Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Machine to Machine HL7 SPL Implementation Specification

Australian Unique Device Identification Database (AusUDID)

Version 1.1, March 2025

Contents

1 Introduction

For the purpose of this document:

- *UDI record* refers to a UDI-DI and related data published as a record to the AusUDID
- *We* refers to the Therapeutic Goods Administration.

1.1 Purpose of this document

We have created this Implementation Specification to assist you in implementing the HL7 SPL data submission and messaging standard for the Australian UDI Database (AusUDID).

This user guide is part of a suite of documents that support the sponsors and manufacturers (or their Third Party Data Providers) who will supply data to the AusUDID via HL7 SPL.

We have created this suite of documents to help you:

- comply with UDI requirements
- understand the IT requirements of the AusUDID
- submit and verify UDI records in the AusUDID.

We have explained the suite of documents in the table below:

Document	Australian UDI Data Dictionary	User Guide	Implementation Specification	Code List	Sample HL7 XML Message
Purpose	Reference listing of all Australian UDI data elements including: • data element names • descriptions • validation rules • Grace Period rules • permitted values • other useful metadata.	Overview of: • UDI concepts • AusUDID submission channels, roles and environments • Data management rules • M2M workflow • API Management Portal • Provisioning security credentials • Testing scenarios – conformance.	Detailed instructions of: • Versioning • Creating UDI records • Maintaining data • Schema and data attribute specifications.	Reference listing of codes and elements.	Series of sample HL7 XML messages for data submission and notifications (success and failure), including message annotations explaining the data attributes and intended purpose.

Audience	• Sponsors • Manufacturers • Agents • Third Party Data Providers • Regulatory teams • Software development and support teams.	• Sponsors • Manufacturers • Third Party Data Providers • Agents • Software development and support teams.	• Software development and support teams.	• Software development and support teams.	• Software development and support teams.
Assumed Knowledge	• UDI concepts • Australian regulations.	TBS Portal including access provisioning and/or understanding of Oauth 2.0 authentication framework.	HL7 SPL messaging protocols and system integration architecture patterns using XML schemas.	HL7 SPL messaging protocols and system integration architecture patterns using XML schemas.	HL7 SPL messaging protocols and system integration architecture patterns using XML schemas.

1.2 Symbols and concepts used in this document

1.2.1 Callout boxes

Items that need your attention are shown by a callout box. Callout boxes have an exclamation mark showing their importance.

1.2.2 XML components

When we refer to XML components, for example elements or attributes, versus the concept – this is shown with the following symbolisation:

- XML elements and attributes:
  - In text: bold, italicised text in Camel case, for example ***ContextOfUse***
  - Within XML: shown as noted in XML snippets
- Concept without attribution to the model or message:
  - Plain text with the first letter capitalised as it is a defined concept, for example Unit of Use[1].

[1] These concepts are defined in the Australian UDI Data Dictionary.

1.2.3 XML snippets

We have used colour coding in the XML snippets to illustrate their meaning. The table below explains this.

Legend for XML snippets

Text colour	Description sample
Teal	Schema components *<?xml version "1.0" encoding="UTF-8"?>*
Blue	XML notations *< ….= ""><*
Brown	XML element *id code*
Red	XML attribute *root extension*
Blue	Value of the element or attribute *2.16.840.1.113883*

XML editors may display these XML components differently. You can use the legend above to understand XML presented in this document.

1.2.4 Required schema attributes

The AusUDID HL7 SPL message contains attributes that are not fixed values to provide for future extensibility of the schema. When you submit an AusUDID HL7 SPL submission, you need to send these attributes with the value as specified in this document. We have specifically stated all schema attributes for each element, when required.

For example:

- The ***manufacturedProduct@classCode*** value must be equal to 'MANU' to pass schema validation. Any other value in this field may cause the schema validation to fail.

In the example above, the value for the ***classCode*** attribute should be 'MANU'. In the future, this may be fixed in the schema, but for increased extensibility of the schema, it has not been constrained any further.

1.2.5 XML elements table

We have provided a table for each element in the XML message.

When elements have multiple element parts of attributes, they are provided in one table.

Where there are no attributes or values for an element, the cell is greyed out to indicate that no value is required in the XML message.

1.2.5.1 Sample XML element table

Table Name: <element>

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
	XPATH:			
Business Rules				

Table Name: Each table is named for the elements it is representing in the XML – i.e. <element> or <element 2>.

Element: Identifies the XML element.

Attribute: Identifies the XML attribute.

Cardinality: Provides information on how many times the element/attribute can be repeated in the XML message.

Value(s) Allowed/Examples: Identifies the values allowed using simple data types and any associated examples. References to controlled vocabulary will also be provided.

Description/Instructions: Provides a description of the element or attribute.

XPATH: Identifies the location of the data element or attribute in the XML.

Business Rules: Identifies any business rules that are in place for AusUDID.

2 Unique Device Identification (UDI)

The Australian Government is strengthening patient safety by introducing the Australian UDI system for medical devices.

The UDI system supports the identification of medical devices and other medical device reforms. It is designed to improve the effectiveness of the regulatory framework, including management of post-market safety-related activities such as recalls.

By introducing a UDI system, Australia joins a globally harmonised approach that enables more accurate identification of medical devices.

2.1 Unique Device Identifiers

For detailed information about Australia's UDI system and unique device identifiers, refer to the UDI Hub.

2.2 Australian UDI Database (AusUDID)

We have established the AusUDID as the repository for UDI-DIs and related data in Australia. The AusUDID stores the UDI-DI and related information for most medical devices and in vitro diagnostic (IVD) devices supplied in Australia. UDIs can help to improve tracking and traceability of medical devices supplied in Australia.

There are 2 environments for the AusUDID:

- AusUDID Production
- AusUDID Pre-Production.

There are 4 data submission methods supported by the AusUDID:

- AusUDID Online Portal
- Bulk Upload via Microsoft Excel Template
- Machine to Machine via HL7 SPL
- Machine to Machine via GS1's National Product Catalogue.

2.2.1 AusUDID Pre-Production

The AusUDID Pre-Production environment is a test and training environment for medical device sponsors and manufacturers. As the information in the AusUDID Pre-Production environment is testing and training data, patients, consumers, healthcare and the general public do not use the data stored in this database.

It operates alongside the AusUDID Production environment, serving as an environment for sponsors and manufacturers to:

- familiarise themselves with the AusUDID
- test their respective data submission methods prior to submitting live data to the AusUDID.

Data submitted to the AusUDID Pre-Production environment is not transferred to the AusUDID Production environment.

2.2.2 AusUDID Production

The AusUDID Production environment is the live database for medical device sponsors and manufacturers to submit live, accurate data to meet UDI requirements.

2.3 The AusUDID API Portal

The AusUDID API Portal:

- Enables the TGA to process submissions automatically
- Functions as a single point of entry for the receipt and processing of all electronic submissions in a secure environment that complies with messaging standards.

Access to the TGA API Portal is described in the document *Machine to Machine HL7 SPL User Guide.*

If you are authorised, the HL7 message will be sent to the AusUDID API for processing and will generate either a success message or error message.

If you are not authorised to use the HL7 SPL channel, for example if you are not registered or your Client ID and Secret is incorrect, you will receive a HL7 SPL gateway error.

If you do not receive an acknowledgement, you must contact the UDI Support Team at UDI@health.gov.au including the message identifier and the UDI-DI of the respective UDI record.

3 AusUDID HL7 SPL submission

AusUDID uses HL7 SPL Draft Standard for Trial Use (DSTU) Release 5 along with standard vocabularies.

3.1 Pre-requisites

If you choose HL7 SPL to submit UDI records to AusUDID Production, you must first complete testing in AusUDID Pre-Production.

Testing in Pre-Production helps to identify data issues early and prevent submission of inaccurate or low quality data to the AusUDID Production environment.

We have provided testing requirements in the document *Machine to Machine HL7 SPL Channel User Guide.*

3.2 Versioning HL7 SPL submissions

An AusUDID HL7 SPL submission contains only one UDI record to optimise the processing of submissions.

The initial UDI record submission establishes a UDI record in the AusUDID.

After initial submission, any updates must include the entire UDI record device data – i.e. the AusUDID message does not contain partial UDI records or individual changes to a prior submission. Each time the submission is received, all business rules will be executed on the contents of the HL7 SPL submission.

A sponsor will only provide their own sponsor data in the message. i.e. if a UDI record already has Sponsor A's ARTG data associated with it, Sponsor B will not include this in the message.

The AusUDID HL7 SPL submission contains document information for the message that allows the AusUDID system to link the initial submission to any subsequent updates. All submissions must include a setId and versionNumber in accordance with the following rules:

- The setId indicates the group of submissions that are related
- Updates to a UDI record typically use the same setId value provided in the initial submission
- An organisation may reset the setId (send a new setId)**.** The versionNumber must be restarted at 1
- If the setId is changed, the old setId will be made inactive. Attempting to reuse it will result in the submission being rejected
- For subsequent transmissions, the versionNumber must be incremented by 1. This ensures that the setId and versionNumber are unique and that submissions are processed in the correct order and prevents older versions from overwriting newer versions
- Organisations must maintain setId and versionNumber to submit updates to the UDI record
- Once the UDI record has been published, the UDI record Publish Date cannot be changed. For UDI record edits after the UDI record is published, you must still provide a current UDI record Publish Date as this is a required field. However, the original submitted Publish Date will not be changed in the UDI record. See 5.1.3, UDI record Publish Date for more information.

3.3 Updating UDI records

UDI records that you create through the HL7 SPL submission method should not be updated by any other submission option when the UDI record is in the Grace Period, or UDI record status is 'Unpublished' as this may cause unexpected synchronisation issues during future updates.

If you wish to update a UDI record that you originally created in the online portal using HL7 SPL, you need to assign a new setId and a new version number. This is because the UDI record will not have either of these values associated with it. We recommend testing this in the AusUDID Pre-Production environment before applying updates in AusUDID Production environment.

The system will update the entire UDI record with the new version if all business rules are passed (i.e. any changes must comply with all business rules before, during or after the Grace Period). The Grace Period is a set time frame that begins once you have published your initial version of the UDI record. During this time, you can make changes to any data element. The purpose of the Grace Period is to allow you fix errors in the UDI record due to data entry errors or technical issues.

The length of the Grace Period is subject to change as we introduce UDI and the AusUDID. You can find the current length of the Grace Period on the UDI Hub, or when updating or correcting a UDI record.

- Grace Period does not apply – i.e. an unpublished UDI record with future UDI record Publish Date – the system will update the existing UDI record if the submitted changes meet all business rules. There are no restrictions on changing values for any data elements.
- During the Grace Period – i.e. a published UDI record with current UDI record Publish Date and during the Grace Period – the system will update the existing UDI record if the submitted changes meet all business rules.
- After the Grace Period – i.e. a published UDI record that was published and the Grace Period has passed the system will update the existing UDI record if the submitted changes meet all business rules. Changes related to UDI Trigger data elements[2] will be rejected unless a correction request is made via the AusUDID Online portal.

Refer to Correcting UDI records for more information on correction requests.

3.4 Correcting UDI records

When a UDI record is initially submitted and published, the UDI record starts the 'Grace Period'. During the Grace Period, all UDI record data elements (except the UDI record Publish Date, Device Manufacturer and Primary DI) may be edited. The Grace Period gives organisations a short period to review and correct their data. After the Grace Period passes, UDI record edits are restricted, specifically, edits to the UDI Trigger data elements are not allowed.

When a device is associated with Multiple Sponsors, a correction must be used to change any of the common device data elements. A sponsor can change their own sponsor data without the use of a correction.

Refer to the Australian UDI Data Dictionary for more information on which data elements are UDI Triggers, and details of which data elements may be edited during or after the Grace Period.

[2] DI Trigger data elements are those, which when changed, require a new Device Identifier to be assigned.

Data corrections, including corrections to the UDI Trigger data elements, is necessary to ensure quality device identification information is available to healthcare and the public. AusUDID supports corrections to a UDI record with the reason for the correction captured in update logs.

Do not use the 'Request a Correction' function to submit edits to UDI records if the changes require the assignment of a new UDI-DI. When a new UDI-DI is assigned, you must submit a new UDI record in the AusUDID.

- Corrections can be submitted via the M2M HL7 SPL using the specific AU1002 correction code.
- Alternatively, you can pre-file a correction request via the AusUDID Online Portal and then use the standard C101716 submission create/vary code which will be converted to a correction.
- The pre-filed correction request is a one-time use, and further corrections will require a new request to be filed.
- Any Published UDI record that has passed Grace Period (i.e. after-grace-period) can have a correction request.
- A single UDI record or multiple UDI records may be selected at any given time for a correction request.
- Corrections can be made within 5 calendar days (starting the day the correction request is made).
- All data elements except the UDI record Publish Date, Device Manufacturer and Primary DI can be edited as part of a correction.
- When the device is associated with Multiple Sponsors, a correction is required to change any common data elements.
- Corrections can be submitted through the AusUDID Online Portal, M2M via National Product Catalogue, or M2M HL7 SPL.
- Updates submitted using M2M HL7 SPL must follow the versioning rules. UDI records created or previously modified using M2M HL7 SPL should not be updated through the AusUDID Online portal as this may cause unexpected errors or issues during future updates.
- The correction request will be removed upon successful processing of the submitted correction (or after completion of the 5-calendar day period, whichever is earlier).
- All prior published versions of a given UDI record will remain accessible through the AusUDID Online Portal as device record history to public users.

4 Essential components of the HL7 SPL submission

Essential components of the AusUDID HL7 SPL specification includes:

- Controlled Vocabulary
- Object Identifiers (OIDs) and Universally Unique Identifiers (UUIDS)
- Data Types
- AusUDID HL7 SPL XML Schema
- AusUDID HL7 SPL XML Message.

The schema does not include the business rules that need to be dynamic in the process. The business rules outlined in the subsequent sections should be handled by any system generating the XML message.

4.1 Controlled vocabulary

AusUDID makes extensive use of controlled vocabularies. The information in the following sub-sections will outline the controlled vocabulary used to implement HL7 SPL for AusUDID. There are several different authoritative sources for the controlled vocabulary, which include TGA, Unified Code of Units of Measure (UCUM) and the Global Medical Device Nomenclature (GMDN)[3]. All controlled vocabulary is provided in a separate XML file.

The controlled vocabulary required by the HL7 SPL standard enables system to system communications and is not always the ideal way to display concepts in a system graphical interface (GUI). Be cautious not to apply the technical codes in the GUI, instead use the business friendly terms.

4.2 OIDs and UUIDs

There are 2 types of unique identifiers:

- Object Identifiers (OIDs)
- Universally Unique Identifiers (UUIDs).

4.2.1 Object identifiers

An OID is a sequence of numbers that uniquely identify an object and represent a hierarchically assigned namespace. OIDs are formally defined using the International Telecommunications Union ASN.1 standard[4]. OIDS are represented as follows:

[3] Global Medical Device Nomenclature (GMDN) is a system of internationally agreed descriptors used to identify medical device products and is managed by the GMDN Agency. Visit: https://www.gmdnagency.org.

[4] International Telecommunication Union, x680: Information technology – Abstract Syntax Notation One (ASN.1): Specification of basic notation

- Example – An OID is a string of digits separated by periods: 2.16.840.1.113883

The list of named branches is as follows: {joint-iso-itu-t(2) country(16) us(840) organization(1) hl7(113883)}.

In the AusUDID HL7 SPL submission, OIDs will be used to provide the codeSystem value for each element that requires a code. Each required element with a code will indicate when an OID should be provided. For example, the XML Snippet below illustrates the code element with a code (C101716 is the code value for a AusUDID Submission) and codeSystem (2.16.840.1.113883.3.26.1.1 is the OID for the NCI Thesaurus code system):

```
<code code="C101716" codeSystem="2.16.840.1.113883.3.26.1.1"/>
```

For specific OIDs used in the AusUDID implementation, refer to the AusUDID Code List document which is part of the AusUDID HL7 SPL Implementation package of files.

4.2.2 Universally Unique Identifiers

A UUID is a hexadecimal number in the form of 8-4-4-4-12, including 32 characters and 4 hyphens[5]. UUIDs are formally defined by ISO/IEC 11578:1996 and ITU-T Rec X.667 | ISO/IEC 9834-8:2005. UUIDs are represented as follows:

- String of characters separated by hyphens: 36589652-7894-6589-3256-321852697531

In the AusUDID HL7 SPL Submission, UUIDs will be used for any instance identifier root attribute value. Each required element with an identifier (e.g. id or code) will indicate when a UUID should be provided. For example, the XML Snippet below illustrates the id@root attribute for the SPL Submission that includes a globally unique value (760ae98c-eada-4678-90f4-fe97232292ce) for an identifier – e.g. document identifier:

```
<id root="760ae98c-eada-4678-90f4-fe97232292ce"/>
```

4.3 Data types

To provide all information required in the HL7 SPL message, the data types are represented as additional elements and attributes in the XML. The data type for the elements and attributes are as follows:

- Alpha: allowing only alpha characters to be used in a string.
- Alphanumeric: allowing alpha, numeric and special characters to be used in a string. XML should follow W3C standards for alphanumeric values.
- Special Characters: When adding special characters to AusUDID HL7 SPL XML submissions, you need to use decimal or hex forms of the ISO Latin codes. More information can be found here: http://www.w3schools.com/charsets/ref_html_utf8.asp. We recommend you fully test the special characters you plan to submit before submitting it in the Production environment. For a list of special characters that are tested and will be accepted as part of AusUDID UDI record submissions, please refer to the AusUDID Code List document which is part of the AusUDID HL7 SPL Implementation package of files. The comments column highlights exceptions.

[5] International Telecommunication Union, x667: Information technology – Open Systems Interconnection – Procedures for the operation of OSI Registration Authorities: Generation and registration of Universally Unique Identifiers (UUIDs) and their use as ASN.1 object identifier components

- Numeric: only allows numeric characters (e.g. 0 through 9) to be used in a string for integers and real numbers.
- Boolean: allows a true or false value.
- nullFlavors: used when required values need to be left blank. Null flavors are based on HL7 Messaging standard.[6]

4.4 AusUDID HL7 SPL XML schema

The HL7 SPL XML Schema will be provided as a flattened schema file with all the necessary schema files for AusUDID implementation.

4.5 AusUDID HL7 SPL XML message

The following AusUDID HL7 SPL message components are based on HL7 Version 3 SPL DSTU Release 5. The information for each element is provided in discrete sections. The following table provides a breakdown of the SPL XML structure with the relevant elements presented in this document.

XML Structure
The XML starts with administrative information about the XML file, including the XML version and encoding found in the XML. The ***Document*** element contains information about the AusUDID UDI Record and relates to the ***author.assignedEntity***, which provides information about the submitting organisation.

```
<?xml version="1.0" encoding="UTF-8"?>
<document xmlns="urn:hl7-org:v3"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xsi:schemaLocation="urn:hl7-org:v3 ../SPL.xsd">
<id root="80c7aca6-9307-4722-aa63-c40ef1fd6f36"/>
<code code="C101716" codeSystem="2.16.840.1.113883.3.26.1.1"/>
<effectiveTime  xsi:type="TS" value="20120531"/>
<setId  root="57863671-1527-4e51-b26b-3065a868d949"/>
<versionNumber value="1"/>
<author>
<assignedEntity>
<representedOrganization>
<assignedEntity1>
<code code=""/>
<representedOrganization>
</representedOrganization>
</assignedEntity1>
</representedOrganization>
</assignedEntity>
</author>
```

[6] Currently, nullFlavors are not used in the AusUDID HL7 SPL submission.

