Australian Government
Department of Health, Disability and Ageing

Australian Unique Device Identification (UDI)

Preparing for the introduction of UDI in Australia

Preparing for UDI and AusUDID checklist

This checklist outlines key considerations for sponsors and manufacturers preparing to comply with Australia's Unique Device Identification (UDI) requirements. It includes suggested timeframes, related resources, and roles that may be involved in each activity.

This is a general guide and not an exhaustive list. Sponsors and manufacturers are responsible for reviewing and meeting all regulatory obligations.

Please note that suggested timeframes and roles involved may vary depending on your organisation's structure, processes, and resources.

🕑 1-2 months	Understand UDI requirements	Responsible stakeholders	Related resources
Learn which medical devices and in vitro diagnostic (IVD) devices must comply with UDI requirements and when compliance is mandatory for each device class. Assess if your current labelling and packaging may need to change.			
➢ Understand the UDI basics, including common terms and acronyms	➢ Sponsors ➢ Manufacturers ➢ Third party data providers		☐ About UDI in Australia ☐ UDI glossary ☐ Australian UDI Data Dictionary
➢ Identify which of your devices are subject to UDI requirements	➢ Sponsors ➢ Manufacturers		☐ Decision Tree: Does UDI apply to my device? ☐ UDI requirements guidance
➢ Understand UDI requirements for specific device types, such as implantable devices, Software as a Medical Device and reusable devices	➢ Sponsors ➢ Manufacturers		☐ UDI requirements guidance
➢ Determine when UDI requirements apply to your devices, including any transitional arrangements your devices may qualify for	➢ Sponsors ➢ Manufacturers		☐ Decision Tree: When does UDI apply to my device? ☐ UDI timing guidance

➢ Educate staff on UDI regulations and requirements that apply to your devices
 	
➢ Establish subject matter experts (SMEs) within your organisation. These individuals should have a deep understanding of UDI requirements, data standards, and submission processes. Their role may include:
 	
   o coordinating UDI implementation across departments (e.g. Regulatory Affairs, IT, Quality Assurance)
 	
   o advising on compliance strategies and timelines
 	
   o training internal teams on UDI concepts
 	
   o acting as the primary point of contact for TGA and external partners.
 	
Note: *The number and scope of SMEs may vary depending on your organisation's size, product portfolio, and complexity.*
	➢ Sponsors
	
	➢ Manufacturers	

⏱️ 1-3 months	Agree responsibilities	Responsible stakeholders	Related resources
	Review your current agreements and define the responsibilities of the manufacturer and sponsor in meeting Australia's UDI requirements.		
	➢ Choose a TGA recognised Issuing Agency	➢ Manufacturers	☐ Getting a UDI ☐ UDI requirements guidance
	➢ Allocate UDI Device Identifiers (UDI-DIs) and UDI Production Identifiers (UDI-PIs) to your devices ***Tip***: *UDI Carriers that meet EU or US UDI requirements are accepted in Australia, if:* • *the UDI-DI has been issued by a TGA recognised Issuing Agency, and* • *the label complies with Australia's existing regulatory and labelling requirements.*	➢ Manufacturers	☐ UDI labelling requirements ☐ UDI requirements guidance
	➢ Generate a UDI Carrier using barcode software offered by your chosen Issuing Agency ➢ Ensure the barcode scans and has the correct data encoded	➢ Manufacturers	☐ Refer to your chosen Issuing Agency for guidance on generating UDI Carriers and technical specifications

Task	Responsible stakeholders	Related resources
➢ Apply a UDI Carrier in Human Readable Interpretation (HRI) and Automatic Identification Data Capture (AIDC) forms to the device ➢ Ensure each applicable higher level of packaging bears UDI compliant labelling	➢ Manufacturers	☐ UDI labelling requirements ☐ UDI requirements guidance ☐ Refer to your chosen Issuing Agency for technical specifications
➢ Understand UDI record submission requirements and responsibilities for the Australian UDI Database (AusUDID)	➢ Sponsors ➢ Manufacturers	☐ Australian UDI Data Dictionary ☐ AusUDID for sponsors and manufacturers
➢ If applicable, develop agreements with third party data providers for the electronic submission of UDI records	➢ Sponsors ➢ Manufacturers ➢ Third party data providers	☐ M2M HL7 SPL Document Suite
➢ Assess and update your Quality Management System(s) as needed	➢ Sponsors ➢ Manufacturers ➢ Third party data providers	
➢ Review and adjust other TGA-related processes, such as adverse event reporting and market actions	➢ Sponsors ➢ Manufacturers	☐ UDI and TGA processes

⏱ 2-4 months	Define standard operating procedures	Responsible stakeholders	Related resources
Create internal procedures for assigning, managing and maintaining UDIs and related data.			
➢ Evaluate your existing procedures and identify any gaps. You should consider how changes to your devices and the device data will be managed and co-ordinated across entities, and how these changes will be submitted to the TGA	➢ Sponsors ➢ Manufacturers		
➢ Determine the most appropriate submission method for your organisation to submit data to the AusUDID ➢ Develop procedures for submitting and maintaining UDI records	➢ Sponsors ➢ Manufacturers	☐ AusUDID for sponsors and manufacturers	
➢ Identify if changes are required for your records management processes, procedures and tools	➢ Sponsors ➢ Manufacturers ➢ Third party data providers		

