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 seeking to comply with Australia's Unique Device Identification (UDI) requirements.

This is a general guide and not an exhaustive list. It is your responsibility to review and meet all regulatory obligations. Timeframes provided for completing each activity may vary for your organisation.

Understand UDI requirements 1-2 months	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	☐ About UDI in Australia ☐ UDI glossary
☐ Identify which of your devices are subject to UDI requirements	☐ UDI requirements guidance ☐ Devices in scope of UDI requirements
☐ Understand UDI requirements for specific device types	☐ UDI requirements guidance ☐ UDI requirements for specific device types
☐ Determine when UDI requirements apply to your devices	☐ UDI timing guidance
☐ Educate staff on UDI regulations and requirements that apply to your devices	

Agree responsibilities 1-3 months	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	☐ Getting a UDI ☐ UDI requirements guidance

☐	Assign UDI Device Identifiers (UDI-DIs) and UDI Production Identifiers (UDI-PIs) to your devices	☐ UDI labelling requirements ☐ UDI requirements guidance
☐	Ensure each model of device and applicable higher level of packaging bears UDI compliant labelling	☐ UDI labelling requirements ☐ UDI requirements guidance
☐	Understand data submission requirements and responsibilities for the Australian UDI Database (AusUDID)	☐ Australian UDI Data Dictionary
☐	If applicable, develop agreements with third party data providers for the electronic submission of UDI records	☐ M2M HL7 SPL Document Suite
☐	Assess and update your Quality Management System(s) as needed	
☐	Review and adjust other TGA-related processes, such as adverse event reporting and market actions	☐ UDI and TGA processes

Define standard operating procedures 2-4 months	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.	
☐ Determine the most appropriate submission method for your organisation. Develop procedures for submitting and maintaining UDI records	
☐ Identify if changes are required for your records management processes, procedures and tools	
☐ Create procedures for validating UDI data before submission	

Organise and validate your data 3-8 months	Related resources
Ensure your UDI data is accurate, complete and aligned with Australian regulatory requirements.	
☐ Implement version and change management procedures for UDI data	

☐ Prepare your data for submission – in accordance with the Australian UDI Data Dictionary	☐ Australian UDI Data Dictionary
☐ Validate that all data is accurate, up to date and complete	☐ Australian UDI Data Dictionary
☐ Enrich data with comprehensive values and optional data fields for greater detail	
☐ Ensure data aligns with related ARTG inclusions and certificates of conformity	
☐ Map data across any relevant internal systems to compile consistent and complete records	

Test your UDI record submissions

1-2 months

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	☐ TGA Business Services
☐ Ensure all staff submitting and maintaining UDI records have user accounts and the relevant TBS system roles	☐ TBS system roles
Online portal including Bulk Upload	☐ AusUDID for sponsors and manufacturers
☐ Test individual UDI record submissions using the AusUDID Pre-Production environment	☐ Bulk Upload Microsoft Excel template
☐ Test bulk UDI record submissions using the Bulk Upload Microsoft Excel template	
HL7 SPL (if applicable)	☐ M2M HL7 SPL Document Suite
☐ Review the M2M HL7 SL document suite, including the implementation specification and user guide	
☐ Collaborate with internal IT teams or third party data provider to establish systems	
☐ Test UDI record submissions using the AusUDID Pre-Production environment	

National Product Catalogue (NPC) (if applicable)

- ☐ Review the NPC and AusUDID user guide
- ☐ 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

- ☐ AusUDID for sponsors and manufacturers
- ☐ National Product Catalogue | GS1 Australia

Submit and maintain your UDI records

1-2 months

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
- ☐ Review UDI records to ensure accuracy and completeness
- ☐ Maintain UDI records in line with regulatory requirements and internal processes
- ☐ Stay up to date with changes to the AusUDID through AusUDID release notes
- ☐ Stay up to date with events and communications through the UDI mailing list

- ☐ Australian UDI Data Dictionary
- ☐ Managing UDI records
- ☐ AusUDID Production release notes
- ☐ AusUDID Pre-Production release notes
- ☐ 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.

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