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

# Complying with the Unique Device Identification requirements for medical devices

Understand the regulatory requirements for supplying UDI compliant medical devices in Australia.

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## Contents

# Purpose

We developed this guidance to help sponsors and manufacturers understand and comply with Australia's Unique Device Identification (UDI) requirements. It provides examples and practical instructions for implementing UDI.

While this document may reference the UDI implementations of other countries, it does not provide a comparison of Australia's UDI rules, requirements and data elements with other jurisdictions.

**For this Guidance:**

- *we* refers to the Therapeutic Goods Administration (TGA)
- *you* refers to sponsor or manufacturer of medical devices or IVD devices
- *medical devices* refers to both medical devices and IVDs
- *UDI record* refers to a UDI-DI and related data published as a record to the Australian Unique Device Identification Database (AusUDID)
- *devices in scope of UDI requirements* refers to devices that are of a risk classification that must meet UDI requirements and are not otherwise exempt.

For a full list of definitions used throughout this document, see Appendix C.

# Legislation

## Therapeutic Goods Legislation Amendment (Australian Unique Device Identification Database and Other Measures) Regulations 2025

### Downloads

Complying with the Unique Device Identification requirements for medical devices [PDF, 1.96 MB]

**Topics** Unique Device Identification (UDI) hub

# Page history

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# Related guidance

## Complying with the Unique Device Identification timeframes for medical devices

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Timeframes for supplying UDI compliant medical devices in Australia

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