN?

Adding the UDI to the recall notices will see the full UDI captured on the recall notice, that is the UDI-DI and the UDI-PI. As the UDI-PI contains the device production information, such as lot or batch number, healthcare professionals are not required to find and confirm the device's production information.

Essential principles checklist

Could you please provide examples on how we should provide evidence of compliance with UDI related clauses in the Essential Principles Checklist?

Examples of evidence that you may provide include:

- A copy of the UDI label showing both HRI and AIDC forms
- Documentation of UDI-DI assignment from a TGA recognised Issuing Agency
- A screenshot or export from the AusUDID showing a draft UDI record
- A justification for examples (e.g. direct marking infeasibility)
- A summary of internal procedures for UDI data management and submission.

The Essential Principles Checklist has been updated with UDI requirements, but the compliance date is years away for some devices. What is TGA's expectation for completing the checklist in the interim?

Currently, you may choose to note in the checklist that the requirements do not yet apply to your devices.

We are exploring options to add additional guidance to the Essential Principles Checklist to clarify this.

Evidence of UDI compliance

Do sponsors need to submit labelling reflecting UDI for approval before it can be supplied?

Sponsors are not required to submit UDI-compliant labelling for formal approval before supply. However, after the UDI compliance date for a device has passed, sponsors may need to provide evidence of their intention to meet UDI requirements when submitting new applications. This may include demonstrating how UDI will be incorporated into labelling and packaging.

Record keeping obligations

For record keeping of device data, how long must data be kept if a product has been discontinued?

UDI records remain in the AusUDID indefinitely. They must not be deleted.

Distribution records must be retained for:

- 10 years for Class III, IIb implantable and Class 4 IVDs
- 5 years for all other classifications.

This applies even if the product has been discontinued.

The UDI Guidance states that sponsors have to meet record keeping requirements. Other than maintaining UDI records in the AusUDID, are there any internal UDI-specific record keeping requirements we should be aware of?

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.

Consent to supply

Can consent to supply apply to medical devices supplied under MDD?

Consent to supply cannot be requested for medical devices supplied in Australia under MDD certificates after the EU transitional dates have passed as the MDD certificate would be considered expired.

The UDI implementation dates cater for the MDD transition requirements and devices supplied under MDD are not required to meet the UDI requirements. Therefore, a Consent to Supply is not required for these devices if they cannot meet all the UDI requirements of the Medical Device Regulations.

Audits

Are audits post-launch required by the sponsor?

There is no requirement for a sponsor to undertake an audit to demonstrate compliance with UDI requirements. Sponsors should record and retain all UDI related decisions and be able to supply evidence of these decisions when requested by the TGA or other appropriate certification bodies.

What would TGA look at during a TGA audit with respect to UDI requirements? Would it look at systems implemented, etc in addition to fulfilling requirements on the label

During regulatory compliance activities, including audits by the TGA or other certification bodies, the auditor may look at any aspect of compliance with the UDI-related Essential Principles. This could include fulfilling labelling requirements, decisions relating to indications and reflecting this in the UDI data, direct marking of devices and keeping data in the AusUDID up to date.

Language and accessibility

Will the TGA UDI guidelines be available in different languages for our overseas manufacturers who do not speak English?

The TGA currently does not plan to make the UDI guidance available in additional languages.

Organisations operating outside Australia are responsible for ensuring they understand and comply with the guidance, which may require translation or interpretation at their own discretion.

Will the AusUDID only be in English?

The TGA currently does not plan to make the AusUDID available in additional languages.

Organisations operating outside Australia are responsible for ensuring they understand the content, which may require translation support.

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Version	Description of change	Author	Effective date
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