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

Unique Device Identification (UDI) system responsibilities

High-level overview

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Australian UDI system

The Australian Government is strengthening patient safety by introducing Unique Device Identification (UDI) for medical devices.

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

The Australian UDI Database (AusUDID), established and maintained by the Therapeutic Goods Administration (TGA), allows patients, consumers and healthcare professionals to access product information about the devices they use.

Healthcare organisations are critical stakeholders in the UDI system. Realising the full benefits of UDI requires UDI-enabled clinical, supply chain and care processes that support device traceability from procurement through to patient care, incident management and post-market surveillance. When fully adopted in healthcare, UDI can enable more accurate identification of devices in adverse event reporting and more efficient and effective responses to safety alerts and recalls.

UDI can also improve device performance assessment by regulatory bodies, clinical quality registries and device manufacturers through accurate product identification, supporting more reliable analysis and comparative studies.

With the introduction of UDI, Australia joins a globally harmonised approach to medical device identification.

For more information on UDI in Australia, see: Unique Device Identification (UDI) hub | Therapeutic Goods Administration (TGA).

Responsibilities

Multiple stakeholders must be involved to realise the full benefits of UDI:

- **Manufacturers** serve as the foundation by assigning standardised identifiers to the devices they manufacture.
- **Australian sponsors** maintain accurate AusUDID data. They support procurement, use, identification and, where required, device disposal. They capture UDIs in incident reports and recalls.
- **The TGA** uses UDIs to accurately identify device models and support regulatory activities, including approvals, post-market surveillance and recall management. The TGA applies a risk-based approach to monitor compliance with UDI requirements across the medical device lifecycle.
- **Healthcare providers** integrate UDI data into existing systems and processes to enhance patient safety and supply chain efficiency. This could include:
  - procurement and inventory systems
  - patient health records, both electronic and paper-based
  - governance and accountability
  - clinical workflow implementation
  - scanning infrastructure
  - traceability processes
  - patient safety and surveillance activities.

These responsibilities are further defined in the table below.

Note: The TGA does **not** regulate healthcare. UDI requirements may be reflected in the third edition of the Australian Commission on Safety and Quality in Health Care's National Safety and Quality Health Service Standards.

Australian UDI requirement	Manufacturer	Sponsor	TGA	Healthcare (Recommended)
Use a TGA recognised Issuing Agency and allocate UDI-DI and UDI-PI	Select a recognised Issuing Agency (e.g. GS1/HIBCC/ICCBBA). Allocate UDI-DI to each model of device and format UDI-PI per the Issuing Agency rules. Ensure packaging design and label is suitable for scanning and use in healthcare Ensure the UDI-PI on the device label is updated when production information (e.g. batch, date of manufacturer) changes. Assign a new UDI-DI when a UDI Trigger creates a new device model/when a UDI Trigger field is changed in the AusUDID.	Confirm the manufacturer has correctly assigned UDI-DI/UDI-PI before supply; ensure the chosen coding standard is appropriate for the device. Ensure packaging design and label is suitable for scanning and use in healthcare.	Recognise Issuing Agencies who set technical standards and formats to assign unique identifiers. Work with Issuing Agencies to monitor integrity of the Australian UDI system. Collect UDI information for applications to include goods on the ARTG. Support recording of UDI information for devices supplied under existing ARTG inclusions. Support traceability of changes to UDI data (including UDI Trigger fields that force creation of a new UDI-DI) in Device variations.	Consider regulatory requirements for point-of-care manufacturing. For example, UDI requirements may apply to Patient Matched Medical Devices.
Apply UDI carrier in HRI and AIDC on label, device (if applicable), and higher	Apply UDI Carrier on the label, on the device where applicable, and on all higher packaging levels.	Ensure the UDI Carrier format is appropriate for intended use and that packaging levels bear the	Review labelling conformance (as required) during	Record the UDI in healthcare systems, processes, clinical notes and discharge summaries. (Note: ideally this is supported by