XML Structure
StructuredBody contains the product information for a UDI record. ***ManufacturedProduct*** element contains the key information about the medical device. ***AsIdentifiedEntity*** elements contain information about the device's model/version number, approval to supply, supporting documents and any other identifying value that may not be globally unique. (Note: this element can be repeated as many times as necessary.) ***AsSpecializedKind*** elements contain information about the classification of the medical device and the GMDN code. (Note: this element can be repeated as many times as necessary.) ***asEquivalentEntity*** elements contain information about the medical device that are considered alternative identifiers to the Primary DI. This includes Secondary DI, Direct Marked DI and unit-of-use DI values. (Note: this XML element can be repeated as many times as necessary, but the cardinality of each data element requires conformance – e.g. you can only provide one direct marking or unit-of-use device identifier.) ***asContent*** elements contain information about the base packaging, device count and any packaging configurations (and their DI). (Note: the ***containerPackagedProduct*** element can be repeated as many times as necessary.) ***subjectOf*** elements contain one of the following types of data: production information characteristics and device characteristics such as Sterilisation methods and Clinical Sizes.

```
<component>
<structuredBody>
<component>
    <section>
        <subject>
            <manufacturedProduct>
                <manufacturedProduct>
                <code></code>
                <name></name>
                <desc></desc>
                <asIdentifiedEntity>
                    <id></id>
                    <code></code>
                    <assigningOrganization>
                        <id></id>
                    </assigningOrganization>
                    <subjectOf>
                        <document>
                            <id></id>
                            <code></code>
                            <effectiveTime>
                                <low />
                                <high />
                            </effectiveTime>
                        </document>
                    </subjectOf>
                </asIdentifiedEntity>
                <asSpecializedKind>
                    <generalizedMaterialKind>
                    <code></code>
                    </generalizedMaterialKind>
                </asSpecializedKind>
                <asEquivalentEntity>
                    <code></code>
                    <definingMaterialKind>
                        <code></code>
                    </definingMaterialKind>
                </asEquivalentEntity>
                 <asContent>
```

XML Structure

```
                        <quantity>
                            <numerator></numerator>
                            <denominator></denominator>
                        </quantity>
                        <containerPackagedProduct>
                            <code></code>
                            <name></name>
                            <capacityQuantity></capacityQuantity>
                            <asManufacturedProduct>
                                <subjectOf>
                                    <marketingAct>
                                        <effectiveTime></effectiveTime>
                                    </marketingAct>
                                </subjectOf>
                            </asManufacturedProduct>
                        </containerPackagedProduct>
                    </asContent>
                    </manufacturedProduct>
                    <subjectOf>
                        <characteristic>
                            <code></code>
                            <value xsi:type="CD"></value>
                        </characteristic>
                    </subjectOf>
                </manufacturedProduct>
            </subject>
        </section>
    </component>
    </structuredBody>
    </component>
</document>
```

4.6 HL7 element - displayName

DisplayName is optional in all cases where it is shown. It is provided only to allow the message to be more easily understood if it is being viewed by a person.

It does not need to be included in the M2M HL7 submission.

5 AusUDID HL7 SPL submission

The following section outlines the implementation specific rules for creating an AusUDID HL7 SPL submission that will be compliant with the AusUDID HL7 SPL schema and AusUDID business rules. The content is organised by the order of the elements as they appear in the XML file, see AusUDID HL7 SPL XML message.

5.1 SPL document

The ***document*** element includes specific information about the AusUDID HL7 SPL submission, to include required schema attributes (e.g***. xmlns, xmlns:xsi*** and ***xsi:schemaLocation***), a unique identifier of the SPL submission (***id@root***), a document type code to indicate that the HL SPL submission is a AusUDID submission, the publish date of the UDI record, and a versioning set identifier and version number to maintain the AusUDID submission over time. Additional details on the following XML elements are provided below – ***document.id, document.code, document.code.translation, document.effectiveTime, setId*** and ***versionNumber.***

The following is an example of the XML section related to the AusUDID Submission information:

```
<document xmlns="urn:hl7-org:v3" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xsi:schemaLocation="urn:hl7-org:v3 GUDIDSPL.xsd">
    <id root="57863671-1527-4e51-b26b-3065a868d949"/>
    <code code="C101716" codeSystem="2.16.840.1.113883.3.26.1.1"/>
    <effectiveTime xsi:type="TS" value="20131118"/>
    <setId root="57863671-1527-4e51-b26b-3065a868d948"/>
    <versionNumber value="1"/>
```

5.1.1 AusUDID submission Identifier (document.id)

Element	Attribute	Cardinality		Value(s) Allowed *Examples*	Description *Instructions*
id		1..1			This is the container element for the AusUDID submission identifier.
	Root	1..1		*UUID*	This is a globally unique identifier for the AusUDID submission.
		XPATH: /document/id/@root			
Business Rules	• The ***id@root*** should always be globally unique. Do not reuse document identifiers even if resending a submission after a submission failure.				

5.1.2 Types of submission (document.code)

The document.code indicates the type of HL7 SPL submission. AusUDID allows 2 values, C101716 to indicate the UDI record is being created or varied, and AU1002 to indicate the UDI record is being corrected.

5.1.2.1 Submission – create or vary (document.code)

```
<code code="C101716" codeSystem="2.16.840.1.113883.3.26.1.1"/>
```

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
Code		1..1		This is the container element for the type of AusUDID submission.
	Code	1..1	Alphanumeric C101716	This is the ***code*** for the type of document being sent via the XML Message.
	XPATH: /document/code/@code			
	codeSystem	1..1	OID 2.16.840.1.113883. 3. 26.1.1	This is the unique identifier for the ***codeSystem*** associated with the code attribute.
	XPATH: /document/code[@code=”C101716”]/@codeSystem			
Business Rules	• There must be one and only one code attribute for “C101716” or “AU1002” • The ***code*** attribute must have the value of “C101716” for Vary message • If the value is different, or missing, or both codes exist, or are given more than once, the AusUDID submission will be rejected as a submission with an invalid document code • No other processing or validation will be completed if there is an invalid document code.			

5.1.2.2 Submission – correction

```
<code code="AU1002" codeSystem="1.2.36.1.2001.1005.85">
```

Element	Attribute	Cardinality	Value(s) Allowed *Examples*	Description *Instructions*
Code		1..1		This is the container element for the type of AusUDID submission.
	Code	1..1	Alphanumeric AU1002	This is the ***code*** for the type of document being sent via the XML Message.
	XPATH: /document/code/@code			
	codeSystem	1..1	OID 1.2.36.1.20 01.1005.85	This is the unique identifier for the ***codeSystem*** associated with the code attribute.
	XPATH: /document/code[@code=”AU1002”]/@codeSystem			
Business Rules	• There must be one and only one code attribute for “C101716” or “AU1002” • The ***code*** attribute must have the value of “AU1002” for Correction • If the value is different, or missing, or both codes exist, or are given more than once, the AusUDID submission will be rejected as a submission with an invalid document code • No other processing or validation will be completed if there is an invalid document code.			

5.1.2.2.1 Translation – use a correction reason code (document.code.translation)

```
<code code="AU1002" codeSystem="1.2.36.1.2001.1005.85">
    <translation code="AU1031" displayName="Data entry error"/>
```

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
Translation		1..1		This is the container element for the type of AusUDID submission.
	Code	1..1	Alphanumeric AU1031 AU1032 AU1034	This is the ***code*** for the reason for this correction message.
	XPATH: /document/code[@code="AU1002”]/translation/@code			
Business Rules	• Translation element code or originalText is required if document/code [@code="AU1002”] • The value must be one of the allowed values: ○ AU1031 ○ AU1032 ○ AU1034 • See the *M2M HL7 SPL - SPL Code List - AusUDID* for a definition and when to use these codes • If the value is missing, or both code and originalText is given, or are given more than once, the AusUDID submission will be rejected as a submission with an invalid translation code.			

5.1.2.2.2 Translation – use a free text correction reason (document.code.translation)

```
<code code="AU1002" codeSystem="1.2.36.1.2001.1005.85">
    <translation>
        <originalText>Free-text reason for correction</originalText>
    </translation>
</code>
```

Element	Attribute	Cardinality	Value(s) Allowed *Examples*	Description *Instructions*
originalText		0..1		This is the container element for the type of AusUDID submission.
		1..1	Alphanumeric *E.g. Free text reason for correction*	This is a free text reason for the correction, where one of the coded reasons is not suitable.
	XPATH: /document/code[@code="AU1002”]/translation/originalText/text()			
Business Rules	• Translation element code or originalText is required if document/code [@code="AU1002”] • The reason provided must be no more than 80 characters and length and can only contain accepted special characters. Refer to Data types and the *M2M HL7 SPL - SPL Code List – AusUDID* for a list of accepted special characters.			

	• If the value is missing, or both code and originalText is given, or are given more than once, the AusUDID submission will be rejected as a submission with an invalid translation code.

5.1.3 Device Identifier (DI) record publish date (document.effectiveTime)

The UDI record Publish date indicates the date the UDI record can be published and made available via public search. The following XML snippet includes the elements and attributes required for the UDI record Publish date:

```
<document xmlns="urn:hl7-org:v3" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xsi:schemaLocation="urn:hl7-org:v3 GUDIDSPL.xsd">
    <id root="57863671-1527-4e51-b26b-3065a868d949"/>
    <code code="C101716" codeSystem="2.16.840.1.113883.3.26.1.1"/>
    <effectiveTime xsi:type="TS" value="20131118"/>
    <setId root="57863671-1527-4e51-b26b-3065a868d948"/>
    <versionNumber value="1"/>
```

5.1.3.1 DI record publish date (document.effectiveTime)

Element	Attribute	Cardinality	Value(s) Allowed *Examples*	Description *Instructions*
effectiveTime		1..1		This is the container element for the UDI record Publish Date
	xsi:type	1..1	Timestamp *TS*	The **xsi:type** indicates the data type for the element.
	XPATH: /document/effectiveTime/@xsi:type			
	Value	1..1	Date Format YYYYMMDD e.g. “20111016”	This is the publish date value for the UDI record.
	XPATH: /document/effectiveTime/@value			
Business Rules	• The date must follow the format YYYYMMDD • The date may be a past, current or future date. It would normally be the current date for immediate publishing, or a future date • If the value is missing, invalid, or given more than once, the AusUDID submission will be rejected as a submission with an invalid UDI record Publish Date • If the date is in the past or is the current date, the UDI record will be published immediately • If the date is in the past, the UDI record publish date will be the date AusUDID receives the UDI record.			

5.1.4 AusUDID submission versioning set identifier (document.setId)

```
<document xmlns="urn:hl7-org:v3" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xsi:schemaLocation="urn:hl7-org:v3 GUDIDSPL.xsd">
    <id root="57863671-1527-4e51-b26b-3065a868d949"/>
    <code code="C101716" codeSystem="2.16.840.1.113883.3.26.1.1"/>
    <effectiveTime xsi:type="TS" value="20131118"/>
    <setId root="57863671-1527-4e51-b26b-3065a868d948"/>
    <versionNumber value="1"/>
```

Element	Attribute	Cardinality	Value(s) Allowed *Examples*	Description *Instructions*
setId		1..1		This is the container element for the versioning set identifier.
	Root	1..1	UUID	This is the unique identifier used to track a document and its versions.
	XPATH: /document/setId/@root			
Business Rules	• The ***setId*** element is the attribute used to keep updates linked to the initial UDI submission. This value will be unique for a UDI record • For initial AusUDID submissions the ***setId*** must be unique; if the ***setId*** is already in the system, the submission will be rejected • For all submission updates, before or after the Grace Period, the ***setId*** should already be in the system for the Primary DI and should be used with the ***versionNumber*** incremented by one • An organisation may change the ***setId.*** The **versionNumber** must be restarted at 1 and the old ***setId*** will be made inactive • A ***setId*** cannot be used after it has been made inactive • For first time edits to UDI records initially entered via a different channel, provide a new ***setId*** since other channels will not have a ***setId*** • If the ***setId*** is missing, invalid, given more than once, not unique (exists for another organisation or another UDI record), or has been marked as inactive, the AusUDID submission will be rejected as a submission with an invalid ***setId***.			

5.1.5 AusUDID submission version number (document.versionNumber)

```
<document xmlns="urn:hl7-org:v3" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xsi:schemaLocation="urn:hl7-org:v3 GUDIDSPL.xsd">
    <id root="57863671-1527-4e51-b26b-3065a868d949"/>
    <code code="C101716" codeSystem="2.16.840.1.113883.3.26.1.1"/>
    <effectiveTime xsi:type="TS" value="20131118"/>
    <setId root="57863671-1527-4e51-b26b-3065a868d948"/>
    <versionNumber value="1"/>
```

Element	Attribute	Cardinality	Value(s) Allowed *Examples*	Description *Instructions*
versionNumber		1..1		This is the container element for the AusUDID submission version number.
	Value	1..1	Integer *e.g. 1, 2, 3*	The ***value*** attribute provides the version of document that is being sent in the message.

	XPATH: /document/versionNumber/@value
Business Rules	• The value attribute should increment by one for each update • A ***versionNumber*** cannot be incremented for an inactive ***setId*** • For first time edits to UDI records initially entered via a different channel, provide a new ***versionNumbe***r since other channels will not have a ***versionNumber*** • The combination of ***setId*** and ***versionNumber*** shall be unique for the UDI record (i.e. for that Primary DI, the combination should not already exist in the database) • See Versioning HL7 SPL submissions for more information • If the versionNumber is missing, invalid, given more than once, not 1 for a new ***setId***, is not 1 more than the stored versionNumber, the AusUDID submission will be rejected as a submission with an invalid versionNumber.

5.2 Submitter

Device information can be submitted to the AusUDID by Manufacturers, Sponsors, Agents or third parties. Each AusUDID HL7 SPL xml submission must indicate the author of the document, i.e. the document sender.

Note: AusUDID does not use DUNS numbers.

- Labeller as the sender of the HL7 SPL xml submission – used by the Manufacturer and must provide the TGA Business Services (TBS) Organisation number for the Manufacturer.
- Sponsor as sender of the HL7 SPL xml submission – used by the Sponsor and must provide the TBS Organisation number for the Sponsor.
- Agent as sender of the HL7 SPL xml submission – used by an organisation registered as an Agent within TBS and must provide the TBS Organisation number for the Agent.
- A Third Party Data Provider who is not registered in TBS as an Agent must provide the TBS Organisation number for the Sponsor or Manufacturer on whose behalf they are providing the data.

Prior to submitting data to AusUDID, you should organise, collect and validate your data.

During HL7 SPL submission processing, the “sender” is authenticated via the API keys that accompany the message, i.e. the “sender” and the API subscription keys must be for the same organisation.

If the sender organisation does not match the API subscription keys, or is not associated to the AusUDID account, i.e. the Manufacturer, Sponsor or Agent Organisation number is not associated to the account, the entire submission will be rejected. The error message will state that that the submitter is not authorised to send AusUDID submissions for the Organisation.

5.2.1 Manufacturer organisation (author.assignedEntity.representedOrganization)

The following XML Snippet includes the elements and attributes required for the Manufacturer:

```
<author>
    <assignedEntity>
        <representedOrganization>
            <assignedEntity1>
                <code code="C101684" codeSystem="2.16.840.1.113883.3.26.1.1"/>
                <representedOrganization>
                    <id root="1.2.36.1.2001.1005.84" extension="12345"/>
                </representedOrganization>
            </assignedEntity1>
        </representedOrganization>
    </assignedEntity>
</author>
```

5.2.1.1 Manufacturer (assignedEntity1.code)

Element	Attribute	Cardinality	Value(s) Allowed *Examples*	Description *Instructions*
Code		1..1		The code element is the container for the identification of the type of submitter for the AusUDID submission.
	Code	1..1	Alphanumeric C101684	This is the ***code*** for the type of submitter for a AusUDID submission, in this case, the Manufacturer Organisation.
	XPATH: /document/author/assignedEntity/representedOrganization/assignedEntity1/code[@code="C101684"]			
	codeSystem	1..1	OID 2.16.840.1.113883. 3.26.1.1	This is the unique identifier for the ***codeSystem*** associated with the code attribute.
	XPATH: /document/author/assignedEntity/representedOrganization/assignedEntity1/code[@code="C101684"]/@codeSystem			

Business Rules	• One and only one representedOrganization is required
	• The code must be one of the allowed values:
	  ○ C101684
	  ○ AU1000
	  ○ AU1001
	  ○ C101710
	• The ***code*** attribute must have the value of “C101684” if the submitter is the Manufacturer Organisation. See Sponsor organisation if the sender is a Sponsor, or Agent organisation if the sender is an Agent
	• If the value is missing, or given more than once, the AusUDID submission will be rejected as a submission with an invalid Submitter			

	• Note: no other processing or validation will be completed if there is an invalid Submitter.

5.2.2 Sponsor organisation

The following XML Snippet includes the elements and attributes required for the Sponsor:

```
<author>
    <assignedEntity>
        <representedOrganization>
            <assignedEntity1>
                <code code="AU1000" codeSystem="1.2.36.1.2001.1005.85"/>
                <representedOrganization>
                    <id root="1.2.36.1.2001.1005.84" extension="12345"/>
                </representedOrganization>
            </assignedEntity1>
        </representedOrganization>
    </assignedEntity>
</author>
```

5.2.2.1 Sponsor (assignedEntity1.code)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
Code		1..1		The code element is the container for the identification of the type of submitter for the AusUDID submission.
	Code	1..1	Alphanumeric AU1000	This is the ***code*** for the type of submitter for a AusUDID submission, in this case, the Sponsor Organisation.
	XPATH: /document/author/assignedEntity/representedOrganization/assignedEntity1/code[@code="AU1000"]			
	codeSystem	1..1	OID 1.2.36.1.2001.1005.85	This is the unique identifier for the ***codeSystem*** associated with the code attribute.
	XPATH: /document/author/assignedEntity/representedOrganization/assignedEntity1/code[@code=”AU1000”]/@codeSystem			
Business Rules	• One and only one representedOrganization is required • The code must be one of the allowed values: ○ C101684 ○ AU1000 ○ AU1001 ○ C101710			

	• The ***code*** attribute must have the value of “AU1000” if the submitter is the Sponsor Organisation. See Section Manufacturer organisation (author.assignedEntity.representedOrganization) if the sender is a Manufacturer, or Agent organisation if the sender is an Agent • If the value is missing, or given more than once, the AusUDID submission will be rejected as a submission with an invalid Submitter • Note: no other processing or validation will be completed if there is an invalid Submitter.

