DISTINCT COMPLIANCE ENGINEERING
FOR ENGINEERED TECHNICAL SOLUTIONS, "THINK DISTINCT"
PART OF THE DISTINCT ENGINEERING GROUP PTY. LTD.

Suite 156, 139 Cardigan Street
Carlton, 3053, Victoria, Australia
Email : Info@distinctengineering.com.au
Web : www.distinctengineering.com.au
ABN : 74 247 149 468
ACN : 626 538 181

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.

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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
0 – Not Started	No evidence of planning or implementation	No documentation, no process, no assigned responsibility
1 – Partially Implemented	Early work underway	Some documentation exists, responsibilities unclear, process not fully defined
2 – Mostly Implemented	Near completion	Documented process exists, partially deployed, minor gaps remain
3 – Fully Implemented	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.

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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.

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Section 1 — Governance & Regulatory Planning

Item	Score (0–3)
UDI included in regulatory strategy and compliance planning	☐ 0 ☐ 1 ☐ 2 ☐ 3
Device classifications confirmed for UDI timelines	☐ 0 ☐ 1 ☐ 2 ☐ 3
UDI responsibilities assigned across teams	☐ 0 ☐ 1 ☐ 2 ☐ 3
UDI gap analysis completed	☐ 0 ☐ 1 ☐ 2 ☐ 3
Transition plan developed for 2026–2030 deadlines	☐ 0 ☐ 1 ☐ 2 ☐ 3
Risk management updated to include UDI	☐ 0 ☐ 1 ☐ 2 ☐ 3

Section 2 — UDI Data Management & System Readiness

2.1 Data Structure & Integrity

Item	Score
UDI-DI and UDI-PI generation rules established	☐ 0 ☐ 1 ☐ 2 ☐ 3
Device master records updated with UDI fields	☐ 0 ☐ 1 ☐ 2 ☐ 3
Data validation process implemented	☐ 0 ☐ 1 ☐ 2 ☐ 3
Master Data Management (MDM) updated for UDI	☐ 0 ☐ 1 ☐ 2 ☐ 3

2.2 IT & System Integration

Item	Score
ERP/PLM systems configured for UDI data	☐ 0 ☐ 1 ☐ 2 ☐ 3
Label printing systems updated for UDI carriers	☐ 0 ☐ 1 ☐ 2 ☐ 3
AusUDID submission capability established	☐ 0 ☐ 1 ☐ 2 ☐ 3
Cybersecurity controls reviewed for UDI data	☐ 0 ☐ 1 ☐ 2 ☐ 3

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Section 3 — Labelling & Packaging Compliance

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

Section 4 — AusUDID Submission Readiness

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

Section 5 — QMS Updates (ISO 13485 Alignment)

Item	Score
QMS procedures updated to include UDI	☐ 0 ☐ 1 ☐ 2 ☐ 3
Device master records updated	☐ 0 ☐ 1 ☐ 2 ☐ 3
Technical documentation updated	☐ 0 ☐ 1 ☐ 2 ☐ 3
Training delivered to relevant teams	☐ 0 ☐ 1 ☐ 2 ☐ 3
Competency records maintained	☐ 0 ☐ 1 ☐ 2 ☐ 3

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Section 6 — Supply Chain & Operational Readiness

Item	Score
Distributors informed of UDI requirements	☐ 0 ☐ 1 ☐ 2 ☐ 3
Hospitals/procurement partners notified	☐ 0 ☐ 1 ☐ 2 ☐ 3
Scanning and traceability processes tested	☐ 0 ☐ 1 ☐ 2 ☐ 3
Legacy devices assessed for re-labelling	☐ 0 ☐ 1 ☐ 2 ☐ 3

Section 7 — Post-Market Surveillance & Lifecycle Management

Item	Score
UDI integrated into PMS processes	☐ 0 ☐ 1 ☐ 2 ☐ 3
UDI used in complaints and vigilance reporting	☐ 0 ☐ 1 ☐ 2 ☐ 3
UDI incorporated into recall procedures	☐ 0 ☐ 1 ☐ 2 ☐ 3
Process established for updating UDI records	☐ 0 ☐ 1 ☐ 2 ☐ 3

Section 8 — Internal Audit & Pre-Compliance Review

Item	Score
UDI included in internal audit schedule	☐ 0 ☐ 1 ☐ 2 ☐ 3
Mock AusUDID submission completed	☐ 0 ☐ 1 ☐ 2 ☐ 3
Labelling and packaging audits completed	☐ 0 ☐ 1 ☐ 2 ☐ 3
Management review updated to include UDI readiness	☐ 0 ☐ 1 ☐ 2 ☐ 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