Australian Government
Department of Health, Disability and Ageing

Australian Unique Device Identification (UDI)

In vitro diagnostic (IVD) medical devices

UDI requirements

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

To comply, sponsors and manufacturers must meet **3 key requirements**:

- **Placement of a UDI Carrier** on the device label and all applicable higher levels of packaging, including the device itself where applicable
- **Submission of UDI data** to the Australian UDI Database (AusUDID) in the form of a UDI record
- **Compliance with any additional obligations** that apply to specific device types, such as reusable devices.

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

Scope of requirements

UDI requirements apply to some IVD classifications.

IVD classification	UDI required?
Class 4	Yes
Class 3	Yes
Class 2	Yes
Class 1	Partial* *Instrument/analyser IVDs (GMDN Code CT943) and Software IVDs (GMDN Code CT944)
In house IVDs	No

Key dates

UDI compliance for IVDs is phased over multiple years. Compliance begins with high-risk devices, followed by lower risk devices over later years.

Requirement	Class 4	Class 3	Class 2	Class 1
UDI Carrier on the label	1 July 2028		1 July 2029	
Submission of UDI records	1 July 2028		1 July 2029	
Direct Marking	1 July 2029		1 July 2030	

Specific devices

Software

UDI requirements apply to IVDs that are **software** or **incorporate software**.

Accessories

Accessories **included in an IVD kit** do **not** require a separate UDI if the **kit itself has a UDI**.

Systems

If an IVD system includes **test reagents or accessories** that are a **higher classification** than the instrument and are **commercially available on their own**, they must be listed separately in the AusUDID.

IVD kits

UDIs are allocated to:

- The **kit itself**
- **Components** regulated as devices and sold separately
- **Replacement** parts, whether single use or reusable.

IVDs sold in retail

The **point-of-sale packaging** must include:

- **UDI-DI** in Automatic Identification Data Capture (AIDC) form and either Human Readable Interpretation (HRI) or non-HRI form
- **Production information** in human readable (non-HRI) form.

All **higher levels of packaging** must include:

- **Full UDI** (UDI-DI and UDI-PI) in both AIDC and HRI.

Direct Marking is not required for IVDs sold in retail.

Retailers are not required to keep records for the over-the-counter sales.

AusUDID – GMDN codes

Each UDI record in the AusUDID can include up to 2 GMDN codes.

ARTG GMDN Code

This is the GMDN code from the ARTG inclusion that is linked to the UDI record. It may be a GMDN Collective Term or Preferred Term Code.

Manufacturer GMDN Code

This is the Preferred Term Code specified by the manufacturer. It is only visible to the sponsor supplying the IVD and is not publicly displayed.

Additional resources

You can find resources to support you implementing UDI on the UDI Hub.

Introductory resources

- Unique Device Identification (UDI) hub | Therapeutic Goods Administration (TGA)
- About UDI in Australia | 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)

Support

Contact the UDI Support Team at UDI@health.gov.au.