5.2.3 Agent organisation

The following XML Snippet includes the elements and attributes required for the Agent:

```
<author>
    <assignedEntity>
        <representedOrganization>
            <assignedEntity1>
                <code code="AU1001" codeSystem="1.2.36.1.2001.1005.85"/>
                <representedOrganization>
                    <id root="1.2.36.1.2001.1005.84" extension="12345"/>
                </representedOrganization>
            </assignedEntity1>
        </representedOrganization>
    </assignedEntity>
</author>
```

5.2.3.1 Agent (assignedEntity1.code)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
Code		1..1		The code element is the container for the identification of the type of submitter for the AusUDID submission.
	Code	1..1	Alphanumeric AU1001	This is the ***code*** for the type of submitter for a AusUDID submission, in this case, the Agent Organisation.
	XPATH: /document/author/assignedEntity/representedOrganization/assignedEntity1/code[@code="AU1001"]			
	codeSystem	1..1	OID 1.2.36.1.2001.1005.85	This is the unique identifier for the ***codeSystem*** associated with the code attribute.
	XPATH: /document/author/assignedEntity/representedOrganization/assignedEntity1/code[@code="AU1001"]/@codeSystem			
Business Rules	• One and only one representedOrganization is required • The code must be one of the allowed values			

	○ C101684 ○ AU1000 ○ AU1001 ○ C101710 • The ***code*** attribute must have the value of “AU1001” if the submitter is the Agent Organisation. See Manufacturer organisation (author.assignedEntity.representedOrganization) if the sender is a Manufacturer, or see Sponsor organisation if the sender is a Sponsor • If the value is missing, or given more than once, the AusUDID submission will be rejected as a submission with an invalid Submitter • Note: no other processing or validation will be completed if there is an invalid Submitter.

5.2.4 Third Party Data Provider

The following XML Snippet includes the elements and attributes required for the Third Party Data Provider:

```
<author>
    <assignedEntity>
        <representedOrganization>
            <assignedEntity1>
                <code code="C101710" codeSystem="2.16.840.1.113883.3.26.1.1"/>
                <representedOrganization>
                    <id root="1.2.36.1.2001.1005.84" extension="12345"/>
                </representedOrganization>
            </assignedEntity1>
        </representedOrganization>
    </assignedEntity>
</author>
```

5.2.4.1 Third Party Data Provider (assignedEntity1.code)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
Code		1..1		The code element is the container for the identification of the type of submitter for the AusUDID submission.
	Code	1..1	Alphanumeric C101710	This is the ***code*** for the type of submitter for a AusUDID submission, in this case, the Third Party Data Provider.
	XPATH: /document/author/assignedEntity/representedOrganization/assignedEntity1/code[@code="C101710"]			
	codeSystem	1..1	OID 2.16.840.1.113883. 3.26.1.1	This is the unique identifier for the ***codeSystem*** associated with the code attribute.

	XPATH: /document/author/assignedEntity/representedOrganization/assignedEntity1/code[@code="C101710"]/@codeSystem

Business Rules	• One and only one representedOrganization is required
	• The code must be one of the allowed values:
	  ○ C101684
	  ○ AU1000
	  ○ AU1001
	  ○ C101710
	• The ***code*** attribute must have the value of "C101710" if the submitter is a Third Party Data Provider. See Sponsor organisation if the sender is a Sponsor, or Manufacturer organisation (author.assignedEntity.representedOrganization) if the sender is a Manufacturer
	• If the value is missing, or given more than once, the AusUDID submission will be rejected as a submission with an invalid Submitter
	• No other processing or validation will be completed if there is an invalid Submitter.

5.2.5 TGA organisation number (assignedEntity1.representedOrganization.id)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
Id		1..1		The id element is the container element for the TGA Organisation associated with the submitter of the AusUDID Submission.
	Root	1..1	TGA OID 1.2.36.1.2001.1005.84	This is the OID for TGA Organisations.
	XPATH: /document/author/assignedEntity/representedOrganization/assignedEntity1/representedOrganization/id/@root			
	Extension	1..1	Organisation Number e.g. 12345	This is the assigned TGA Organisation number.
	XPATH: /document/author/assignedEntity/representedOrganization/assignedEntity1/representedOrganization/id/@extension			
Business Rules	• The ***root*** attribute should provide the TGA OID • The ***extension*** attribute should provide a value for the TGA Organisation number • The ***id@extension*** will be used to pull the Organisation Name from the TGA stakeholder management system			

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
	• If the submitter is a Manufacturer, the Organisation number provided here must match the Manufacturer ID • If the submitter is a Sponsor, the Organisation number provided here must match the Sponsor ID • If the submitter is an Agent, the Agent must be an Agent for either the Manufacturer or Sponsor • If the submitter is an Agent, the Agent number provided here will be checked against the Manufacturer ID and Sponsor ID. See Manufacturer (manufacturerOrganization.id) for Manufacturer ID of the medical device, i.e. the manufacturer associated to the UDI record. Sponsor (asIdentifiedEntity.assigningOrganization.id) for Sponsor ID for the medical device, i.e. the sponsor associated to the UDI record. In this case, the Submitter must be an Agent for either the Manufacturer or Sponsor • If the submitter is a Third Party Data Provider, use the organisation number for the organisation on whose behalf you are providing the data • If the submitter value is missing, or given more than once, the AusUDID submission will be rejected as a submission with an invalid Submitter • No other processing or validation will be completed if there is an invalid Submitter • Must be a valid TBS organisation number			

5.3 Device information

The device information in the manufactured product element includes the following: the Primary DI, brand name, device description, model or version number, catalogue number, approval to supply, device class, GMDN Preferred Term code, manufacturer, alternative identifiers (Unit of Use, Direct Marking, Secondary DIs), base package device count and package configurations. This section includes all device information listed above in the relative order that it should appear.

Note: that some elements can be serialised (repeated) and the order in the XML is not strictly defined. The elements that fit in this category are as follows:

- Identified Entity – includes how the Manufacturer may identify a medical device – e.g. model or version number and catalogue number, and the Sponsor approval to supply details
- Specialized Kind – includes device class, and GMDN Preferred Term Code
- Equivalent Entity – includes all device identifiers that are of equivalent representation of a medical device – e.g. Unit of Use DI, Direct Marked DI, and Secondary DI
- Manufacturer Organization – identifies the manufacturer of the device.

The order of the elements in the XML is only critical to group them in like elements and in the order presented above – i.e. all ***IdentifiedEntity*** elements are placed before ***SpecializedKind*** elements and all ***EquivalentEntity*** elements are last in the order. Specific instructions are provided in the subsections below.

5.3.1 Device identifier (DI) information – Primary Device Identifier

The Primary Device Identifier (Primary DI) is an identifier that is the main (primary) lookup for a medical device product and meets the requirements to uniquely identify a device through its distribution and use. The Primary DI will be located on the base package, which is the lowest level of a medical device containing a full UDI. The following XML snippet shows the Primary DI:

```
<subject>
    <manufacturedProduct classCode="MANU">
        <manufacturedProduct>
            <code code="10010010010011" codeSystem="1.3.160"/>
            <name>Trade Name/Brand Name</name>
            <desc>add device description here</desc>
```

5.3.1.1 ManufacturedProduct classCode

The ***manufacturedProduct@classCode*** value must be equal to “MANU” to pass schema validation. Any other value in this field may cause the schema validation to fail.

Primary Device Identifier (manufacturedProduct.code)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
code (1..1)		1..1		This is the container element for the Primary DI.
	code	1..1	Numeric or Alphanumeric e.g. 14-digit number	This is the device identifier for the Record.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/code/@code			
	codeSystem	1..1	OID GS11.3.160 HIBCC 2.16.840.1.113883.6.40 ICCBBA 2.16.840.1.113883.6.18	This is the identifier for the Issuing Agency for the DI.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/code/@codeSystem			
Business Rules	• One and only one manufacturedProduct.code is required • See Common DI Validation. • One and only one manufacturedProduct.code@codeSystem is required • codeSystem must be one of the valid values: GS1, ICCBBA, HIBCC • If the code is missing, invalid, or given more than once, the AusUDID submission will be rejected as a submission with an invalid Primary DI			

	• If the codeSystem is missing, or given more than once, or does not match the format for the Primary DI Issuing Agency, the AusUDID submission will be rejected as a submission with an invalid Primary DI • No other processing or validation will be completed if there is an invalid Primary DI.

5.3.2 Device information – Brand Name

Brand Name is a trade/proprietary name assigned by the device manufacturer, and under which the device is sold, distinguished from other similar devices, and recognised by the user or purchaser. A brand name is often registered and/or protected by a trademark.

The following XML Snippet includes the brand name element:

```
<subject>
    <manufacturedProduct classCode="MANU">
        <manufacturedProduct>
            <code code="10010010010011" codeSystem="1.3.160"/>
            <name>Trade Name/Brand Name</name>
            <desc>add device description here</desc>
```

5.3.2.1 ManufacturedProduct.name

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
name		1..1		The ***name*** element is the container element for describing the Brand/Proprietary, Trade name of the medical device product.
		1..1	Alphanumeric[7] e.g. Brand Name	This is the value for the brand name of the medical device.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/name/text()			
Business Rules	• One and only one manufacturedProduct.name is required • The Brand Name should be no more than 80 characters in length and can only contain accepted special characters. Refer to Data types and the *M2M HL7 SPL - SPL Code List – AusUDID* in the HL7 SPL Implementation package of files for a list of accepted special characters			

[7] Refer to 'AusUDID_SPLCodeList.xls' file in the HL7 SPL Implementation package of files for a list of accepted special characters

	• If the value is missing, invalid, or given more than once, the AusUDID submission will be rejected as a submission with an invalid Brand name.

5.3.3 Device Information – Device Description

The device description provided by the Manufacturer should provide any additional relevant information about the device that is not already captured as a distinct AusUDID data attribute. The following XML Snippet includes the elements and attributes required for the description:

```
<subject>
    <manufacturedProduct classCode="MANU">
        <manufacturedProduct>
            <code code="10010010010011" codeSystem="1.3.160"/>
            <name>Trade Name/Brand Name</name>
            <desc>add device description here</desc>
```

5.3.3.1 ManufacturedProduct.desc

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
Desc		0..1		This is a container element for the medical device's description.
		1..1	Alphanumeric[8] E.g. Device Description	This is the description of the medical device that is provided by the Manufacturer.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/desc/text()			
Business Rules	• manufacturedProduct.desc is optional, but can only be provided once • The Description should be no more than 2000 characters in length and can only contain accepted special characters. Refer to Data types and the *M2M HL7 SPL - SPL Code List - AusUDID* in the HL7 SPL Implementation package of files for a list of accepted special characters • If the value is invalid, or given more than once, the AusUDID submission will be rejected as a submission with an invalid Device Description.			

[8] Refer to 'AusUDID_SPLCodeList.xls' file in the HL7 SPL Implementation package of files for a list of accepted special characters

5.3.4 Device Information – Model or Version

The model or version number found on the device label or accompanying packaging used to identify a category or design of a device. The model or version identifies all devices that have specifications, performance, size, and composition within limits set by the Manufacturer. The following XML Snippet includes the elements and attributes for the model or version number:

```
<asIdentifiedEntity>
    <id root="12345678-1234-1234-1234-123456789012" extension="Model T-1000"/>
    <code code="C99285" codeSystem="2.16.840.1.113883.3.26.1.1"/>
</asIdentifiedEntity>
```

The following elements will be found in the AusUDID HL7 SPL submission:

5.3.4.1 Model or Version Number (asIdentifiedEntity.id)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
Id		0..1		This is the container element for the model number.
	Root	1..1	UUID	This is a globally unique identifier for the id being provided.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asIdentifiedEntity/code[@code="C99285"]/../id/@root			
	Extension	1..1	Alphanumeric[9] e.g. Model A1	This is used to indicate any additional identifiers for the ManufacturedProduct.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asIdentifiedEntity/code[@code="C99285"]/../id/@extension			
Business Rules	• The ***asIdentifiedEntity.id@root***, is a globally unique identifier, which is required by the schema; it should be unique to the Model Number that is provided in the extension. Currently we do not use this value in the AusUDID – i.e. it does not have any business rules associated with it • Only the ***id@extension*** value will be displayed by the AusUDID system for the model number or version number • asIdentifiedEntity with code 'C99285' and/or 'C99286' must be provided. • The Version or Model should be no more than 80 characters in length and can only contain accepted special characters. Refer to Data types and the *M2M HL7 SPL - SPL Code List – AusUDID* in the HL7 SPL Implementation package of files for a list of accepted special characters			

[9] Refer to 'AusUDID_SPLCodeList.xls' file in the HL7 SPL Implementation package of files for a list of accepted special characters

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
	• If Model or Version is missing, or code C99285 is provided and Model or Version is missing, invalid, or given more than once, the AusUDID submission will be rejected as a submission with an invalid Model or Version.			

5.3.4.2 Model or Version Number Type (asIdentifiedEntity.code)

The code identifies that the data element is providing a Model or Version Number value.

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
Code		1..1		This is the container element that identifies the ***identifiedEntity*** as the model or version number.
	Code	1..1	Alphanumeric C99285	This is the ***code*** that indicates the value is a model or version number.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asIdentifiedEntity/code[@code="C99285"]			
	codeSystem	1..1	OID 2.16.840.1.113883.3.26 .1.1	This is the ***codeSystem*** that manages the controlled vocabulary.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asIdentifiedEntity/code[@code="C99285"]/@codeSystem			
Business Rules	• Model or version number must be provided • The code value must be provided and have a value of “C99285” for the model or version number.			

5.3.5 Device Information – Catalogue Number

The catalogue, reference, or product number used by the Sponsor and found on the device label or accompanying packaging to identify a particular product should be included in the UDI record if applicable. Catalogue Number is critical for UDI adoption in electronic health records. Please provide catalogue number as part of your UDI record. The following XML Snippet includes the elements and attributes for the catalogue number:

```
<asIdentifiedEntity>
    <id root="12345678-1234-1234-1234-123456789013" extension="Catalog-1000"/>
    <code code="C99286" codeSystem="2.16.840.1.113883.3.26.1.1"/>
</asIdentifiedEntity>
```

The following elements will be found in the AusUDID HL7 SPL submission:

5.3.5.1 Catalogue Number (asIdentifiedEntity.id)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
Id		0..1		This is the container element for the catalogue number.

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
	Root	1..1	UUID	This is a globally unique identifier for the id being provided.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asIdentifiedEntity/code[@code="C99286"]/../id/@root			
	Extension	1..1	Alphanumeric[10] e.g. CatalogNumber1234	This is used to indicate any additional identifiers for the ***ManufacturedProduct***.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asIdentifiedEntity/code[@code="C99286"]/../id/@extension			
Business Rules	• The ***asIdentifiedEntity.id@root*** is a globally unique identifier, which is required by the schema; it should be unique to the Catalogue Number that is provided in the extension. Currently we do not use this value in the AusUDID – i.e. it does not have any business rules associated with it • Only the ***id@extension*** value will be displayed by the AusUDID system for the catalogue number • The Catalogue Number should be no more than 80 characters in length and can only contain accepted special characters. Refer to Data types and the *M2M HL7 SPL - SPL Code List – AusUDID* in the HL7 SPL Implementation package of files for a list of accepted special characters • If code C99286 is provided and Catalogue Number is missing, invalid, or given more than once, the AusUDID submission will be rejected as a submission with an invalid Catalogue Number • Catalogue number is not required if the message is provided by a Manufacturer. If catalogue number is provided by a Manufacturer it will be ignored • Catalogue number, if available, should be provided by a Sponsor. It will be associated with each ARTG ID included in the HL7 message.			

5.3.5.2 Catalogue Number Type (asIdentifiedEntity.code)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
Code		0..1		This is the container element that identifies the ***identifiedEntity*** as the catalogue number.

[10] Refer to 'AusUDID_SPLCodeList.xls' file in the HL7 SPL Implementation package of files for a list of accepted special characters

	Code	1..1	Alphanumeric C99286	This is the ***code*** that indicates the value is a catalogue number.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asIdentifiedEntity/code[@code="C99286"]			
	codeSystem	1..1	OID 2.16.840.1.113883.3.26 .1.1	This is the ***codeSystem*** that manages the controlled vocabulary.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asIdentifiedEntity/code[@code="C99286"]/@codeSystem			
Business Rules	• If the catalogue number element is provided, the code value must be provided and have a value of “C99286” for the catalogue number • If there is no catalogue number, the ***asIdentifiedEntity*** element should not be included with this code value.			

5.3.6 Device Information – Approval to Supply

Unless specifically exempted, Medical Devices supplied in Australia must be included on the Australian Register of Therapeutic Goods (ARTG). An application to include a device is made by a Sponsor. The Sponsor may also provide supporting documents that relate to the ARTG inclusion.

The ARTG ID, Sponsor and any supporting documents should be included in the UDI record if applicable. UDI records are only available to the Public once the Approval to Supply details have been added to the UDI record.

The following XML Snippet includes the elements and attributes for the Approval to Supply:

```
<asIdentifiedEntity>
    <id root="1.2.36.1.2001.1005.83" extension="413471"/>
    <code code="AU1016" codeSystem="1.2.36.1.2001.1005.85"/>
    <assigningOrganization>
        <id root="1.2.36.1.2001.1005.84" extension="12345"/>
    </assigningOrganization>
        <subjectOf>
        <document>
            <id extension="http://example.org/documents/123456789/product_leaflet.html"/>
            <code code="AU1008" codeSystem="1.2.36.1.2001.1005.85" displayName="Patient
                Information Leaflet"/>
            <effectiveTime>
                <low value="20010914"/>
                <high value="20200914"/>
            </effectiveTime>
        </document>
    </subjectOf>
</asIdentifiedEntity>
```

The following elements will be found in the AusUDID HL7 SPL submission:

5.3.6.1 ARTG ID (asIdentifiedEntity.id)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
Id		0..1		This is the container element for the ARTG ID.
	Root	1..1	TGA OID 1.2.36.1.2001.1005.83	This is the OID for TGA ARTG numbers
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asIdentifiedEntity/code[@code="AU1016"]/../id/@root			
	Extension	1..1	ARTG ID e.g. 12345	This is the assigned TGA ARTG ID.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asIdentifiedEntity/code[@code="AU1016"]/../id/@extension			
Business Rules	• If the Submitter is a Sponsor, one or more asIdentifiedEntity with code ‘AU1016’ must be provided • If the Submitter is a Manufacturer, asIdentifiedEntity with code ‘AU1016’ must not be provided • If ‘AU1016’ is missing for a Sponsor, or provided for a Manufacturer, the AusUDID submission will be rejected as a submission with an invalid ARTG • A UDI record can contain many ARTG IDs • The ARTG ID must be valid and must exist in the ARTG system for the same Sponsor and Manufacturer • The only data elements that are compared with the ARTG is the device Manufacturer and Sponsor.			

