

## UDI Readiness Checklist

A practical resource for assessing your organisation's readiness for Australia's new UDI requirements.  
*Aligned to ISO 13485:2016 and TGA UDI Requirements (2026–2030)*

### Forewords

The intent of this checklist is to assess your organisation's readiness to comply with Australia's new Unique Device Identification (UDI) requirements.

This UDI Readiness Checklist is provided as a general guidance tool only. Completing this checklist, in whole or in part, **does not guarantee compliance** with the Therapeutic Goods Administration (TGA) Unique Device Identification (UDI) requirements, ISO 13485:2016, or any other regulatory obligations.

Regulatory compliance depends on the accuracy of the information provided, the effectiveness of your organisation's quality management system, and the implementation of appropriate processes, controls, and documentation.

This checklist should be used as a **supporting resource**, not as a substitute for professional regulatory advice, detailed gap analysis, or formal conformity assessment. Organisations remain fully responsible for ensuring their devices, systems, and processes meet all applicable regulatory requirements.

### How to Use This UDI Readiness Checklist

This checklist helps you evaluate how prepared your organisation is to meet the Therapeutic Goods Administration (TGA) Unique Device Identification (UDI) requirements coming into force between 2026 and 2030. It is aligned with ISO 13485:2016, making it suitable for both manufacturers and sponsors.

Follow the steps below to complete the assessment effectively.

#### 1. Gather the Right People Before You Begin

UDI affects multiple parts of your organisation. For an accurate assessment, involve representatives from:

- Regulatory Affairs
- Quality Assurance
- Labelling & Packaging
- IT / ERP / PLM Systems
- Supply Chain / Logistics
- Post-Market Surveillance
- Senior Management

This ensures each section is scored by the people who understand it best.

## 2. Review Each Item Carefully

The checklist is divided into eight sections, each covering a key part of UDI compliance:

1. Governance & Planning
2. Data Management
3. IT & System Integration
4. Labelling & Packaging
5. AusUDID Submission
6. QMS Updates
7. Supply Chain Readiness
8. Post-Market & Audit Processes

Read each item and discuss whether your organisation has fully implemented the requirement.

## 3. Score Each Item Using the 0–3 Scale

Use the scoring criteria consistently:

| Score                            | Meaning                                   | Criteria                                                                       |
|----------------------------------|-------------------------------------------|--------------------------------------------------------------------------------|
| <b>0 – Not Started</b>           | No evidence of planning or implementation | No documentation, no process, no assigned responsibility                       |
| <b>1 – Partially Implemented</b> | Early work underway                       | Some documentation exists, responsibilities unclear, process not fully defined |
| <b>2 – Mostly Implemented</b>    | Near completion                           | Documented process exists, partially deployed, minor gaps remain               |
| <b>3 – Fully Implemented</b>     | Ready for compliance                      | Process fully deployed, documented, controlled, and effective                  |

**Total possible score: 72** Use the score ranges below to interpret readiness.

**Be honest** — this checklist is a diagnostic tool, not a pass/fail test.

## 4. Add Up the Scores

Once all sections are complete, total the scores.

Maximum score: 72

Use the ranges below to interpret your readiness:

- 0–24: High Risk Significant gaps. Immediate action required to avoid compliance issues.
- 25–48: Moderate Risk Several areas need improvement. A structured remediation plan is recommended.
- 49–72: Low Risk Strong readiness. You are well-positioned for mandatory UDI compliance.

## 5. Prioritise Your Remediation Actions

Use your scores to identify where to focus next:

- Scores of 0 or 1 indicate urgent gaps.
- Scores of 2 indicate areas needing refinement.
- Scores of 3 indicate compliance-ready processes.

Create an action plan that includes:

- Owners
- Deadlines
- Required resources
- Dependencies (e.g., IT system upgrades)

## 6. Use the Checklist as a Living Document

UDI compliance is not a one-off activity. Update this checklist:

- After major device changes
- When new UDI guidance is released
- During internal audits
- Before regulatory submissions
- As part of annual management review

This ensures your organisation stays compliant as requirements evolve.