Australian UDI requirement	Manufacturer	Sponsor	TGA	Healthcare (Recommended)
packaging levels	Ensure format meets Issuing Agency specifications. Ensure it supplements (does not replace) existing labelling. Include Package DI where required.	UDI Carrier/Package DI.	regulatory activities.	barcode scanning capability.) Incorporate UDI capture into clinical documentation workflows. Use UDI to support patient to device traceability. Use the UDI in sourcing, contract management, and inventory management. Use UDI to identify, and prevent use of, expired or recalled devices. Use UDI to support recall and field safety corrective action processes. Include the UDI in communication with bodies such as Clinical Quality Registries. Advise the TGA when a UDI is expected but not present or when it is present but unable to be read/scanned.
Direct marking of reusable devices (if applicable)	Directly mark the UDI on reusable devices that are reprocessed and used on multiple patients, unless an exemption applies (e.g. safety/performance concerns).	Verify direct marking exists where required before supply. Document any justified exemptions.	Review justification reasons (as required) where direct marking is not applied.	Record Direct Marking DI information through healthcare systems and processes including sourcing, inventory, point of care, discharge summaries and in communication with bodies such as Clinical Quality Registries. Incorporate direct marking information into asset management systems.

Australian UDI requirement	Manufacturer	Sponsor	TGA	Healthcare (Recommended)
				Leverage UDI in recalls, maintenance, servicing and lifecycle management processes.
Unit of Use DI (if applicable)	Allocate Unit of Use DI when items are used/supplied individually but packaged in multiples. Note that this is a virtual identifier and therefore not evident on the label, packaging or on the device itself.	Confirm Unit of Use DI is allocated to applicable devices.		Record Unit of Use DI through healthcare systems and processes including sourcing, inventory, point of care, discharge summaries and in communication with bodies such as Clinical Quality Registries.
Patient Implant Cards (PICs) for implantable devices	Include UDI on PICs per Essential Principles.	Ensure PICs include UDI per Essential Principles.	Review PICs (as required) to verify UDI inclusion. Check for accuracy and readability on PICs.	When fulfilling the mandatory requirements for providing PICs to recipients of implantable devices, ensure that the PIC includes the full UDI.
Submit UDI-DI and mandatory data to the AusUDID	Provide UDI-DI and related data to AusUDID (directly or via sponsor) within 30 days of supply in Australia. Maintain data accuracy.	Ensure each UDI record is submitted, linked to the correct ARTG inclusion, and kept current. Ensure data is added/updated a maximum of 30 days after supply to the Australian market.	Administer and maintain the AusUDID. Confirm the UDI-DI used matches the Issuing Agency syntax through inbuilt validation checks. Undertake periodic data quality checks. Ensure that healthcare and consumers can freely access device information in the AusUDID. Work with stakeholders (including healthcare) to	Utilise AusUDID as a source of data for healthcare systems including sourcing, inventory, point of care and patient records. Participate in data quality improvement by reporting discrepancies and usability issues via udi@health.gov.au: • regarding quality, value and applicability of AusUDID data • when device data is unavailable in the AusUDID. Examples of quality issues that could be raised with the TGA include: • device missing UDI on the label

Australian UDI requirement	Manufacturer	Sponsor	TGA	Healthcare (Recommended)
			monitor quality, value and applicability of AusUDID data. Support provision of high-quality data that meets the needs of TGA, healthcare and consumers through education and support documents.	and compliance date has past • reusable device direct marking is unreadable.
Quality Management System	Implement a quality management system that maintains UDI consistency and validity across all device variations and software updates.		Ensure manufacturer has processes in place to obtain and manage UDI information across all models of device.	
Record keeping and alignment with Essential Principles	Maintain technical documentation evidencing UDI assignment, UDI Carrier placement, direct marking information or rationale, and ongoing compliance with Essential Principles.	Keep records demonstrating verification of the manufacturer's UDI compliance, and of timely AusUDID submissions (may be as UDI records themselves). Provide relevant records as requested.	Request and review documentation to support regulatory activities.	
Comply with staged implementation timeframes	Plan label updates, data readiness (if submitting as manufacturer), and direct marking (if applicable) to meet class-based	Ensure devices supplied after UDI compliance start dates comply with all applicable UDI requirements.	Monitor compliance with class-specific start dates. Manage 'Consent to Supply'	Leverage UDIs and device data as it becomes available. Highest risk devices will yield the greatest patient safety benefits and will