5.3.6.2 ARTG ID Type (asIdentifiedEntity.code)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
Code		0..1		This is the container element that identifies the ***identifiedEntity*** as the ARTG ID.
	Code	1..1	Alphanumeric AU1016	This is the ***code*** that indicates the value is an ARTG ID.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asIdentifiedEntity/code[@code="AU1016"]			

	codeSystem	1..1	OID 1.2.36.1.2001.1005.85	This is the ***codeSystem*** that manages the controlled vocabulary.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asIdentifiedEntity/code[@code="AU1016"]/@codeSystem			
Business Rules	• If the ARTG ID element is provided, the code value must be provided and have a value of "AU1016" for the ARTG ID • If there is no ARTG ID, the ***asIdentifiedEntity*** element should not be included with this code value.			

5.3.6.3 Sponsor (asIdentifiedEntity.assigningOrganization.id)

The following XML Snippet includes the elements and attributes for the Sponsor:

```
<asIdentifiedEntity>
    <id root="1.2.36.1.2001.1005.83" extension="413471"/>
    <code code="AU1016" codeSystem="1.2.36.1.2001.1005.85"/>
    <assigningOrganization>
        <id root="1.2.36.1.2001.1005.84" extension="12345"/>
    </assigningOrganization>
        <subjectOf>
        <document>
            <id extension="http://example.org/documents/123456789/product_leaflet.html"/>
            <code code="AU1008" codeSystem="1.2.36.1.2001.1005.85" displayName="Patient
                Information Leaflet"/>
            <effectiveTime>
                <low value="20010914"/>
                <high value="20200914"/>
            </effectiveTime>
        </document>
    </subjectOf>
</asIdentifiedEntity>
```

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
Id		0..1		This is the container element for the Sponsor identifier.
	Root	1..1	TGA OID 1.2.36.1.2001.1005.84	This is the OID for TGA Organisations
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asIdentifiedEntity/code[@code="AU1016"]/../assigningOrganization/id/@root			
	Extension	1..1	Organisation Number e.g. 12345	This is the assigned TGA Organisation number.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asIdentifiedEntity/code[@code="AU1016"]/../assigningOrganization/id/@extextens			

Business Rules	• Sponsor must be provided if the ARTG ID element is provided • The TBS organisation number for the Sponsor must exist within TBS • Only one Sponsor can be provided for each ARTG entry • An assigningOrganisation must be provided for each 'AU1016' • If the assigningOrganisation is missing, or given more than once, the AusUDID submission will be rejected as a submission with an invalid ARTG.

5.3.6.4 Supporting Document URL (asIdentifiedEntity.subjectOf.document.id)

Supporting documents can be provided if an ARTG ID has been provided. The following XML Snippet includes the elements and attributes for Supporting Documents:

```
<asIdentifiedEntity>
    <id root="1.2.36.1.2001.1005.83" extension="413471"/>
    <code code="AU1016" codeSystem="1.2.36.1.2001.1005.85"/>
    <assigningOrganization>
        <id root="1.2.36.1.2001.1005.84" extension="12345"/>
    </assigningOrganization>
        <subjectOf>
        <document>
            <id extension="http://example.org/documents/123456789/product_leaflet.html"/>
            <code code="AU1008" codeSystem="1.2.36.1.2001.1005.85" displayName="Patient
                Information Leaflet"/>
            <effectiveTime>
                <low value="20010914"/>
                <high value="20200914"/>
            </effectiveTime>
        </document>
    </subjectOf>
</asIdentifiedEntity>
```

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
Id		0..1		This is the container element for the Supporting Document.
	Extension	1..1	Alphanumeric e.g. http://example.org/documents/123456789	This is the URL for the supporting document.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asIdentifiedEntity/code[@code="AU1016"]/../subjectOf/document/id/@extension			
Business Rules	• The URL is checked for basic formatting, but not for correctness or content • One or more subjectOf.document can be provided for each 'AU1016' • URL should be no more than 2000 characters in length • If URL is invalid, or given more than once in the document structure, the AusUDID submission will be rejected as a submission with an invalid Supporting Document.			

5.3.6.5 Supporting Document Type (asIdentifiedEntity.subjectOf.document.code)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
Code		0..1		This is the container element that identifies the type of supporting document.
	Code	1..1	Alphanumeric AU1008	This is the ***code*** that indicates the type of supporting document. AU1008 = Patient Information Leaflet.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asIdentifiedEntity/code[@code="AU1016"]/../subjectOf/document/code/@code			
	codeSystem	1..1	OID 1.2.36.1.2001.1005.85	This is the ***codeSystem*** that manages the controlled vocabulary.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asIdentifiedEntity/code[@code="AU1016"]/../subjectOf/document/code/@codeSystem			
Business Rules	• A document type must be provided if Document URL is provided • The value must be one of the allowed values: ○ AU1008 – Patient Information Leaflet • If document type is invalid, is missing when document URL is given, or given when document URL is missing, or given more than once in the document structure, the AusUDID submission will be rejected as a submission with an invalid Supporting Document.			

5.3.6.6 Supporting Document Effective and End dates (asIdentifiedEntity.subjectOf.document.effectiveTime)

The supporting document has an effective (start) date and optionally an end date. The effective date indicates when this document is effective from. If the document is no longer effective, e.g. it has been superseded, then you can include an end date.

5.3.6.7 Supporting Document Effective Date (document.effectiveTime.low)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
Low		1..1		This is the container element for the supporting document effective dates.

	value	1..1	Date Format YYYYMMDD E.g. “20111016”	This is the value for the date the supporting document is valid.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asIdentifiedEntity/code[@code="AU1016"]/../subjectOf/document/effectiveTime/low/@value			
Business Rules	• A document effective date must be provided if Document URL is provided • The date must follow the format YYYYMMDD • It must be a valid date – Current or in the past • If document effective date is invalid, is missing when document URL is given, or given when document URL is missing, or given more than once in the document structure, the AusUDID submission will be rejected as a submission with an invalid Supporting Document.			

5.3.6.8 Supporting Document End Date (document.effectiveTime.high)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
High		0..1		This is the container element for the supporting document effective dates.
	value	1..1	Date Format YYYYMMDD E.g. “20111016”	This is the value for the date the supporting document is no longer valid.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asIdentifiedEntity/code[@code="AU1016"]/../subjectOf/document/effectiveTime/high/@value			
Business Rules	• A document end date may be provided if Document URL is provided. The date is only provided when the document is no longer valid • The date must follow the format YYYYMMDD • It must be a valid date – Current or in the past • If document end date is invalid, the end date occurs before the document effective date, or given when document URL is missing, or given more than once in the document structure, the AusUDID submission will be rejected as a submission with an invalid Supporting Document.			

5.3.6.8.1 Supporting Documents Behaviour

Supporting documents (currently Patient Information Leaflet) may be provided to AusUDID by either uploading a pdf attachment via the portal, or by providing a URL that can be used to obtain the document.

Within the bulk channels – only a URL can be provided. The URL can point to a specific document, or a website location that can be used to search for and retrieve the relevant document.

If a replaced document is to remain available to the public, then the document details are provided to AusUDID and an end date is provided. There is no validation check to ensure that the URLs for the old and new locations of supporting documents are different in AusUDID submissions.

If a replaced document is not to remain available to the public, then the document details are no longer provided to AusUDID. AusUDID will mark the document as deleted.

5.3.6.8.2 Examples for specific document

Examples when a Sponsor provides a URL that points to a specific document.

a) When a Sponsor adds a URL, they provide the following data:

ARTG ID	Type	URL	Effective Date	End Date
12345	Patient Information Leaflet	https://example.com/doc/device-v1.pdf	01/07/2023	(not provided)

b) If the Sponsor updates the document on their site, and the document keeps the same name, then any future submission will continue to send the previous details:

ARTG ID	Type	URL	Effective Date	End Date
12345	Patient Information Leaflet	https://example.com/doc/device-v1.pdf	01/07/2023	(not provided)

c) If the Sponsor updates the document on their site, and gives the document a new name, any future submission depend on what happens to the old document version:

i) if the old document is to be removed from the site and never referenced by the public, then the submission will include the new document details, and will not include the old document details:

ARTG ID	Type	URL	Effective Date	End Date
12345	Patient Information Leaflet	https://example.com/doc/device-**v2**.pdf	02/11/2023	(not provided)

In this instance, the original document URL is marked as deleted, and the new one added.

ii) if the old document is to remain on the site for historical reference by the public, then the submission will include the new document details, and will include the old document details now with an end date:

ARTG ID	Type	URL	Effective Date	End Date
12345	Patient Information Leaflet	https://example.com/doc/device-v1.pdf	01/07/2023	01/11/2023

ARTG ID	Type	URL	Effective Date	End Date
12345	Patient Information Leaflet	https://example.com/doc/device-v2.pdf	02/11/2023	(not provided)

In this instance, the original document URL is updated with the end date, and the new one added.

5.3.6.8.3 Examples for website location

Examples when a Sponsor provides a URL that points to a website location.

a) When a Sponsor adds a URL, they provide the following data:

ARTG ID	Type	URL	Effective Date	End Date
12345	Patient Information Leaflet	https://example.com/docs	01/07/2023	(not provided)

b) If the Sponsor updates the document on their site, and the location remains the same, then any future submission will continue to send the previous details:

ARTG ID	Type	URL	Effective Date	End Date
12345	Patient Information Leaflet	https://example.com/docs	01/07/2023	(not provided)

c) If the Sponsor changes the location on their site, any future submission depend on what happens to the old location:

i) if the old location is removed from the site and never referenced by the public, then the submission will include the new location details, and will not include the old location details:

ARTG ID	Type	URL	Effective Date	End Date
12345	Patient Information Leaflet	https://example.com/pils	02/11/2023	(not provided)

In this instance, the original document URL is marked as deleted, and the new one added.

ii) if the old location is to remain on the site for historical reference by the public, then the submission will include the new location details, and will include the old location details now with an end date:

ARTG ID	Type	URL	Effective Date	End Date
12345	Patient Information Leaflet	https://example.com/docs	01/07/2023	01/11/2023

ARTG ID	Type	URL	Effective Date	End Date
12345	Patient Information Leaflet	https://example.com/pils	02/11/2023	(not provided)

In this instance, the original document URL is updated with the end date, and the new one added.

5.4 Device Status – Product Classification

The medical device can be categorised using the following two systems:

- the TGA Device Class
- the GMDN Term.

Both code systems will be used in the UDI record for a medical device:

5.4.1 TGA Device Class

Medical devices are classified according to the level of harm they may pose to users or patients. Visit https://www.tga.gov.au/resources/what-classification-my-medical-device for more information. See Device Class for additional information on submitting device class codes as part of your AusUDID UDI record submission.

5.4.2 GMDN Term

GMDN is a system of internationally agreed descriptors used to represent common device types for the purposes of grouping or categorisation. Each GMDN Term has 3 components: Term Code, Term Name, and Term Description. GMDN is managed by the GMDN Agency https://www.gmdnagency.org/.

Medical devices are classified using the GMDN Preferred Term/Term Code.

- **GMDN Preferred Term Code** –Unique five-digit code associated with a GMDN Preferred Term.

Class 1, 2 and 3 IVDs use GMDN Collective Terms (referred to as 'categories' by the GMDN Agency). Collective Terms represent a group of similar IVDs.

- **GMDN Collective Term Code** – Unique code which starts with 'CT' followed by three or four numbers.

AusUDID does not currently support the submission of Collective Term codes.

The following sections provide the details for submitting each of the product classification elements.

5.4.3 Device Class

The following XML Snippet includes the elements and attributes required for the manufacturer Device Class:

```
<asSpecializedKind>
    <generalizedMaterialKind>
        <code code="AU1020" codeSystem="1.2.36.1.2001.1005.85"/>
    </generalizedMaterialKind>
</asSpecializedKind>
```

5.4.3.1 Device Class (asSpecializedKind.generalizedMaterialKind.code)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
generalizedMaterialKind.code		1..1		This is the container element for the Device Class.
	Code	1..1	Alphanumeric AU1020 AIMD AU1021 Class III AU1022 Class IIb AU1023 Class IIa AU1024 Class Im AU1025 Class Is AU1026 Class I AU1027 Cl. 4 IVD AU1028 Cl. 3 IVD AU1029 Cl. 2 IVD AU1030 Cl. 1 IVD	This will be the ***code*** in the code system for the device class.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asSpecializedKind/generalizedMaterialKind/code[@codeSystem="1.2.36.1.2001.1005.85"]/@code			
	codeSystem	1..1	OID 1.2.36.1.2001.1005.85	This is the ***codeSystem*** that manages the controlled vocabulary.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asSpecializedKind/generalizedMaterialKind/code[@codeSystem="1.2.36.1.2001.1005.85"]			

Business Rules	• Device class is optional.
	• Device class is the classification as determined by the Manufacturer
	• Device class is not required to match what is recorded on the ARTG
	• If provided, a generalizedmaterialKind is required.
	• If the device class is invalid, or given more than once, the AusUDID submission will be rejected as a submission with an invalid Device Class
	• If provided, it must be one of the valid values:
	  ○ AU1020 AIMD
	  ○ AU1021 Class III
	  ○ AU1022 Class IIb
	  ○ AU1023 Class IIa			

	○ AU1024 Class Im ○ AU1025 Class Is ○ AU1026 Class I ○ AU1027 Class 4 IVD ○ AU1028 Class 3 IVD ○ AU1029 Class 2 IVD ○ AU1030 Class 1 IVD.

5.4.4 GMDN Term Code

The following XML Snippet includes the elements and attributes required for the GMDN Term Code:

```
<asSpecializedKind>
    <generalizedMaterialKind>
        <code code="99999" codeSystem="2.16.840.1.113883.6.276"/>
    </generalizedMaterialKind>
</asSpecializedKind>
```

5.4.4.1 GMDN Term Code (asSpecializedKind.generalizedMaterialKind.code)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
generalizedMaterialKind.code		1..1		This is the container element for the GMDN code.
	code	1..1	Numeric GMDN Code e.g. 99999	This will be the ***code*** in the code system for the concept sent to describe the medical device.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asSpecializedKind/generalizedMaterialKind/code[@codeSystem="2.16.840.1.113883.6.276"]/@code			
	codeSystem	1..1	OID 2.16.840.1.113883. 6.276	This is the ***codeSystem*** that manages the controlled vocabulary.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asSpecializedKind/generalizedMaterialKind/code[@codeSystem="2.16.840.1.113883.6.276"]			
Business Rules	• GMDN Term code is optional. • GMDN Term code is the term code as determined by the Manufacturer.			

	• GMDN Term code is not required to match what is recorded on the ARTG • If provided, it must be a valid GMDN Preferred Term Code. • It must be a 5-digit number. • Category Term Codes (codes starting with CT) are not supported. • The code will be used to pull the GMDN Term name and definition from the controlled GMDN agency vocabulary. • If an invalid e.g. the code does not exist) GMDN code is provided, the AusUDID submission will be rejected • If you feel a rejected code is active and valid, contact the GMDN Agency. If there is confirmation that the code is valid and active, contact UDI@health.gov.au and request further assistance. • If a GMDN Code is provided, a generalizedmaterialKind must be provided • If the GMDN code is invalid, or given more than once, the AusUDID submission will be rejected as a submission with an invalid GMDN Code

5.5 Device Information – Alternate or Additional Identifiers

There are three device identifiers that are considered alternate or additional identifiers for a medical device product. Each of these is considered an equivalent identifier in the SPL XML and are composed of a code that indicates the type of identifier (e.g. unit of use, direct marking or secondary), a code for the actual device identifier and the Issuing Agency of that device identifier. The alternate or additional identifiers may be any one of the following:

- **Unit of Use Device Identifier** - An identifier assigned to an individual medical device when a UDI is not labeled on the individual device at the level of its unit of use. Its purpose is to associate the use of a device to/on a patient
- **Direct Marked Device Identifier**– An identifier that is marked directly on the medical device and is different than the Primary DI; only applicable to devices subject to Direct Marking requirements
- **Secondary Device Identifier** - An identifier that is an alternate (secondary) lookup for a medical device that is issued from a different issuing agency than the Primary DI.

Another identifier is the Previous Device Identifier. Previous Device Identifier is an identifier assigned to a version/model of a medical device before the same version/model of the device was assigned a new or substitute device identifier for reasons other than changes to the device itself.

The ***asEquivalentEntity*** element can be used for any of the device identifiers listed above.

There are three types of Alternative Device identifiers depicted in the subsections below: Unit of Use, Direct Marking and Secondary DI, followed by an Additional Device identifier: Previous DI.

5.5.1 Unit of Use Device Identifier

The following XML Snippet includes the elements and attributes required for the Unit of Use device identifier:

```
<asEquivalentEntity>
    <code code="C101717" codeSystem="2.16.840.1.113883.3.26.1.1"/>
    <definingMaterialKind>
        <code code="123456794830384" codeSystem="1.3.160"/>
    </definingMaterialKind>
</asEquivalentEntity>
```

5.5.1.1 Unit of Use Type (EquivalentEntity.code)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
Code		0..1		The code element is the container element for the type of device identifier.
	Code	1..1	Alphanumeric C101717	The ***code*** attribute indicates the type of device identifier, specifically for unit of use device identifier.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asEquivalentEntity/code[@code="C101717"]			
	codeSystem	1..1	OID 2.16.840.1.113883. 3.26.1.1	This is the ***codeSystem*** for the type of device identifier.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asEquivalentEntity/code[@code="C101717"]/@codeSystem			
Business Rules	• The code must be “C101717” • The Unit of Use Device Identifier or Direct Marking (DM) Device Identifier is required if the device count is greater than one • If device count > 1, then one of asEquivalentEntity with code ‘C101717’ or ‘C101678’ must be provided. • If device count = 1, then asEquivalentEntity with code ‘C101717’ must not be provided • If Device Count > 1 and both ‘C101717’ and ‘C101678’ is provided, or Device Count = 1 and ‘C101717’ is provided, the AusUDID submission will be rejected as a submission with an invalid Unit of Use.			

5.5.1.2 Unit of Use Device Identifier (EquivalentEntity.definingMaterialKind.code)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
code		1..1		The code element is the container element for the unit of use device identifier. Note: A code is required for each definingMaterialKind present in the XML.
	code	1..1	Alphanumeric e.g. 14-digit number	This is the Unit of Use DI for the medical device.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asEquivalentEntity/code[@code="C101717"]/../definingMaterialKind/code/@code			
	codeSystem	1..1	OID GS1 1.3.160 HIBCC 2.16.840.1.113883.6.40 ICCBBA 2.16.840.1.113883.6.18	This is the ***codeSystem*** for the Issuing Agency of the unit of use device identifier.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asEquivalentEntity/code[@code="C101717"]/../definingMaterialKind/code/@codeSystem			

Business Rules	• Base package Device Count should be greater than 1 in order to provide a Unit of Use DI
	• The Unit of Use DI value can be changed before or after the Grace Period, as long as the device count > 1 before the Grace Period expires
	• If provided, the Unit of Use Issuing Agency must be the same as the Primary DI Issuing Agency, but the DI must be different
	• See Common DI Validation.
	• The following scenarios will result in the submission being rejected with an invalid Unit of Use DI
	  ○ If Device Count > 1 and both Unit of Use DI and Direct Marked DI is missing, or both have been provided
	  ○ Device Count = 1 and Unit of Use DI is provided
	  ○ Unit of Use DI Issuing Agency does not match Primary DI Issuing Agency
	  ○ Unit of Use DI does not match the format for the Unit of Use DI Issuing Agency
	  ○ Unit of Use DI is the same as Primary DI			

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
	○ Unit of Use DI given more than once, the AusUDID submission will be rejected as a submission.			