## Section 1 — Governance & Regulatory Planning

| Item                                                        | Score (0–3)                                                                                                 |
|-------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------|
| UDI included in regulatory strategy and compliance planning | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 |
| Device classifications confirmed for UDI timelines          | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 |
| UDI responsibilities assigned across teams                  | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 |
| UDI gap analysis completed                                  | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 |
| Transition plan developed for 2026–2030 deadlines           | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 |
| Risk management updated to include UDI                      | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 |

## Section 2 — UDI Data Management & System Readiness

### 2.1 Data Structure & Integrity

| Item                                           | Score                                                                                                       |
|------------------------------------------------|-------------------------------------------------------------------------------------------------------------|
| UDI-DI and UDI-PI generation rules established | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 |
| Device master records updated with UDI fields  | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 |
| Data validation process implemented            | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 |
| Master Data Management (MDM) updated for UDI   | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 |

### 2.2 IT & System Integration

| Item                                            | Score                                                                                                       |
|-------------------------------------------------|-------------------------------------------------------------------------------------------------------------|
| ERP/PLM systems configured for UDI data         | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 |
| Label printing systems updated for UDI carriers | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 |
| AusUDID submission capability established       | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 |
| Cybersecurity controls reviewed for UDI data    | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 |

### Section 3 — Labelling & Packaging Compliance

| Item                                                               | Score                                                                                                       |
|--------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------|
| UDI carrier format selected (GS1 DataMatrix, barcode, etc.)        | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 |
| Carrier placement rules defined (label, packaging, direct marking) | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 |
| Label artwork updated to include UDI                               | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 |
| Change control applied to all labelling updates                    | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 |
| Verification & validation completed (scanability, durability)      | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 |
| Packaging specifications updated                                   | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 |

### Section 4 — AusUDID Submission Readiness

| Item                                                           | Score                                                                                                       |
|----------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------|
| UDI-DI records created for all devices                         | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 |
| Device attributes populated (model, version, packaging levels) | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 |
| Production identifiers defined                                 | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 |
| Internal procedure for AusUDID submissions established         | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 |
| Roles and approvals defined                                    | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 |
| Process for updating AusUDID records implemented               | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 |
| Audit trail maintained for all submissions                     | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 |

### Section 5 — QMS Updates (ISO 13485 Alignment)

| Item                                  | Score                                                                                                       |
|---------------------------------------|-------------------------------------------------------------------------------------------------------------|
| QMS procedures updated to include UDI | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 |
| Device master records updated         | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 |
| Technical documentation updated       | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 |
| Training delivered to relevant teams  | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 |
| Competency records maintained         | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 |

## Section 6 — Supply Chain & Operational Readiness

| Item                                       | Score                                                                                                       |
|--------------------------------------------|-------------------------------------------------------------------------------------------------------------|
| Distributors informed of UDI requirements  | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 |
| Hospitals/procurement partners notified    | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 |
| Scanning and traceability processes tested | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 |
| Legacy devices assessed for re-labelling   | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 |

## Section 7 — Post-Market Surveillance & Lifecycle Management

| Item                                           | Score                                                                                                       |
|------------------------------------------------|-------------------------------------------------------------------------------------------------------------|
| UDI integrated into PMS processes              | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 |
| UDI used in complaints and vigilance reporting | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 |
| UDI incorporated into recall procedures        | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 |
| Process established for updating UDI records   | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 |

## Section 8 — Internal Audit & Pre-Compliance Review

| Item                                               | Score                                                                                                       |
|----------------------------------------------------|-------------------------------------------------------------------------------------------------------------|
| UDI included in internal audit schedule            | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 |
| Mock AusUDID submission completed                  | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 |
| Labelling and packaging audits completed           | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 |
| Management review updated to include UDI readiness | <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 |

**Final Score:** \_\_\_\_\_ / 72

### Readiness Interpretation

- **0–24:** High risk — major gaps, urgent remediation required
- **25–48:** Moderate risk — structured improvement plan needed
- **49–72:** Low risk — ready for transition to mandatory UDI