Australian Government
Department of Health, Disability and Ageing

Australian Unique Device Identification (UDI)

Medical devices

UDI requirements

Australia's **Unique Device Identification (UDI) system** was formally introduced following changes to the *Therapeutic Goods (Medical Devices) Regulations 2002* in March 2025.

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

- **Place a UDI Carrier** on the device label and all applicable higher levels of packaging, including the device itself, where applicable
- **Submit UDI data** to the Australian UDI Database (AusUDID) and link it to the applicable ARTG inclusion(s)
- **Comply with any additional obligations** that apply to specific device types.

For details on Australia's UDI requirements, see UDI requirements guidance.

Scope of requirements

UDI requirements apply to selected medical device classifications.

Device classification	UDI required?
Class I	No
Class Im (measuring)	No
Class Is (supplied sterile)	Yes
Class IIa	Yes
Class IIb	Yes
Class III	Yes

Key dates

UDI compliance is phased by device risk class over multiple years. Higher-risk devices will be first, followed by lower risk devices in later years.

Requirement	Class III	Class IIb	Class IIa	Class Is
UDI Carrier on the label	1 July 2026		1 July 2027	1 July 2028
Submission of UDI records	1 July 2026		1 July 2027	1 July 2028
Direct Marking	1 Jan 2028	1 Jan 2029	1 Jan 2029	1 Jan 2029

Specific devices

Some devices have additional UDI requirements due to their design or intended use. It is important to review the UDI guidance to ensure you meet all applicable obligations for your devices.

Reusable devices

Reusable devices must be **Directly Marked** with the UDI in a way that can withstand normal use and reprocessing for the lifetime of the device.

Implantable devices

The UDI-Production Identifiers must include specific data elements depending on the type of device:

- for an **active implantable** device, the **serial number**
- for **other implantable** devices, the **serial number or lot number** in accordance with the manufacturer's quality management system.

Components of a Surgical Loan Kit

SLKs are exempt at the **kit-level**, however **individual components** that are regulated as medical devices and in scope must comply with UDI requirements.

System or Procedure Packs (SOPPs)

SOPPs must comply if they contain **one or more in-scope medical device.** Each component that is in scope must also meet UDI requirements.

Devices principally 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 f**ull UDI** (UDI-DI and UDI-PI) in both AIDC and HRI.

Direct Marking is not required for medical devices sold in retail. Retailers are not required to keep records for over-the-counter sales.

Multiple devices packaged together

When multiple devices are **packaged together without individual labels or packaging**, a **Unit of Use Device Identifier** (UoU DI) is required. It ensures traceability of each device unit, especially in clinical and inventory settings.

This is a **virtual identifier** used to represent each device in the package.

The UoU DI is **not displayed on the label**, but it must be submitted to the AusUDID.

Software

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

Accessories

Accessories must meet UDI requirements if they are:

- **in scope** of UDI requirements, and
- commercially available on **their own**.

Additional resources

You can find resources that support your UDI implementation on the TGA's 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

For additional support contact the UDI Support Team at UDI@health.gov.au.