5.5.2 Direct Marking Device Identifier

The following XML Snippet includes the elements and attributes required for the Direct Marking device identifier:

```
<asEquivalentEntity>
    <code code="C101678" codeSystem="2.16.840.1.113883.3.26.1.1"/>
    <definingMaterialKind>
        <code code="123456794" codeSystem="1.3.160"/>
    </definingMaterialKind>
</asEquivalentEntity>
```

5.5.2.1 Direct Marking Type (EquivalentEntity.code)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
code		0..1		The code element is the container element for the type of device identifier.
	code	1..1	Alphanumeric C101678	The ***code*** attribute indicates the type of device identifier, specifically for Direct Marked DI.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asEquivalentEntity/code[@code="C101678]			
	codeSystem	1..1	OID 2.16.840.1.113883. 3.26.1.1	This is the ***codeSystem*** for the type of device identifier.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asEquivalentEntity/code[@code="C101678"]/@codeSystem			

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
Business Rules	• The code should be 'C101678' for a Direct Marked DI • The Direct Marked DI is not required in a UDI record unless the value is different than the Primary DI • If device count > 1, then one of asEquivalentEntity with code 'C101717' or 'C101678' must be provided • If Device Count > 1 and both 'C101717' and 'C101678' is provided, the AusUDID submission will be rejected as a submission with an invalid Direct Marked.			

5.5.2.2 Direct Marking Device Identifier (EquivalentEntity.definingMaterialKind.code)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
code		1..1		The code element is the container element for the direct marking device identifier. Note: A code is required for each ***definingMaterialKind*** present in the XML.
	code	1..1	Alphanumeric, e.g. 1111111111111111	This is the Direct Marked DI for medical device.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asEquivalentEntity/code[@code="*C101678*"]/../definingMaterialKind/code/@code			
	codeSystem	1..1	OID GS1 1.3.160 HIBCC 2.16.840.1.113883.6.40 ICCBBA 2.16.840.1.113883.6.18	This is the ***codeSystem*** for the issuing agency of the direct marked DI.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asEquivalentEntity/code[@code="*C101678*"]/../definingMaterialKind/code/@codeSystem			
Business Rules	• Only one Direct Marking Device Identifier shall be provided for each UDI record • If provided, the Direct Marked Issuing Agency can be from any Issuing Agency • Direct Marked DI must not be provided if it is the same as the Primary DI			

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
	• Direct Marked DI must not be provided if the Direct Marking Exempt is True • See Common DI Validation. • The following scenarios will result in the submission being rejected with an invalid Unit of Use DI • If Device Count > 1 and both Unit of Use and Direct Marked DI is missing, or both have been provided • Direct Marked Issuing Agency is missing or invalid • Direct Marked DI does not match the format for the Direct Marked Issuing Agency • Direct Marked DI is the same as Primary DI • Direct Marked DI provided when Direct Marking Exempt is True. • Direct Marked DI given more than once. • If a Direct Marking Device Identifier is provided, the “DM DI Different from Primary DI” checkbox will be displayed for the UDI record. No additional values need to be submitted via SPL. The value can be changed before and after the Grace Period			

5.5.3 Secondary DI

The following XML Snippet includes the elements and attributes required for the Secondary DI:

```
<asEquivalentEntity>
    <code code="C101724" codeSystem="2.16.840.1.113883.3.26.1.1"/>
    <definingMaterialKind>
        <code code="H123456789" codeSystem="2.16.840.1.113883.6.40"/>
    </definingMaterialKind>
</asEquivalentEntity>
```

5.5.3.1 Secondary DI Type (EquivalentEntity.code)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
Code		0..1		The code element is the container element for the type of device identifier.
	Code	1..1	Alphanumeric e.g. C101724	The ***code*** attribute indicates the type of device identifier.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asEquivalentEntity/code[@code="C101724"]			
	codeSystem	1..1	OID e.g. 2.16.840.1.113883. 3.26.1.1	This is the ***codeSystem*** for the type of device identifier.

	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asEquivalentEntity/code[@code="C101724"]/@codeSystem
Business Rules	• The ***code*@*code*** value must be “C101724” • asEquivalentEntity with code ‘C101724’ is optional

5.5.3.2 Secondary Device Identifier (EquivalentEntity.definingMaterialKind.code)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
Code		1..1		The code element is the container element for the Secondary DI. Note: A code is required for each ***definingMaterialKind*** present in the XML.
	Code	1..1	Alphanumeric e.g. 1231234566	This is the Secondary DI for the medical device.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asEquivalentEntity/code[@code="C101724"]/../definingMaterialKind/code/@code			
	codeSystem	1..1	OID GS1 1.3.160 HIBCC 2.16.840.1.113883.6.40 ICCBBA 2.16.840.1.113883.6.18	This is the ***codeSystem*** for the issuing agency of the Secondary DI.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asEquivalentEntity/code[@code="C101724"]/../definingMaterialKind/code/@codeSystem			

Business Rules	• After the UDI record Grace Period expires, Secondary DI values cannot be edited, however, additional Secondary DIs may be added. • See Common DI Validation. • The Secondary DI provided cannot be from the same Issuing Agency as the Primary DI. • Only one Secondary DI value can be added for each Issuing agency. • The following scenarios will result in the submission being rejected with an invalid Secondary DI: • If Secondary DI Issuing Agency matches Primary DI Issuing Agency • Secondary DI Issuing Agency is used more than once • Secondary DI does not match the format for the Secondary DI Issuing Agency • Secondary DI is the same as Primary DI.

5.5.4 Previous DI

Previous Device Identifier is an identifier that was assigned to a given version/model of a medical device before the same version/model of the device was assigned a new or substitute device identifier for reasons other than changes to the device physical specifications or new indications for use that change the model or version.

The following XML Snippet includes the elements and attributes required for the Previous Device Identifier:

```
<asEquivalentEntity>
    <code code="C125195" codeSystem="2.16.840.1.113883.3.26.1.1"/>
    <definingMaterialKind>
        <code code="12345678901234" codeSystem="1.3.160"/>
    </definingMaterialKind>
</asEquivalentEntity>
```

5.5.4.1 Previous DI Type (EquivalentEntity.code)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
Code		0..1		The code element is the container element for the type of device identifier.
	Code	1..1	Alphanumeric e.g. C125195	The ***code*** attribute indicates the type of device identifier.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asEquivalentEntity/code[@code="C125195"]			
	codeSystem	1..1	OID e.g. 2.16.840.1.113883. 3.26.1.1	This is the ***codeSystem*** for the type of device identifier.

	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asEquivalentEntity/code[@code="C125195"]/@codeSystem
Business Rules	• The ***code@code*** value must be “C125195” • asEquivalentEntity with code ‘C125195’ is optional.

5.5.4.2 Previous Device Identifier (EquivalentEntity.definingMaterialKind.code)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
code		1..1		The code element is the container element for the previous device identifier. Note: A code is required for each ***definingMaterialKind*** present in the XML.
	Code	1..1	Alphanumeric e.g. 1231234566	This is the Previous Device Identifier for the medical device.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asEquivalentEntity/code[@code="C125195"]/../definingMaterialKind/code/@code			
	codeSystem	1..1	OID GS1 1.3.160 HIBCC 2.16.840.1.113883.6.40 ICCBBA 2.16.840.1.113883.6.18	This is the ***codeSystem*** for the Issuing Agency of the previous device identifier.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asEquivalentEntity/code[@code="C125195"]/../definingMaterialKind/code/@codeSystem			
Business Rules	• The Previous DI provided must exist as a valid Primary DI for another published UDI record in AusUDID. • Previous DI can be added or edited after the Grace Period. • Previous DI cannot be deleted after the Grace Period. • See Common DI Validation. • Only one Previous DI value can be added for each UDI record.			

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
	• The following scenarios will result in the submission being rejected with an invalid Previous DI: ○ Previous DI does not match the format for the Previous DI Issuing Agency. ○ Previous DI is the same as Primary DI. ○ Previous DI given more than once.			

5.5.5 Device Information – Manufacturer

The manufacturer of the medical device. The following XML Snippet includes the elements and attributes for the manufacturer:

```
<manufacturerOrganization>
    <id root="1.2.36.1.2001.1005.84" extension="12345"/>
    <name>Manufacturer Name</name>
</manufacturerOrganization>
```

The following elements will be found in the AusUDID HL7 SPL submission:

5.5.5.1 Manufacturer (manufacturerOrganization.id)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
Id		1..1		This is the container element for the manufacturer.
	Root	1..1	TGA OID 1.2.36.1.2001.1005.84	This is the OID for TGA Organisations.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturerorganization/id/@root			
	Extension	1..1	Organisation Number e.g. 12345	This is the assigned TGA Organisation number.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturerOrganisation/id/@extension			
Business Rules	• The TBS organisation number for the Manufacturer must be provided and must exist within TBS • A manufacturerOrganization must be provided • Only one manufacturer can be provided • It must be a number.			

	• If the manufacturerOrganization is missing, invalid, or given more than once, the AusUDID submission will be rejected as a submission with an invalid Manufacturer.

5.5.5.2 ManufacturerOrganization.name

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
name.item		1..1		The ***name.item*** element is the container element for the organisation name of the manufacturer.
		1..1	Alphanumeric[11] e.g. Manufacturer Pty Ltd	This is the name of the manufacturer.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturerOrganization/name/text()			
Business Rules	• A manufacturer name must be provided. • The manufacturer name must match what is recorded in TBS. • Only one manufacturer name can be provided. • The manufacturer name should be no more than 80 characters and length and can only contain accepted special characters. Refer to Data types and the *M2M HL7 SPL - SPL Code List - AusUDID* in the HL7 SPL Implementation package of files for a list of accepted special characters. • If the manufacturer name is missing, invalid, or given more than once, the AusUDID submission will be rejected as a submission with an invalid Manufacturer.			

5.6 Device Characteristics

```
<subjectOf>
    <characteristic>
        <code code="C101679" codeSystem="2.16.840.1.113883.3.26.1.1"/>
        <value xsi:type="BL" value="false"/>
    </characteristic>
</subjectOf>
```

A number of elements are described using the following structure.

<subjectOf>

<characteristic>

<code ../> …

</characteristic>

</subjectOf>

[11] Refer to 'AusUDID_SPLCodeList.xls' file in the HL7 SPL Implementation package of files for a list of accepted special characters

When an unrecognised code is used, the code and it's attributes are ignored.

5.6.1 Device Characteristics – Device Count

The Device Count is the number of medical devices in the base package (i.e. the base package is the package configuration as labeled with and identified by the UDI record's Primary DI). The following XML Snippet includes the elements and attributes required for the device count:

For example, Base Package = Box of 100 gloves, Primary DI = 101; Device Count = 100

```
<asContent>
    <quantity>
        <numerator value="100"/>
        <denominator/>
    </quantity>
    <containerPackagedProduct>···
    </containerPackagedProduct>
</asContent>
```

5.6.1.1 Device Count Value (quantity.numerator)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
Numerator		1..1		This is the container element for the device count
	Value	1..1	Numeric e.g. 100, 1000	This is the device count value of the base package.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asContent/quantity/numerator/@value			
Denominator		1..1		Leave empty
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asContent/quantity/denominator			
Business Rules	• The Denominator element should be provided in your XML file, no value is required • asContent.quantity is required • The numerator@value is required • If more than one package configuration is provided, the ***numerator*** value of each ***asContent*** element must be the same • If the asContent.quantity is missing, invalid, or given more than once, or has different values in other package configurations, the AusUDID submission will be rejected as a submission with an invalid Device Count.			

5.6.2 Device Characteristics – Packaging Configuration

A package configuration is made up of the following elements:

- **Package DI** - A device identifier for the package configuration that contains multiple units of the base package
    - Examples Package DI (in bold)
        - Base Package DI = 101
        - 4 glove boxes in a Carton -- **Package DI =201** (the DI on the Carton)
        - 5 Cartons in a Case -- **Package DI=301** (the DI on the Case)
- **Package Type –** Text to describe the outer packaging of the product and enables users to understand higher level packaging configurations. The package type can only be 20 characters
    - Examples of Package Type
        - Carton
        - Case
- **Quantity per Package** – The number of packages with a unique Primary DI within a given packaging configuration
    - Examples of Quantity (in bold)
        - Package DI 201 is a Carton which contains **4** glove boxes
        - Package DI 301 is a Case which contains **5** Cartons
- **Sponsor Package Commercial Distribution End Date:** Indicates the date a particular package configuration is no longer offered for commercial distribution by the Sponsor
- **Contains DI Package** - The Primary DI for the base package or any lower-level package configuration contained within a given package configuration. In the SPL, the Contains DI package configuration is nested and takes the value of the lower-level package
    - Examples of Contains DI:
        - Package DI 201 contains base Package DI 101
        - Package DI 301 contains Package DI 201

The following XML Snippet includes the elements and attributes required for the package configuration above:

- 4 glove boxes in a Carton -- **Package DI =201** (the DI on the Carton)

```
<asContent>
    <quantity>
        <numerator value="100"/>
        <denominator/>
    </quantity>
    <containerPackagedProduct>
        <code code="201" codeSystem="1.3.160"/>
        <name>carton</name>
        <capacityQuantity value="4"/>
        <asManufacturedProduct>
            <subjectOf>
                <marketingAct>
                    <effectiveTime>
                        <low/>
                        <high value="20140901"/>
                    </effectiveTime>
                </marketingAct>
            </subjectOf>
        </asManufacturedProduct>
```

- 5 Cartons in a Case -- **Package DI=301** (the DI on the Case)

```
<asContent>
    <containerPackagedProduct>
        <code code="301" codeSystem="1.3.160"/>
        <name>case</name>
        <capacityQuantity value="5"/>
        <asManufacturedProduct>
            <subjectOf>
                <marketingAct>
                    <effectiveTime>
                        <low/>
                        <high value="20140901"/>
                    </effectiveTime>
                </marketingAct>
            </subjectOf>
        </asManufacturedProduct>
    </containerPackagedProduct>
</asContent>
```

5.6.2.1 Package DI (containerPackagedProduct.code)

The following XML Snippet includes the elements and attributes required for the package DI:

```
<containerPackagedProduct>
    <code code="201" codeSystem="1.3.160"/>
    <name>carton</name>
    <capacityQuantity value="4"/>
    <asManufacturedProduct>
        <subjectOf>
            <marketingAct>
                <effectiveTime>
                    <low/>
                    <high value="20140901"/>
                </effectiveTime>
            </marketingAct>
        </subjectOf>
    </asManufacturedProduct>
```

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
Code		1..1		This is the container element for the package Device identifier.
	Code	1..1	Alphanumeric e.g. 14-digit value	This is the device identifier.
	XPATH: Varies /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asContent/containerPackagedProduct/code/@code /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asContent/containerPackagedProduct/asContent/containerPackagedProduct[12]/code/@code			
	codeSystem	1..1	OID GS1 1.3.160 HIBCC 2.16.840.1.113883.6.40 ICCBBA 2.16.840.1.113883.6.18	This is the ***codeSystem*** for the Issuing Agency of the package device identifier.
	XPATH: Varies /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asContent/containerPackagedProduct/code/@codeSystem /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asContent/containerPackagedProduct/asContent/containerPackagedProduct/code/@codeSystem			

[12] asContent/containerPackagedProduct repeats for each package level

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
Business Rules	• Once the grace period expires, a package configuration cannot be removed from the UDI record. The only change that can be made to a package configuration is changes to the package commercial distribution end date – adding a date if null, or updating an existing date • containerPackagedProduct is optional. It is required when there is a package configuration • See Common DI Validation. • Package Configurations can be removed via the portal by the use of a correction. • The Issuing Agency for Package DI should be the same as the Primary DI • The following scenarios will result in the submission being rejected with an invalid Package DI: ○ Package Issuing Agency does not match Primary DI Issuing Agency. ○ Package DI does not match the format for the Package Issuing Agency. ○ Package DI is the same as Primary DI. ○ Package DI given more than once.			

5.6.2.2 Package Type (containerPackagedProduct.name)

The following XML Snippet includes the elements and attributes required for the package type:

```
<containerPackagedProduct>
    <code code="201" codeSystem="1.3.160"/>
    <name>carton</name>
    <capacityQuantity value="4"/>
    <asManufacturedProduct>
        <subjectOf>
            <marketingAct>
                <effectiveTime>
                    <low/>
                    <high value="20140901"/>
                </effectiveTime>
            </marketingAct>
        </subjectOf>
    </asManufacturedProduct>
```

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
name		0..1		This is the container element for the package type.
		0..1	Alphanumeric e.g. box, case	This is a short package type description.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asContent/containerPackagedProduct/name/text()			

	/document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asContent/containerPackagedProduct/asContent/containerPackagedProduct/name/text()
Business Rules	• If the package type is provided, it cannot be changed after the Grace Period • Package type is optional • If provided, can only be maximum 20 characters in length • If name is invalid or given more than once, the AusUDID submission will be rejected as a submission with an invalid Package.

5.6.2.3 Quantity per Package (containerPackagedProduct.capacityQuantity)

The following XML Snippet includes the elements and attributes required for the package quantity:

```
<containerPackagedProduct>
    <code code="201" codeSystem="1.3.160"/>
    <name>carton</name>
    <capacityQuantity value="4"/>
    <asManufacturedProduct>
        <subjectOf>
            <marketingAct>
                <effectiveTime>
                    <low/>
                    <high value="20140901"/>
                </effectiveTime>
            </marketingAct>
        </subjectOf>
    </asManufacturedProduct>
```

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
capacityQuantity		1..1		This is the container element for the quantity in Package value.
	value	1..1	Numeric e.g. 20, 30	This is the number of products in the package.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asContent/containerPackagedProduct/capacityQuantity/@value /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asContent/containerPackagedProduct/asContent/containerPackagedProduct/capacityQuantity/@value			

Business Rules	• The value needs to be greater than or equal to 1 if the Contains DI is the Primary DI (i.e. base package) • The quantity per package cannot be changed after the Grace Period • capacityQuantity is required when there is a package configuration • It must be a number > 0 • If capacityQuantity is missing, invalid, or given more than once, the AusUDID submission will be rejected as a submission with an invalid Package.

5.6.2.4 Sponsor Package Commercial Distribution End Date

The Sponsor package commercial distribution end date consists of two elements as follows.