Australian UDI requirement	Manufacturer	Sponsor	TGA	Healthcare (Recommended)
	compliance start dates and transition rules. Optionally adopt early compliance to minimise risk of non-compliance.	Seek 'Consent to Supply' approval to supply devices that are non-compliant with UDI requirements. Share 'Consent to Supply' evidence with healthcare on request. Optionally adopt early compliance to minimise risk of non-compliance.	applications for non-compliant devices. Review new applications for ARTG inclusions for UDI compliance in line with UDI compliance start dates. Include review of UDI compliance in existing audits, post-market reviews, recalls, market actions.	become compliant first.
Integration with TGA processes (incident notifications, adverse events, recalls, etc.)	Use UDI in adverse event/recall communications and device traceability activities.	Include UDI in reports/market actions and communications to stakeholders.	Review notifications for inclusion of UDI. Validate UDI-DI against AusUDID.	Include the UDI in incident notifications and adverse event reports when reporting to the TGA.

Other considerations

The following information highlights key aspects of the Australian UDI framework and provides additional context to support understanding of stakeholder responsibilities.

Device scope

UDI requirements apply only to devices included in the ARTG from **Class Is (supplied sterile) and above**.

- UDI requirements **do not apply** to:
  - Class I non-sterile, non-measuring devices
  - Class Im (measuring) devices
  - certain Class 1 IVDs.
- UDI requirements also do not apply to:
  - exempt devices

  - surgical loan kits (at the kit level)
  - export-only devices
  - devices supplied under special access pathways, including the SAS, Authorised Prescriber Scheme, and Clinical Trials.

These exclusions apply regardless of whether the device otherwise falls within a UDI-eligible risk class.

UDI implementation timing

UDI requirements are being implemented through a **phased, risk-based approach**. UDI obligations commence with **Class III and Class IIb devices**, followed by lower-risk device classes in later years.

Key implementation considerations include:

- Devices unable to meet UDI requirements by their mandatory compliance date may continue to be imported and supplied in Australia through the TGA's Consent to Supply process.
- Devices transitioning from **EU MDD to EU MDR** or **EU IVDD to EU IVDR** benefit from transitional arrangements that extend the timeframe to meet UDI requirements.
- Devices manufactured and labelled **before the applicable compliance date** for their risk classification are considered *existing devices*.

Existing devices are generally exempt from UDI requirements for the **lifetime of the device**, with the following exception:

- **Class III and Class IIb existing devices** that remain under sponsor control on or after **1 July 2029** must comply with UDI requirements.
- All existing devices are exempt from **direct marking requirements** for the lifetime of the device.

UDI labelling

UDI labelling is required on all applicable packaging levels. Each packaging level must bear its own unique UDI to support traceability throughout the supply chain.

Labelling requirements may vary depending on:

- Device type
- Intended use
- Technical feasibility of UDI placement.

TGA accepts **EU and US UDI-compliant labelling**, provided all other Australian labelling requirements are met. Labels must include:

- a machine-readable form of the UDI
- a human-readable forms of the UDI, allowing manual capture if labels are unable to be scanned.

UDI is **additional to**, and does not replace, existing Australian labelling obligations.

AusUDID UDI record submission

UDI records may be created and submitted by either sponsors or manufacturers. However, only the Australian sponsor can link an ARTG ID to a UDI record.

Key UDI record considerations:

- A UDI record is only considered compliant once the UDI record is published and the **ARTG ID is linked** in AusUDID.
- Sponsors and manufacturers are responsible for ensuring UDI data is **accurate, complete, and kept up to date**.
- TGA **cannot edit or correct UDI records** on behalf of sponsors or manufacturers.

Patient information materials

UDI information must be included on Patient Implant Cards (PICs).

UDI information is **not required** on:

- Patient Information Leaflets (PILs)
- Instructions for Use (IFUs)

Sponsors and manufacturers may voluntarily upload these documents to the AusUDID as supporting information associated with a UDI record.

Device specific variations

Some device types have additional UDI requirements.

For example:

- **implantable devices** must include a serial number or batch/lot number in the UDI-PI
- **software-based devices** must include the software version number in the UDI-PI
- **reusable devices**, intended for use on multiple patients and reprocessed between uses, must be **directly marked** unless an exemption applies
- **retail supply devices** are subject to **reduced labelling requirements**.

For full details of UDI requirements refer to the Unique Device Identification Guidance.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Devices Reforms Taskforce	August 2026

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Reference/Publication #