Australian Government
Department of Health, Disability and Ageing

Australian Unique Device Identification (UDI)

Devices principally sold in retail premises

UDI requirements

The **Unique Device Identification (UDI) system** was formally introduced into the *Therapeutic Goods (Medical Devices) Regulations 2002* in March 2025 and includes .

For a full list of UDI requirements, see UDI requirements guidance.

Requirements for devices principally sold in retail

Devices 'principally sold in retail' are those **intended for sale in retail premises.** For example, if an adhesive bandage is intended for sale in retail premises, however an additional use is by a medical centre where they are used on patients, it still qualifies as 'principally sold in retail' and is eligible for the **reduced labelling requirements**.

Reduced labelling

For most medical devices in scope of UDI requirements, both the UDI-Device Identifier (UDI-DI) and UDI-Production Identifier (UDI-PI) must be shown in:

- **Human Readable Interpretation (HRI)** – a textual representation of encoded data
- **Automatic Identification Data Capture (AIDC)** – a group of technologies that automatically identifies objects, collects their data and enters the data directly into systems.

However, devices principally sold in retail can use **more flexible labelling:**

- The **UDI-DI** must be in a **machine-readable form;** however, the standard used can include those that better support retail use rather than the more comprehensive healthcare standard.
- The **UDI-PI** is not required in **machine-readable form**, but you may choose to do so.
- The UDI-DI and UDI-PI must be in a **human-readable form**; however, it does not need to be HRI. Instead, the UDI-DI may be presented without application identifiers, and the UDI-PI can be presented in a human-readable form such as **plain text (non-HRI).**
- The production identifiers provided on the label may vary depending on the medical device type and current practice. At least one production identifier must be included on the label. This may be the manufacturing date.

Retail devices redirected to healthcare settings

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

Devices temporarily redirected due to shortages

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

These devices remain eligible for the reduced labelling requirements.

Devices redirected due to business changes

If a sponsor begins supplying a device that was originally intended for retail directly to healthcare settings on a more permanent basis, then full UDI labelling will be required on the device.

This will ensure the device supports the traceability that is required for clinical environments.

Devices that frequently change supply channels

For devices that frequently shift between retail and healthcare supply channels, it is recommended that manufacturers apply full UDI labelling for these devices.

This approach helps ensure consistent compliance and reduces the need for relabelling as distribution patterns change.

Resources on the UDI Hub

You can find additional resources on the UDI Hub.

Introductory resources

- Unique Device Identification (UDI) hub | Therapeutic Goods Administration (TGA)
- UDI: Information for sponsors and manufacturers | Therapeutic Goods Administration (TGA)

AusUDID resources

- The Australian UDI Database for sponsors and manufacturers | Therapeutic Goods Administration (TGA)
- UDI: Resources and technical documents | Therapeutic Goods Administration (TGA)

Regulatory resources

- Complying with the Unique Device Identification requirements for medical devices | Therapeutic Goods Administration (TGA)
- Complying with the Unique Device Identification timeframes for medical devices | Therapeutic Goods Administration (TGA)
- Therapeutic Goods Legislation Amendment (Australian Unique Device Identification Database and Other Measures) Regulations 2025 | Therapeutic Goods Administration (TGA)