The following XML Snippet includes the elements and attributes required for the sponsor package commercial distribution end date:

```
<containerPackagedProduct>
    <code code="201" codeSystem="1.3.160"/>
    <name>carton</name>
    <capacityQuantity value="4"/>
    <asManufacturedProduct>
        <subjectOf>
            <marketingAct>
                <effectiveTime>
                    <low/>
                    <high value="20140901"/>
                </effectiveTime>
            </marketingAct>
        </subjectOf>
    </asManufacturedProduct>
```

5.6.2.4.1 Sponsor Package Commercial Distribution End Date (marketingAct.effectiveTime.low)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
Low		0..1		This is the container element for the sponsor package commercial distribution end date.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asContent/containerPackagedProduct/asManufacturedProduct/subjectOf/marketingAct/effectiveTime/low/@value /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asContent/containerPackagedProduct/asContent/containerPackagedProduct/asManufacturedProduct/subjectOf/marketingAct/effectiveTime/low/@value			
Business Rules	• effectiveTime is optional			

	• If effective time is provided, the date element is required, but no value should be provided. • If low value is provided, the AusUDID submission will be rejected as a submission with an invalid Package.

5.6.2.4.2 Sponsor Package Commercial Distribution End Date (marketingAct.effectiveTime.high)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
High		0..1		This is the container element for the sponsor package commercial distribution end date.
	value	1..1	Date Format YYYYMMDD E.g. “20111016”	This is the value for the date the package is no longer offered for commercial distribution by the sponsor.
	XPATH: Varies /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asContent/containerPackagedProduct/asManufacturedProduct/subjectOf/marketingAct/effectiveTime/high/@value /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asContent/containerPackagedProduct/asContent/containerPackagedProduct/asManufacturedProduct/subjectOf/marketingAct/effectiveTime/high/@value			
Business Rules	• effectiveTime is optional • If effective time is provided, the date element is required • If date is provided, it must be a valid date in format YYYYMMDD • If effectiveTime is invalid, or given more than once, or high date is missing or invalid, the AusUDID submission will be rejected as a submission with an invalid Package • The date is only provided at the time the package is no longer offered for commercial distribution by the Sponsor • The Package DI will still remain in the AusUDID system after it reaches the Sponsor package commercial distribution end date • If UDI data is uploaded by the Manufacturer, the Sponsor package commercial distribution end date is not required. If it is provided it will be ignored • If UDI data is uploaded by the Sponsor, the Sponsor package commercial distribution end date may be provided. If it is provided, it is the package commercial distribution end date as determined by the Sponsor for this package for each ARTG ID included in the HL7 message.			

5.6.2.5 Contains DI Package (containerPackagedProduct.code or manufacturedProduct.code)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
Code		1..1		This is the container element for the Contains Device identifier.
	code	1..1	Alphanumeric e.g. 14-digit value	This is the Contains Package DI.
	XPATH: Varies			
	code System	1..1	OID GS1 1.3.160 HIBCC 2.16.840.1.113883.6.40 ICCBBA 2.16.840.1.113883.6.18	This is the OID for the Contains Package DI Issuing Agency.
	XPATH: Varies			
Business Rules	• Package configurations are given in a hierarchy • The Contains Package DI within the first package configuration in a hierarchy will always point to the base package DI found in manufacturedProduct.code • The Contains Package DI within the second package configuration in a hierarchy will always point to the first package DI found in containerPackagedProduct.code • Apart from the first package configuration, the Contains Package DI within any package configuration in a hierarchy will always point to the previous package DI found in containerPackagedProduct.code • These rules apply to each distinct hierarchy.			

5.6.3 Device Status and Dates – Sponsor Commercial Distribution End Date

The Sponsor Commercial Distribution End Date indicates the date the device is no longer held or offered for sale by the Sponsor. The device may or may not still be available for purchase in the marketplace. The following XML Snippet includes the elements and attributes required for the Sponsor Commercial Distribution End Date:

```
<subjectOf>
    <marketingAct>
        <effectiveTime>
            <low/>
            <high value="20140901"/>
        </effectiveTime>
    </marketingAct>
</subjectOf>
```

5.6.3.1 Sponsor Commercial Distribution End Date (marketingAct.effectiveTime.low)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
Low		1..1		This is the container element for the Sponsor Commercial Distribution End Date.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/marketingAct/effectiveTime/low/@value			
Business Rules	• effectiveTime is optional • If effective time is provided, the date element is required, but no value should be provided • If low value is provided, the AusUDID submission will be rejected as a submission with an invalid Sponsor Commercial Distribution End Date.			

5.6.3.2 Sponsor Commercial Distribution End Date (marketingAct.effectiveTime.high)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
High		1..1		This is the container element for Sponsor Commercial Distribution End Date
	value	1..1	Date Format YYYYMMDD E.g. “20111016”	This is the date value for the date the device product is no longer in commercial distribution.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/marketingAct/effectiveTime/high/@value			
Business Rules	• The date is only provided at the time the device product is no longer actively marketed by the Sponsor • The UDI record will remain in the AusUDID • effectiveTime is optional			

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
	• If effective time is provided, the date element is required • If date is provided, it must be a valid date in format YYYYMMDD • If effectiveTime is invalid, or given more than once, or high date is missing or invalid, the AusUDID submission will be rejected as a submission with an invalid Sponsor Commercial Distribution End Date • If UDI data is uploaded by the Manufacturer, the Sponsor commercial distribution end date is not required. If it is provided it will be ignored • If UDI data is uploaded by the Sponsor, the Sponsor commercial distribution end date may be provided. If it is provided, it is the commercial distribution end date as determined by the Sponsor for each ARTG ID included in the HL7 message.			

5.6.4 Device Characteristics – Device Subject to Direct Marking, but Exempt

The manufacturer can claim their device is subject to Direct Marking but exempt. The following XML Snippet includes the element that indicates the exemption:

```
<subjectOf>
    <characteristic>
        <code code="C101679" codeSystem="2.16.840.1.113883.3.26.1.1"/>
        <value xsi:type="BL" value="false"/>
    </characteristic>
</subjectOf>
```

5.6.4.1 Device Subject to Direct Marking (DM), but Exempt (characteristic.code)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
Code		0..1		The code element is the container element for Device Subject to Direct Marking (DM), but Exempt.
	code	1..1	Alphanumeric C101679	The ***code*** for Device Subject to Direct Marking (DM), but Exempt.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C101679"]			
	codeSystem	1..1	OID 2.16.840.1.113883. 3.26.1.1	This is the ***codeSystem*** that manages the controlled vocabulary.

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C101679"]/@codeSystem			
Business Rules	• If the Device is subject to Direct Marking, but exempt, the ***code@code*** value must be "C101679" • A characteristic with code 'C101679' is optional • If this data element does not apply to the UDI record, a characteristic data element does not need to be provided.			

5.6.4.2 Device Subject to Direct Marking (DM), but Exempt Value (characteristic.value)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
Value		1..1		This is the container element for the direct marking exempt indicator.
	xsi:type	1..1	Boolean BL	The **xsi:type** indicates the data type for the element.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/ code[@code="C101679"]/../value/@xsi:type			
	Value	1..1	Alpha "true" or "false"	This is the ***value*** attribute for the Boolean operator***.***
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C101679"]/../value/@value			
Business Rules	• If 'C101679' is provided, then value must be provided • If value is provided, value must be true or false • If characteristicValue is missing, invalid, or given more than once, the AusUDID submission will be rejected as a submission with an invalid Direct Marking • If the value is set to "true", a Direct Marked DI will not be allowed • If the value is set to "false", a Direct Marked DI value is required only if the value is different than the Primary DI • If the data element value is not provided, "false" will be stored in the database • The value can be submitted as part of the initial submission, or changed after the Grace Period, but the rules above will always apply.			

5.6.5 Device Characteristics – Clinically Relevant Size

The clinically relevant size measurement for the medical device is captured under device characteristics. The following XML Snippet includes the elements and attributes required for clinically relevant size:

```
<subjectOf>
    <characteristic>
        <code code="C96684" codeSystem="2.16.840.1.113883.3.26.1.1"/>
        <value xsi:type="PQ" value="3" unit="m"/>
    </characteristic>
</subjectOf>
```

5.6.5.1 Clinically Relevant Size Type (characteristic.code)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
Code				
	code	1..1	Alphanumeric e.g. C96684	The ***code*** to indicate clinically relevant size type, the dimension type for the clinically relevant measurement of the medical device.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="see list – codes vary by type"]			
	codeSystem	1..1	OID 2.16.840.1.113883. 3.26.1.1	This is the ***codeSystem*** that manages the controlled vocabulary.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="see list"]/@codeSystem			
Business Rules	• Clinical size codes are optional • The attributes will be treated as a Clinical Size if a recognised Clinical Size code is provided. • The code will determine the valid units of measure for the size type. See controlled vocabulary documentation for details • If characteristic.code value is given more than once, the AusUDID submission will be rejected as a submission with an invalid Clinical Size			

5.6.5.2 Clinically Relevant Size Value and Unit of Measure (characteristic.value)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
value		1..1		This is the container element for the clinically relevant size quantity.
	xsi:type	1..1	Physical Quantity PQ	The ***xsi:type*** indicates the data type for the element.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="see list"]/../value/@xsi:type			
	value	1..1	Alpha Numeric e.g. 3	This is the numeric ***value*** for the clinically relevant size measurement of the medical device.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="see list"]/../value/@value			
	unit	1..1	Alpha Numeric e.g. cm, [in_i], U/L	This is the value of the ***unit*** of measure associated with each clinically relevant size.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="see list"]/../value/@unit			
Business Rules	• If the clinically relevant size code is a structured measure, the value and unit must be provided. • The unit of measure submitted must be allowed for the given size type – e.g. the size type outer diameter (C96684) must have a unit of measure for a valid length size. See controlled vocabulary documentation for details. • Characteristic.value is required unless code is 'C106041' • If provided, the value needs to be one of the valid values for clinically relevant size. • If characteristic.value value is invalid, or given more than once, the AusUDID submission will be rejected as a submission with an invalid Clinical Size			

5.6.5.3 Device Characteristics – Clinically Relevant Size – Device Size Text

Clinically relevant device size text field can be used to provide additional undefined device size not represented in the AusUDID's clinically relevant size list.

The following XML Snippet includes the elements and attributes required for providing a free-text description of the clinically relevant size:

```
<subjectOf>
    <characteristic>
        <code code="C106041" codeSystem="2.16.840.1.113883.3.26.1.1"/>
        <value xsi:type="ST">Size text</value>
    </characteristic>
</subjectOf>
```

Multiple instances of clinical size text values can be submitted for a single device by duplicating the XML Snippet above.

5.6.5.3.1 Clinically Relevant Size Device Size Text Type (characteristic.code)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
code		1..1		This is the container element for clinically relevant size text.
	code	1..1	Alphanumeric C106041	This is the code to indicate the type of characteristic being identified for a device product.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C106041"]			
	codeSystem	1..1	OID 2.16.840.1.113883. 3.26.1.1	This is the ***codeSystem*** that manages the controlled vocabulary.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C106041"]/@codeSystem			
Business Rules	• The ***code*@*code*** value must be "C106041".			

5.6.5.3.2 Clinically Relevant Size Text (characteristic.value)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
value		1..1		This is the container element for the size text.
	xsi:type	1..1	String ST	The ***xsi:type*** indicates the data type for the element.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C106041"]/../value@xsi:type			
	value	1..1	Alphanumeric[13] e.g. medium	This is the value attribute for the clinically relevant size text.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C106041"]/../value/text()			
Business Rules	• The text element can only be used when the code is "C106041" is provided • Characteristic.value is required if code is 'C106041' • The Clinically Relevant Size Text value should be no more than 200 characters in length and can only contain accepted special characters. Refer to Data types and 'AusUDID_SPLCodeList.xls' file in the HL7 SPL Implementation package of files for a list of accepted special characters • If clinical size text is invalid, or given more than once, or given when code is not 'C106041' the AusUDID submission will be rejected as a submission with an invalid Clinical Size.			

[13] Refer to 'AusUDID_SPLCodeList.xls' file in the HL7 SPL Implementation package of files for a list of accepted special characters

5.6.6 Device Characteristics – Storage and Handling Requirements

Storage and handling requirements that are required for the device including temperature, humidity, and atmospheric pressure are provided as device characteristics. The following XML Snippet includes the elements and attributes required for these requirements:

```
<subjectOf>
    <characteristic>
        <code code="C101707" codeSystem="2.16.840.1.113883.3.26.1.1"/>
        <value xsi:type="IVL_PQ">
            <low value="0" unit="Cel"/>
            <high value="10" unit="Cel"/>
        </value>
    </characteristic>
</subjectOf>
```

5.6.6.1 Storage and Handling Type (characteristic.code)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
Code		0..*		This is the container element for the storage and handling type.
	code	1..1	Alphanumeric e.g. C101707	This is the code to indicate the storage and handling type being identified for a device product.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="see list"]			
	codeSystem	1..1	OID 2.16.840.1.113883. 3.26.1.1	This is the ***codeSystem*** that manages the controlled vocabulary.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="see list"]/@codeSystem			
Business Rules	• If a storage and handling element is sent, the ***code@code*** and ***code@codeSystem*** is required • Storage and Handling codes are optional • If provided, the code value needs to be one of the valid values for Storage and Handling • The attributes will be treated as Storage and Handling if a recognised Storage and Handling code is provided. • If characteristic.code value is given more than once, the AusUDID submission will be rejected as a submission with an invalid Storage and Handling.			

5.6.6.2 Storage and Handling Value and Unit of Measure (characteristic.value.low)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
value@xsi:type	***xsi:type***	1..1	String IVL_PQ	The ***xsi:type*** indicates the data type for the element.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="see list"]/../value/@xsi:type			
value.low		1..1		This is the container element for the storage and handling value.
	value	1..1	Numeric e.g. 10, 20	The value of the storage or handling value.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="see list"]/../value/low/@value			
	unit	1..1	Alpha Numeric e.g. Celsius	This is the unit of measure for the storage or handling unit***.***
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="see list"]/../value/low/@unit			

Business Rules	• The following rules can be applied to indicate the low value for storage or handling conditions:
	  ○ provide when the storage and handling condition has a range, this is the lower end of that range (and the upper end of the range should be provided as the high value)
	  ○ provide when the storage and handling condition value is greater than this value (no value will be provided in the high value)
	  ○ provide when the storage and handling condition is exactly equal to a value (note- same value will be entered in high@value)
	• Storage and handling low value must not be provided when the code is “C101704”
	• If a storage or handling requirement is provided – either the low or high value is required
	• The low value can only be 6 characters in length including leading zero, decimal and negative sign. Up to 4 numbers are allowed after the decimal
	• If characteristic low value and high value are both missing when code is not ‘C101704’, or low value is given when code is ‘C101704’, or is invalid, or given more than once, the AusUDID submission will be rejected as a submission with an invalid Storage and Handling
	• Storage and handling low unit of measure is not provided when the code is “C101704”			

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
	• If a low value is provided, the unit of measure must also be provided, and must be a valid value • If the low and high value is provided, the unit of measure must be the same • If low unit of measure is missing when low value is given, or low unit of measure is given when code is 'C101704', or is invalid, or given more than once, or is not the same as the high unit of measure, the AusUDID submission will be rejected as a submission with an invalid Storage and Handling.			

5.6.6.3 Storage and Handling Value and Unit of Measure (characteristic.value.high)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
value@xsi:type	***xsi:type***	1..1	String IVL_PQ	The ***xsi:type*** indicates the data type for the element.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="see list"]/../value/@xsi:type			
value.high		1..1		This is the container element for the storage and handling condition.
	value	1..1	Numeric e.g. 10, 20	The value of the storage or handling condition.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="see list"]/../value/high/@value			
	unit	1..1	Alpha Numeric e.g. Celsius	This is the unit of measure for the storage or handling condition.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="see list"]/../value/high/@unit			
Business Rules	• The following rules can be applied to indicate the high value for storage or handling conditions:			

	○ provide when the storage and handling condition has a range, this is the upper end of that range (and the lower end of the range should be provided as the low value) ○ provide when the storage and handling condition value is less than this value (no value will be provided in the low value) ○ provide when the storage and handling condition is exactly equal to a value (note- same value will be entered in low@value) • Storage and handling high value must not be provided when the code is “C101704” • If a storage or handling requirement is provided – either the low or high value is required. • The high value can only be 6 characters in length including leading zero, decimal and negative sign. Up to 4 numbers are allowed after the decimal • If characteristic low value and high value are both missing when code is not ‘C101704’, or high value is given when code is ‘C101704’, or is invalid, or given more than once, the AusUDID submission will be rejected as a submission with an invalid Storage and Handling • Storage and handling high unit of measure is not provided when the code is “C101704” • If a high value is provided, the unit of measure must also be provided, and must be a valid value • If the low and high value is provided, the unit of measure must be the same • If high unit of measure is missing when high value is given, or high unit of measure is given when code is ‘C101704’, or is invalid, or given more than once, or is not the same as the low unit of measure, the AusUDID submission will be rejected as a submission with an invalid Storage and Handling.

5.6.6.4 Device Characteristics – Special Storage Conditions

Indicates any special storage requirements for the device where the value is not structured (e.g. free text instructions for storage and handling conditions). The following XML Snippet includes the elements and attributes required for special storage conditions:

```
<subjectOf>
    <characteristic>
        <code code="C101704" codeSystem="2.16.840.1.113883.3.26.1.1"/>
        <value xsi:type="ST1">keep out of sunlight</value>
    </characteristic>
</subjectOf>
```

Multiple instances of special storage conditions text values can be submitted for a single device by duplicating the XML Snippet above.

5.6.6.4.1 Special Storage Condition Type (characteristic.code)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
Code		0..*		This is the container element for the storage and handling type.

	Code	1..1	Alphanumeric C101704	Code to indicate special storage and handling conditions for a device product.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C101704"]			
	codeSystem	1..1	OID 2.16.840.1.113883. 3.26.1.1	This is the ***codeSystem*** that manages the controlled vocabulary.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C101704"]/@codeSystem			
Business Rules	• If there is a special storage requirement, the ***code*@*code*** value must be “C101704”. If a special storage requirement does not exist, a characteristic element with this code should not be provided.			

5.6.6.4.2 Special Storage Condition Text (characteristic.value)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
Value		1..1		This is the container element for the special storage text.
	xsi:type	1..1	String ST	The ***xsi:type*** indicates the data type for the element.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C101704"]/../value/@xsi:type			
	Value	1..1	Alphanumeric[14] e.g. "keep out of sunlight"	This is the value attribute for special storage condition.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C101704"]/../value/text()			
Business Rules	• The ***xsi:type*** value must be "ST" • Storage and handling special conditions text is required when the code is "C101704" • The Special Storage Condition Text value should be no more than 200 characters in length and can only contain accepted special characters. Refer to Data types and 'AusUDID_SPLCodeList.xls' file in the HL7 SPL Implementation package of files for a list of accepted special characters • If special conditions text is given when code is not 'C101704', or is missing when code is 'C101704', or is invalid, or given more than once, the AusUDID submission will be rejected as a submission with an invalid Storage and Handling.			