⏱		Responsible stakeholders	Related resources
	➢ Create procedures for validating UDI data before submission	➢ Sponsors ➢ Manufacturers ➢ Third party data providers	
⏱ 3-8 months	**Organise and validate your data**	**Responsible stakeholders**	**Related resources**
Ensure your UDI data is accurate, complete and aligned with Australian regulatory requirements.		
	➢ Implement version and change management procedures for UDI records	➢ Sponsors ➢ Manufacturers ➢ Third party data providers	
	➢ Prepare your data for submission – in accordance with the *Australian UDI Data Dictionary*	➢ Sponsors ➢ Manufacturers	☐ Australian UDI Data Dictionary
	➢ Validate that all data is accurate, up to date and complete	➢ Sponsors ➢ Manufacturers	☐ Australian UDI Data Dictionary
	➢ Enrich data with comprehensive values and optional data fields for greater detail	➢ Sponsors ➢ Manufacturers	
	➢ Ensure data aligns with related ARTG inclusions and certificates of conformity	➢ Sponsors	
	➢ Map data across any relevant internal systems to compile consistent and complete records	➢ Sponsors ➢ Manufacturers	
⏱ 1-2 months	**Test your UDI record submissions**	**Responsible stakeholders**	**Related resources**
Validate your systems and processes for submitting UDI records to the AusUDID using the Pre-Production environment.		
	➢ Ensure your organisation has an active TGA Business Services (TBS) account	➢ Sponsors ➢ Manufacturers	☐ TGA Business Services
	➢ Ensure all staff submitting and maintaining UDI records have user accounts and the relevant TBS system roles	➢ Sponsors ➢ Manufacturers	☐ TBS system roles

Online portal including Bulk Upload ➢ Test individual UDI record submissions using the AusUDID Pre-Production environment ➢ Test bulk UDI record submissions using the *Australian UDI Bulk Upload Template* ***Tip***: *If both sponsors and manufacturers wish to participate in the submission process, it is generally recommended that manufacturers complete the Australian UDI Bulk Upload Template and provide it to the sponsor for finalisation and submission.*	➢ Sponsors ➢ Manufacturers	☐ AusUDID for sponsors and manufacturers ☐ Australian UDI Bulk Upload Template

HL7 SPL (if applicable)
 	
➢ Review the M2M HL7 SPL document suite, including the implementation specification and user guide
 	
➢ Collaborate with internal IT teams or third party data provider to establish systems
 	
➢ For organisations submitting their own UDI records via HL7 SPL:
 	
    o Obtain a Client ID and Secret from the UDI Support Team
 	
    o Generate an Subscription Key in the API Management Portal
 	
➢ For third party data providers submitting UDI records on behalf of sponsors or manufacturers:
 	
    o Obtain a Client ID and Secret from the UDI Support Team
 	
    o Obtain a Subscription Key from your client
 	
➢ Test UDI record submissions using the AusUDID Pre-Production environment
	➢ Sponsors
	➢ Manufacturers
	➢ Third party data providers
		☐ M2M HL7 SPL Document Suite

National Product Catalogue (NPC) (if applicable) ➢ Work with GS1 and your internal IT team to implement applicable system changes and data submission processes ➢ Test UDI record submissions using the AusUDID Pre-Production environment	➢ Sponsors	☐ National Product Catalogue | GS1 Australia ☐ Contact GS1 at npcsupplierengagement@gs1au.org

⏱ 1-2 months	Submit and maintain your UDI records	Responsible stakeholders	Related resources
Finalise your UDI implementation by submitting valid UDI records to the AusUDID Production environment. Establish ongoing maintenance procedures.			
➢ Submit UDI records to the AusUDID Production environment		➢ Sponsors ➢ Manufacturers ➢ Third party data providers	☐ AusUDID for sponsors and manufacturers ☐ UDI - Videos - YouTube
➢ Review UDI records to ensure accuracy and completeness		➢ Sponsors ➢ Manufacturers ➢ Third party data providers	☐ Australian UDI Data Dictionary
➢ Maintain UDI records in line with regulatory requirements and internal processes		➢ Sponsors ➢ Manufacturers ➢ Third party data providers	☐ Managing UDI records
➢ Stay up to date with changes to the AusUDID through AusUDID release notes		➢ Sponsors ➢ Manufacturers ➢ Third party data providers	☐ AusUDID Production release notes ☐ AusUDID Pre-Production release notes
➢ Stay up to date with events and communications through the UDI mailing list		➢ Sponsors ➢ Manufacturers ➢ Third party data providers	☐ Contact the UDI Support Team at UDI@health.gov.au

For further information on UDI in Australia, visit the UDI Hub on the TGA website.

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