5.6.7 Device Characteristics – Packaged as Sterile

The Packaged as Sterile indicator is to designate the medical device is free from viable microorganisms (see ISO/TS 11139). The following XML Snippet includes the elements and attributes required for devices packaged as sterile:

```
<subjectOf>
    <characteristic>
        <code code="C101676" codeSystem="2.16.840.1.113883.3.26.1.1"/>
        <value xsi:type="BL" value="true"/>
    </characteristic>
</subjectOf>
```

[14] Refer to 'AusUDID_SPLCodeList.xls' file in the HL7 SPL Implementation package of files for a list of accepted special characters

5.6.7.1 Device Packaged as Sterile Type (characteristic.code)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
Code		1..1		This is the container element for the device packaged as sterile indicator.
	Code	1..1	Alphanumeric C101676	This is the code to indicate the type of characteristic being identified for a device product, specifically the Packaged as sterile indicator.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C101676"]			
	codeSystem	1..1	OID 2.16.840.1.113883. 3.26.1.1	This is the ***codeSystem*** that manages the controlled vocabulary.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C101676"]/@codeSystem			
Business Rules	• The message must have a Device packaged as Sterile element and the ***code@code*** value must be “C101676”.			

5.6.7.2 Device Packaged As Sterile Value (characteristic.value)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
Value		1..1		This is the container element for the value of Device Packaged as Sterile.
	xsi:type	1..1	Boolean BL	The ***xsi:type*** specifies the data type for the Device Packaged as Sterile Indicator value.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C101676"]/../value/@xsi:type			
	Value	1..1	Alpha “true” or “false”	Value attribute for the Boolean operator**.**
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C101676"]/../value/@value			

Business Rules	• The ***xsi:type*** value must be “BL” • A characteristic with code ‘C101676’ is required • Value must be true or false • If characteristicValue is missing, invalid, or given more than once, the AusUDID submission will be rejected as a submission with an invalid Packaged as Sterile

5.6.8 Device Characteristics – Sterilisation Method

If the medical device should be sterilised prior to use, the sterilisation method should be provided for the medical device. The following XML Snippet includes the elements and attributes required for the sterilisation method:

```
<subjectOf>
    <characteristic>
        <code code="C84382" codeSystem="2.16.840.1.113883.3.26.1.1"/>
        <value xsi:type="CD" code="AU1009" codeSystem="1.2.36.1.2001.1005.85" displayName="Beta Radiation
            Sterilization"/>
    </characteristic>
</subjectOf>
```

5.6.8.1 Sterilisation Method Type (characteristic.code)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
Code		0..*		This is the container element for the sterilisation method.
	Code	1..1	Alphanumeric C84382	The ***code*** attribute indicates the sterilisation method for a device product.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C84382"]			
	codeSystem	1..1	OID 2.16.840.1.113883. 3.26.1.1	This is the ***codeSystem*** that manages the controlled vocabulary.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C84382"]/@codeSystem			
Business Rules	• If the medical device requires sterilisation prior to use, the Sterilisation Method must be in the message and the ***code@code*** value must be “C84382” • If the device does NOT require sterilisation prior to use, then this characteristic element does not need to be provided in the xml • One or more methods can be provided			

	• If a valid sterilisation method is provided, the system will set 'Requires Sterilisation Prior to Use' to Yes • If a valid sterilisation method is not provided, the system will set 'Requires Sterilisation Prior to Use' to No.

5.6.8.2 Sterilisation Method Value (characteristic.value)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
Value		1..1		This is the container element for the Sterilisation Method Value.
	xsi:type	[1..1]	Alphanumeric CD	The ***xsi:type*** specifies the data type for the sterilisation method.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C84382"]/../value/@xsi:type			
	Code	[1..1]	Alphanumeric e.g. C101712	This is the ***value*** attribute for sterilisation method***.***
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C84382"]/../value/@code			
	codeSystem	1..1	OID 2.16.840.1.113883. 3.26.1.1 or 1.2.36.1.2001.1005.85	This is the ***codeSystem*** that manages the controlled vocabulary.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C84382"]/../value/@codeSystem			
Business Rules	• The ***xsi:type*** value must be "CD" • A sterilisation method must be provided if code is 'C84382' • The sterilisation method must be a valid value • If characteristicValue is missing when code is 'C84382', is invalid, or given more than once, the AusUDID submission will be rejected as a submission with an invalid Sterilisation Methods			

5.6.9 Device Characteristics – Device required to be labeled as containing natural rubber latex or dry natural rubber

This attribute is used to indicate that the device or packaging contains natural rubber that contacts humans. The following XML Snippet includes the elements and attributes required for this indicator:

```
<subjectOf>
    <characteristic>
        <code code="C101673" codeSystem="2.16.840.1.113883.3.26.1.1"/>
        <value xsi:type="BL" value="true"/>
    </characteristic>
</subjectOf>
```

5.6.9.1 Device required to be labeled as containing natural rubber latex or dry natural rubber Type (characteristic.code)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
code		1..1		This is the container element for the 'Device required to be labeled as containing natural rubber latex or dry natural rubber' indicator.
	code	1..1	Alphanumeric C101673	Code value to indicate if the 'Device required to be labeled as containing natural rubber latex or dry natural rubber'.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C101673"]			
	codeSystem	1..1	OID 2.16.840.1.113883. 3.26.1.1	This is the ***codeSystem*** that manages the controlled vocabulary.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C101673"]/@codeSystem			
Business Rules	• A characteristic with code 'C101673' is required.			

5.6.9.2 Device required to be labeled as containing natural rubber latex or dry natural rubber Value (characteristic.value)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
value		1..1		This is the container element for the value of Device required to be labeled as containing natural rubber latex or dry natural rubber.
	xsi:type	1..1	Boolean BL	The ***xsi:type*** specifies the data type for the Device required to be labeled as containing natural rubber latex or dry natural rubber indicator.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C101673"]/../value/@xsi:type			
	value	1..1	Alpha “true” or “false”	This is the value attribute for the Boolean operator***.***
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C101673"]/../value/@value			
Business Rules	• The ***xsi:type*** value must be “BL” • Value must be true or false • If characteristicValue is missing, invalid, or given more than once, or both device contains latex and device does not contain latex are true, the AusUDID submission will be rejected as a submission with an invalid Device Label.			

5.6.10 Device Characteristics – Device labeled as "Not made with natural rubber latex"

This attribute is used to indicate that natural rubber latex was not used as materials in the manufacture of the medical product and container. This attribute is only applicable to devices required to label regarding latex and rubber. The following XML Snippet includes the elements and attributes required for this indicator:

```
<subjectOf>
    <characteristic>
        <code code="C106038" codeSystem="2.16.840.1.113883.3.26.1.1"/>
        <value xsi:type="BL" value="true"/>
    </characteristic>
</subjectOf>
```

5.6.10.1 Device labeled as "Not made with natural rubber latex" (characteristic.code)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
code		0..1		Container element for the 'Device labeled as "Not made with natural rubber latex"' indicator.
	code	1..1	Alphanumeric C106038	The ***code*** attribute to indicate the 'Device labeled as "Not made with natural rubber latex"' indicator.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C106038"]			
	codeSystem	1..1	OID 2.16.840.1.113883. 3.26.1.1	This is the ***codeSystem*** that manages the controlled vocabulary.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C106038"]/@codeSystem			
Business Rules	• The element "Not made with natural rubber latex"' is not required. If it is provided, the ***code***@***code*** value must be "C106038" • If this data element does not apply to the UDI record, a characteristic data element does not need to be provided. If the data element value is not provided, the system will consider it "false" in the database.			

5.6.10.2 Device labeled as "Not made with natural rubber latex" Value (characteristic.value)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
value		1..1		Container element for the value of Device labeled as "Not made with natural rubber latex".
	xsi:type	1..1	Boolean BL	The ***xsi:type*** specifies the data type for the Device labeled as "Not made with natural rubber latex" indicator.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C106038"]/../value/@xsi:type			
	value	1..1	Alpha "true" or "false"	This is the ***value*** attribute for the boolean operator***.***

	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C106038"]/../value/@value
Business Rules	• The ***xsi:type*** value must be “BL” • If provided, value must be true or false • If characteristicValue is missing, invalid, or given more than once, or both device contains latex and device does not contain latex are true, the AusUDID submission will be rejected as a submission with an invalid Device Label

5.6.11 Device Characteristics – For Single Use

The Single Use indicator is to designate that the device is intended for one use only or for use on a single patient during a single procedure. The following XML Snippet includes the elements and attributes required for single use products:

```
<subjectOf>
    <characteristic>
        <code code="C53602" codeSystem="2.16.840.1.113883.3.26.1.1"/>
        <value xsi:type="CD" code="C49487" codeSystem="2.16.840.1.113883.3.26.1.1"/>
    </characteristic>
</subjectOf>
```

5.6.11.1 For Single Use Type (characteristic.code)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
code		1..1		This is the container element for the single use indicator.
	code	1..1	Alphanumeric C53602	This is the ***code*** attribute to indicate the type of characteristic being identified for a device product, specifically the single use indicator.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C53602"]			
	codeSystem	1..1	OID 2.16.840.1.113883. 3.26.1.1	This is the ***codeSystem*** that manages the controlled vocabulary.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C53602"]/@codeSystem			
Business Rules	• The Single-use element is required and the ***code*@*code*** value must be “C53602” • A characteristic with code ‘C53602’ is required			

5.6.11.2 For Single Use Value (characteristic.value)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
Value		1..1		This is the container element for the value of the single use indicator.
	xsi:type	1..1	Alphanumeric CD	The ***xsi:type*** specifies the data type for the Single Use indicator.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C53602"]/../value/@xsi:type			
	Code	[1..1]	Alphanumeric C49488 - Yes C49487 - No C48660 - N/A	This is the code for the single use indicator.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C53602"]/../value/@code			
	codeSystem	1..1	OID 2.16.840.1.113883. 3.26.1.1	This is the ***codeSystem*** that manages the controlled vocabulary.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C53602"]/../value/@codesystem			

Business Rules	• The ***xsi:type*** value must be “CD”
	• The value must be one of the allowed values:
	  ○ C49488 – Yes (used if the device is for one use or for a single patient during a single procedure)
	  ○ C49487 – No (used if the device is not for one use or for a single patient during a single procedure and there is a maximum number of reuses)
	  ○ C48660 - N/A (used if the device is not for one use or for a single patient during a single procure and there is no maximum number of reuses, this includes capital equipment where the manufacturer does not enforce restrictions on the number of times it can be reused).
	• If characteristicValue is missing, invalid, or given more than once, the AusUDID submission will be rejected as a submission with an invalid Single Use.			

5.6.12 Device Characteristics – Kit

This attribute is used to indicate that the device is a convenience, combination, in vitro diagnostic (IVD), or medical procedure kit. Kits are a collection of products, including medical devices that are packaged together to achieve a common intended use and is being distributed as a medical device. The following XML Snippet includes the elements and attributes required:

```
<subjectOf>
    <characteristic>
        <code code="C50021" codeSystem="2.16.840.1.113883.3.26.1.1"/>
        <value xsi:type="BL" value="false"/>
    </characteristic>
</subjectOf>
```

5.6.12.1 Kit Type (characteristic.code)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
code		0..1		This is the container element for the Kit indicator.
	Code	1..1	Alphanumeric C50021	Code to indicate the type of characteristic being identified for a device product, specifically the kit indicator.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C50021"]			
	codeSystem	1..1	OID 2.16.840.1.113883. 3.26.1.1	This is the ***codeSystem*** that manages the controlled vocabulary.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C50021"]/@codeSystem			
Business Rules	• The Kit element is not required. If the medical device is a kit, the ***code*@*code*** value must be “C50021” • If this data element does not apply to the UDI record, a characteristic data element does not need to be provided. If the data element value is not provided, the system will consider it “false” in the database.			

5.6.12.2 Kit Value (characteristic.value)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
value		1..1		This is the container element for the kit indicator value.
	xsi:type	1..1	Boolean BL	The ***xsi:type*** specifies the data type for the kit indicator.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C50021"]/../value/@xsi:type			
	value	1..1	Alpha “true” or “false”	This is the value attribute for the Boolean operator.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C50021"]/../value/@value			
Business Rules	• The ***xsi:type*** value must be “BL” • If provided, value must be true or false • If characteristicValue is missing, invalid, or given more than once, the AusUDID submission will be rejected as a submission with an invalid Is Kit.			

5.6.13 Device Characteristics – Production Identifier in UDI

In AusUDID, each production identifier attribute appears as a Boolean value to indicate if the production identifier attribute is included in the UDI:

- the lot or batch number within which a device was manufactured
- the serial number of a specific device
- the expiration date of a specific device
- the date a specific device was manufactured
- for an HCT/P regulated as a device, the donation identification number of a specific device.

5.6.13.1 Production Identifier - Lot or Batch Number

The following XML Snippet includes the elements and attributes required for products labeled with a lot or batch number:

```
<subjectOf>
    <characteristic>
        <code code="C101672" codeSystem="2.16.840.1.113883.3.26.1.1"/>
        <value xsi:type="BL" value="false"/>
    </characteristic>
</subjectOf>
```

5.6.13.1.1 Lot or Batch Number Type (characteristic.code)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
code		1..1		This is the container element for the lot or batch number indicator.
	code	1..1	Alphanumeric C101672	This is the code to indicate the type of characteristic being identified for a device product, specifically the lot or batch number indicator.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C101672"]			
	codeSystem	1..1	OID 2.16.840.1.113883. 3.26.1.1	This is the ***codeSystem*** that manages the controlled vocabulary.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C101672"]/@codeSystem			
Business Rules	• The Lot or Batch Number is required and the ***code*@*code*** value must be “C101672”.			

5.6.13.1.2 Lot or Batch Number Value (characteristic.value)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
Value		1..1		This is the container element for the value of lot or batch number.
	xsi:type	1..1	Boolean BL	The ***xsi:type*** specifies the data type for the lot or batch number indicator.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C101672"]/../value/@xsi:type			
	value	1..1	Alpha “true” or “false”	This is the value attribute for the Boolean operator.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C101672"]/../value/@value			
Business Rules	• The ***xsi:type*** value must be “BL” • Value must be true or false • If characteristicValue is missing, invalid, or given more than once, the AusUDID submission will be rejected as a submission with an invalid Production Information			

5.6.13.2 Production Identifier – Serial Number

The following XML Snippet includes the elements and attributes required for products labeled with a serial number:

```
<subjectOf>
    <characteristic>
        <code code="C101671" codeSystem="2.16.840.1.113883.3.26.1.1"/>
        <value xsi:type="BL" value="false"/>
    </characteristic>
</subjectOf>
```

5.6.13.2.1 Serial Number Type (characteristic.code)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
code		1..1		This is the container element for the serial number indicator.
	code	1..1	Alphanumeric C101671	This is the ***code*** to indicate the type of characteristic being identified for a device product, specifically the serial number.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C101671"]			
	codeSystem	1..1	OID 2.16.840.1.113883. 3.26.1.1	This is the ***codeSystem*** that manages the controlled vocabulary.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C101671"]/@codeSystem			
Business Rules	• The Serial Number element is required and the ***code@code*** value must be “C101671”.			

5.6.13.2.2 Serial Number Value (characteristic.value)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
value		1..1		This is the container element for the value of serial number.
	xsi:type	1..1	Boolean BL	The **xsi:type** specifies the data type for the serial number indicator.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C101671"]/../value/@xsi:type			
	value	1..1	Alpha “true” or “false”	This is the value attribute for the Boolean operator**.**

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C101671"]/../value/@value			
Business Rules	• The ***xsi:type*** value must be “BL” • Value must be true or false • If characteristicValue is missing, invalid, or given more than once, the AusUDID submission will be rejected as a submission with an invalid Production Information.			

5.6.13.3 Production Identifier - Manufacturing Date

The following XML Snippet includes the elements and attributes required for products labeled with manufacturing date:

```
<subjectOf>
    <characteristic>
        <code code="C101669" codeSystem="2.16.840.1.113883.3.26.1.1"/>
        <value xsi:type="BL" value="false"/>
    </characteristic>
</subjectOf>
```

5.6.13.3.1 Manufacturing Date Type (characteristic.code)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
Code		1..1		This is the container element for the manufacture date indicator.
	code	1..1	Alphanumeric C101669	This is the ***code*** to indicate the type of characteristic being identified for a device product, the manufacture date indicator.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C101669"]			
	codeSystem	1..1	OID 2.16.840.1.113883. 3.26.1.1	This is the ***codeSystem*** that manages the controlled vocabulary.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C101669"]/@codeSystem			
Business Rules	• The Manufacturing Date is required and the ***code*@*code*** value must be “C101669”.			

5.6.13.3.2 Manufacturing Date Value (characteristic.value)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
Value		1..1		This is the container element for the value of the manufacturing date indicator.
	xsi:type	1..1	Boolean e.g. BL	The ***xsi:type*** specifies the data type for the manufacturing date indicator.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C101669"]/../value/@xsi:type			
	value	1..1	Alpha “true” or “false”	This is the value attribute for the Boolean operator.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C101669"]/../value/@value			
Business Rules	• The ***xsi:type*** value must be “BL” • Value must be true or false • If characteristicValue is missing, invalid, or given more than once, the AusUDID submission will be rejected as a submission with an invalid Production Information.			

5.6.13.4 Production Identifier – Expiration Date

The following XML Snippet includes the elements and attributes required for products labeled with an expiration date:

```
<subjectOf>
    <characteristic>
        <code code="C101670" codeSystem="2.16.840.1.113883.3.26.1.1"/>
        <value xsi:type="BL" value="false"/>
    </characteristic>
</subjectOf>
```

5.6.13.4.1 Expiration Date Type (characteristic.code)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
Code		1..1		This is the container element for the expiration date indicator.
	code	1..1	Alphanumeric C101670	This is the code to indicate the type of characteristic being identified for a device product, specifically the expiration date indicator.

	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C101670"]			
	codeSystem	1..1	OID 2.16.840.1.113883. 3.26.1.1	This is the ***codeSystem*** that manages the controlled vocabulary.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C101670"]/@codeSystem			
Business Rules	• The Expiration Date element is required and the ***code*@*code*** value must be “C101670”.			

5.6.13.4.2 Expiration Date Value (characteristic.value)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
value		1..1		This is the container element for the value of the expiration date indicator.
	xsi:type	1..1	Boolean BL	The ***xsi:type*** specifies the data type for the manufacture date indicator.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C101670"]/../value/@xsi:type			
	value	1..1	Alpha “true” or “false”	This is the value attribute for the Boolean operator.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C101670"]/../value/@value			
Business Rules	• The ***xsi:type*** value must be “BL”. • Value must be true or false. • If characteristicValue is missing, invalid, or given more than once, the AusUDID submission will be rejected as a submission with an invalid Production Information.			

5.6.13.5 Production Identifier – Donation Identification Number

The Donation Identification Number is applicable to devices that are also regulated as HCT/Ps and is a number that is assigned to each donation. It can be found on the device label or packaging. The following XML Snippet includes the elements and attributes required for products labeled with a donation identification number:

```
<subjectOf>
    <characteristic>
        <code code="C113843" codeSystem="2.16.840.1.113883.3.26.1.1"/>
        <value xsi:type="BL" value="false"/>
    </characteristic>
</subjectOf>
```

5.6.13.5.1 Donation Identification Number Type (characteristic.code)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
code		1..1		This is the container element for the donation identification number indicator.
	code	1..1	Alphanumeric C113843	This is the code to indicate the type of characteristic being identified for a device product, specifically the donation identification number indicator.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C113843"]			
	codeSystem	1..1	OID 2.16.840.1.113883. 3.26.1.1	This is the ***codeSystem*** that manages the controlled vocabulary.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C113843"]/@codeSystem			
Business Rules	• The Donation Identification Number is required and the ***code*@*code*** value must be "C113843".			

5.6.13.5.2 Donation Identification Number Value (characteristic.value)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
value		1..1		This is the container element for the value of donation identification number.
	xsi:type	1..1	Boolean BL	The ***xsi:type*** specifies the data type for the donation identification number indicator.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C113843"]/../value/@xsi:type			
	value	1..1	Alpha “true” or “false”	This is the value attribute for the Boolean operator.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C113843"]/../value/@value			
Business Rules	• The ***xsi:type*** value must be “BL” • Value must be true or false • If characteristicValue is missing, invalid, or given more than once, the AusUDID submission will be rejected as a submission with an invalid Production Information.			

5.6.14 Device Characteristics – MRI Safety Status

This attribute is used to indicate the MR safety status of the device (see ASTM F2503-13 standard). The following XML Snippet includes the elements and attributes required for the MRI Safety Status question, “What MRI safety information does the labelling contain?”:

```
<subjectOf>
    <characteristic>
        <code code="C106044" codeSystem="2.16.840.1.113883.3.26.1.1"/>
        <value xsi:type="CD" code="C106046" codeSystem="2.16.840.1.113883.3.26.1.1"/>
    </characteristic>
</subjectOf>
```

5.6.14.1 MRI Safety Status Type (characteristic.code)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
code		1..1		This is the container element for the sterilisation method.
	code	1..1	Alphanumeric C106044	This is the code to indicate the MRI Safety Status of the medical device product.

	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C106044"]			
	codeSystem	1..1	OID 2.16.840.1.113883. 3.26.1.1	This is the ***codeSystem*** that manages the controlled vocabulary.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C106044"]/@codeSystem			
Business Rules	• A response to, “What MRI safety information does the labeling contain?" is required for all UDI records and the ***code@code*** value must be “C106044”.			

5.6.14.2 MRI Safety Status Value (characteristic.value)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
value		1..1		This is the container element for the MRI Safety Status.
	xsi:type	[1..1]	Alphanumeric CD	The ***xsi:type*** specifies the data type for the MRI Safety Status.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C106044"]/../value/@xsi:type			
	code	[1..1]	Alphanumeric C113844 - Labeling does not contain MRI Safety Information C106046 - MR Conditional C106045 - MR Safe C106047 - MR Unsafe	This is the value attribute for the coded value.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C106044"]/../value/@code			
	codeSystem	1..1	OID 2.16.840.1.113883. 3.26.1.1	This is the ***codeSystem*** that manages the controlled vocabulary.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="C106044"]/../value/@codesystem			

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
Business Rules	• The ***xsi:type*** value must be “CD” • The value must be one of the allowed values: ○ C113844 - Labeling does not contain MRI Safety Information ○ C106046 - MR Conditional ○ C106045 - MR Safe ○ C106047 - MR Unsafe • If characteristicValue is missing, invalid, or given more than once, the AusUDID submission will be rejected as a submission with an invalid MRI Safety			

5.6.15 Device Characteristics – Software

This attribute is used to indicate if the device is Software as a medical device, or is a medical device incorporating software.

```
<subjectOf>
    <characteristic>
        <code code="AU1007" codeSystem="1.2.36.1.2001.1005.85"/>
        <value xsi:type="CD" code="AU1018" codeSystem="1.2.36.1.2001.1005.85"
        displayName="Software as a medical device"/>
    </characteristic>
</subjectOf>
```

5.6.15.1 Software Type (characteristic.code)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
code		1..1		This is the container element for is the device software or it incorporates software.
	Code	1..1	Alphanumeric AU1007	This is the code to indicate the device is software or it incorporates software.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="AU1007"]			
	codeSystem	1..1	OID 1.2.36.1.2001.1005.85	This is the ***codeSystem*** that manages the controlled vocabulary.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="AU1007"]/@codeSystem			
Business Rules	• A response to, “Is the device software or incorporates software?" is required for all UDI records and the ***code@code*** value must be “AU1007”.			

5.6.15.2 Software Value (characteristic.value)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
value		1..1		This is the container element for is the device software or it incorporates software.
	xsi:type	[1..1]	Alphanumeric CD	The ***xsi:type*** specifies the data type for Software value.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="AU1007"]/../value/@xsi:type			
	Code	[1..1]	Alphanumeric AU1017 - Software as a medical device AU1018 - Incorporates Software AU1019 - No	This is the value attribute for the coded value.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="AU1007"]/../value/@code			
	codeSystem	1..1	OID 1.2.36.1.2001.1005.85	This is the ***codeSystem*** that manages the controlled vocabulary.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="AU1017"]/../value/@codesystem			

Business Rules	• The ***xsi:type*** value must be “CD”
	• The value must be one of the allowed values:
	  ○ AU1017 - Software as a medical device
	  ○ AU1018 - Incorporates Software
	  ○ AU1019 - No
	• If characteristicValue is missing, invalid, or given more than once, the AusUDID submission will be rejected as a submission with an invalid Software.			

5.6.16 Device Characteristics – Restricted Number of reuses

This element records the number of reuses if the number of reuses is restricted. The following XML Snippet includes the element that indicates the restricted number of reuses:

```
<subjectOf>
    <characteristic>
        <code code="AU1004" codeSystem="1.2.36.1.2001.1005.85"/>
        <value xsi:type="INT" value="5"/>
    </characteristic>
</subjectOf>
```

5.6.16.1 Restricted number of reuses (characteristic.code)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
Code		0..1		The code element is the container element for Restricted number of reuses.
	code	1..1	Alphanumeric AU1004	The ***code*** for restricted number of reuses.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="AU1004"]			
	codeSystem	1..1	OID 1.2.36.1.2001.1005.85	This is the ***codeSystem*** that manages the controlled vocabulary.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="AU1004"]/@codeSystem			
Business Rules	• If 'For Single Use' is 'No', restricted number of reuses must be provided and the ***code@code*** value must be "AU1004" • If this data element does not apply to the UDI record, a characteristic data element does not need to be provided.			

5.6.16.2 Restricted number of reuses (characteristic.value)

Element	Attribute	Cardinality	Value(s) Allowed Examples	Description Instructions
value		1..1		This is the container element for the restricted number of reuses.
	xsi:type	1..1	Integer INT	The **xsi:type** indicates the data type for the element.
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code=”AU1004”]/../value/@xsi:type			
	Value	1..1	Number e.g. 5	This is the ***value*** attribute for the Integer operator***.***
	XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code[@code="AU1004"]/../value/@value			
Business Rules	• The value must be an integer • Value is required if code ‘AU1004’ is provided • If provided, value must be an integer • If characteristicValue is missing, invalid, or given more than once, the AusUDID submission will be rejected as a submission with an invalid Restricted Number of Reuses			

6 Common DI Validation

Business Rules	• A device identifier with GS1 as Issuing Agency shall be 14 digits in length; DIs with fewer digits should be appended with leading zeros • A device identifier with GS1 Issuing Agency shall be a numeric only value • A device identifier with GS1 Issuing Agency will have a valid check digit as per GS1 guidelines • A device identifier with ICCBBA Issuing Agency shall be 16 digits in length • A device identifier with ICCBBA Issuing Agency shall be an alphanumeric value • A device identifier with HIBCC Issuing Agency shall be 6-23 digits in length, first character alphabetic and last character numeric, and cannot include special characters • A device identifier with HIBCC Issuing Agency shall be an alphanumeric value.

7 XML Message Sample

```
<?xml version="1.0" encoding="UTF-8"?>
<!--Note: This AusUDID SPL XML Sample is not meant to be valid against the business rules for a AusUDID submission.  This is a comprehensive example of all the potential elements that can be submitted to the AusUDID.  Do not attempt to submit this sample as a test submission.-->
<document xmlns="urn:hl7-org:v3" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xsi:schemaLocation=AU"urn:hl7-org:v3 GUDIDSPL.xsd">
   <!--The document element is administrative information. (all elements are required)-->
   <!--id@root is a globally unique identifier for the submission and should be created by the sending system.  The sender should be following the algorithm rules set for in OSF's Universally Unique Identifier standards.-->
   <!--code@code for the submission type (AusUDID Submission = C101716)-->
   <!--code@code for the submission type (AusUDID Correction = AU1002) -->
   <!--effectiveTime@value for the DI Record Publish Date; all dates should be formatted as yyyymmdd -->
   <!--setId@root is a globally unique identifier for the document that will be used to link subsequent versions of the DI Record with previous versions.  Note this is also a UUID, and must follow the rules for generating a globally unique identifier value.-->
   <!--versionNumber@value is "1" for the initial submission and increments by one for any updates to the DI Record-->
   <id root="57863671-1527-4e51-b26b-3065a868d949"/>
   <!--Document Type code is "C101716" for the initial submission and any variations to the DI Record-->
   <code code="C101716" codeSystem="2.16.840.1.113883.3.26.1.1"/>
   <!--Document Type code is "AU1002" for any Correction to the DI Record-->
   <code code="AU1002" codeSystem="1.2.36.1.2001.1005.85">
      <!--Translation code is for codified reasons for correction-->
         <translation code="AU1031" displayName="Data entry error"/>
      <!--Translation original free text is for free text reason for correction-->
      <translation>
         <originalText>Free-text reason for correction</originalText>
      </translation>
   </code>
   <effectiveTime xsi:type="TS" value="20131118"/>
   <setId root="57863671-1527-4e51-b26b-3065a868d948"/>
   <versionNumber value="1"/>
   <!--The author element provides administrative information about who is submitting the DI Record. One author is required-->
   <!--provide the TGA organisation number for the Submitter Organization. This information will be used for validation activities only-->
   <!--code@code is the coded value for either the Manufacturer Organization (C101684), Sponsor (AU1000), Agent (AU1001), or Third-Party (C101710)-->
   <!--code@codeSystem, 2.16.840.1.113883.3.26.1.1 is the OID for NCIt-->
   <!--code@codeSystem, 1.2.36.1.2001.1005.85 is the OID for TGA-->
   <!--id.root= TGA ID; OID is for the TGA Identifier system-->
   <!--id.extension = TGA ID for the Manufacturer, Sponsor, Agent or the Third Party submitting the HL7 SPL-->
```

```
   <!--Note the system will pull the data from TGA Stakeholder Management and ARTG System to display the company name and physical address.-->
   <!--Only one value is expected for the author. The sender should indicate the correct value for who is submitting the XML to the TGA.-->
   <author>
      <!--Organization submitting the SPL XML (one and only one required)-->
      <assignedEntity>
         <representedOrganization>
            <!--If the submitter-organization is the Manufacturer organization, the code=C101684-->
            <assignedEntity1>
               <code code="C101684" codeSystem="2.16.840.1.113883.3.26.1.1"/>
               <representedOrganization>
                  <id root="1.2.36.1.2001.1005.84" extension="12345"/>
               </representedOrganization>
            </assignedEntity1>
         </representedOrganization>
      </assignedEntity>
   </author>
   <component>
      <structuredBody>
         <component>
            <section>
               <id/>
               <code/>
               <effectiveTime/>
               <!--This subject element contains all of the AusUDID DI Record information.-->
               <subject>
                  <!--classCode=MANU for the AusUDID Submission, without this value, the XML may fail validation-->
                  <manufacturedProduct classCode="MANU">
                     <manufacturedProduct>
                        <!--Primary Device Identifier (required)-->
                        <!--code@code is the location of the Primary Device Identifier (DI), base package DI#10010010010011-->
                        <!-- code@codeSystem is the device-issuing-agency associated with the Primary DI number (below the OID for GS1 is shown)-->
                        <code code="10010010010011" codeSystem="1.3.160"/>
                        <!--The Trade Name/Brand name (required) -->
                        <!--The element is the free-text field for the Brand/Proprietary/Trade Name of the medical device-->
                        <name>Trade Name/Brand Name</name>
                        <!--The Additional Product Description (optional)-->
                        <!--The desc element is the free-text description-->
                        <desc>add device description here</desc>
                        <!--The Device Model Number (At least one of Device Model or Catalogue Number is required)-->
                        <asIdentifiedEntity>
```

```
                        <!--id@root is a globally unique identifier assigned by the company for the
model number-->
                        <!--id@extension is the company issued Device Model Number -->
                        <!--code@code, C99285 is the code to indicate the type of Device Model, and
C99286 for Catalogue Number -->
                        <!--code@codeSystem, 2.16.840.1.113883.3.26.1.1 is the OID for NCIt-->
                        <id root="12345678-1234-1234-1234-123456789012" extension="Model T-
1000"/>
                        <code code="C99285" codeSystem="2.16.840.1.113883.3.26.1.1"/>
                    </asIdentifiedEntity>
                    <!--The Catalogue number for the device (At least one of Device Model or
Catalogue Number is required).-->
                    <asIdentifiedEntity>
                        <!--id@root is a globally unique identifier assigned by the company for the
catalogue number-->
                        <!--id@extension is the company issued for the Catalogue Number -->
                        <!--code@code, C99285 is the code to indicate the type of Device Model, and
C99286 for Catalogue Number -->
                        <!--code@codeSystem, 2.16.840.1.113883.3.26.1.1 is the OID for NCIt-->
                        <id root="12345678-1234-1234-1234-123456789013" extension="Catalog-
1000"/>
                        <code code="C99286" codeSystem="2.16.840.1.113883.3.26.1.1"/>
                    </asIdentifiedEntity>
                    <!-- ARTG ID. This is the approval to supply the device in Australia. This can be
repeated for each ARTG-->
                    <asIdentifiedEntity>
                        <!--id@root,1.2.36.1.2001.1005.83-->
                        <!--id@extension is the device ARTG ID -->
                        <!--code@code, AU1016 is the code to indicate the ARTG ID -->
                        <!--code@codeSystem, 1.2.36.1.2001.1005.85 is the OID for Australian Code
System-->
                        <id root="1.2.36.1.2001.1005.83" extension="413471"/>
                        <code code="AU1016" codeSystem="1.2.36.1.2001.1005.85"/>
                            <!--The Sponsor Id. This is the TGA Organisation Number for the Sponsor
for this ARTG approval-->
                        <!--id@root,1.2.36.1.2001.1005.84 is the OID for Australian TGA IDs-->
                        <!--id@extension=AU TGA number for the Sponsoring Organization-->
                        <assigningOrganization>
                            <id root="1.2.36.1.2001.1005.84" extension="12345"/>
                        </assigningOrganization>
                        <!-- Supporting Documents. This is the URL for any required supporting
documents provided by this Sponsor for the device supplied under the ARTG. This can be repeated
for each Supporting Document-->
                            <subjectOf>
                            <document>
                                <!-- Document URL. This is the URL for the supporting document-->
                                <!--id@extension is the URL-->
```

```
                        <id
extension="http://example.org/documents/123456789/product_leaflet.html"/>
                        <!--Document Type-->
                        <!--code@code, the specific type of document information being sent -->
                        <!--code@codeSystem, 1.2.36.1.2001.1005.85 is the OID for Australian
Code System-->
                        <code code="AU1008" codeSystem="1.2.36.1.2001.1005.85"
displayName="Patient Information Leaflet"/>
                        <!-- Document Start and End Date-->
                        <effectiveTime>
                           <low value="20010914"/>
                           <high value="20200914"/>
                        </effectiveTime>
                     </document>
                  </subjectOf>
                  <!--/Supporting Documents-->
               </asIdentifiedEntity>
               <!--/ARTG ID-->
               <!-- C -->
               <asSpecializedKind>
                  <generalizedMaterialKind>
                     <!--code@code is the Device Class code (Optional) -->
                     <!--codeSystem, 1.2.36.1.2001.1005.85, is the OID for Aus Code System -->
                     <code code="AU1020" codeSystem="1.2.36.1.2001.1005.85"/>
                  </generalizedMaterialKind>
               </asSpecializedKind>
               <!--The GMDN Preferred Term (Optional)-->
               <asSpecializedKind>
                  <generalizedMaterialKind>
                     <!--code@code is the 5-digit GMDN Preferred Term code (99999 is a
placeholder)-->
                     <!--code@codeSystem, 2.16.840.1.113883.6.276, is the OID for GMDN
Agency-->
                     <!--The AusUDID system will resolve the Preferred Term name and
definition based on the code provided.-->
                     <code code="99999" codeSystem="2.16.840.1.113883.6.276"/>
                  </generalizedMaterialKind>
               </asSpecializedKind>
               <!--Secondary Device Identifier (optional) -->
               <asEquivalentEntity>
                  <!--code@code, C101724 is the code for Secondary Device Identifier)-->
                  <!--code@codeSystem, 2.16.840.1.113883.3.26.1.1 is the OID for NCIt-->
                  <code code="C101724" codeSystem="2.16.840.1.113883.3.26.1.1"/>
                  <!--definingMaterialKind is the element used to provide the Secondary Device
Identifier-->
                  <!--code@code is the Secondary Device Identifier value-->
```

```
                        <!--code@codeSystem, 2.16.840.1.113883.6.40 is the OID for HIBCC.  The
code system must not be the same issuing agency as the one for the Primary Device Identifier - i.e., it
needs to be one of the other two options available for the Secondary Device Identifier.-->
                        <definingMaterialKind>
                           <code code="H123456789" codeSystem="2.16.840.1.113883.6.40"/>
                        </definingMaterialKind>
                     </asEquivalentEntity>
                     <!--Unit of Use Device Identifier (optional) -->
                     <asEquivalentEntity>
                        <!--The Unit of Use Device Identifier is provided with the asEquivalentEntity
element.-->
                        <!--code@code, C101717 is the code for a Unit of Use Device Identifier)-->
                        <!--code@codeSystem, 2.16.840.1.113883.3.26.1.1 is the OID for NCIt-->
                        <code code="C101717" codeSystem="2.16.840.1.113883.3.26.1.1"/>
                        <!--definingMaterialKind indicates the Unit of Use Device Identifier-->
                        <!--code@code is the Unit of Use Device Identifier Number-->
                        <!--code@codeSystem 1.3.160, is the OID for GS1.  Note that this codeSystem
needs to be the same codeSystem as provided for the Primary Device Identifier, otherwise it will not
pass validation.)-->
                        <definingMaterialKind>
                           <code code="123456794830384" codeSystem="1.3.160"/>
                        </definingMaterialKind>
                     </asEquivalentEntity>
                     <!--Direct Marking Device Identifier (optional) -->
                     <asEquivalentEntity>
                        <!--The Direct Marking Device Identifier is provided with the asEquivalentEntity
element.-->
                        <!--code@code, C101678 is the code for a Direct Marking Device Identifier)-->
                        <!--code@codeSystem, 2.16.840.1.113883.3.26.1.1 is the OID for NCIt-->
                        <code code="C101678" codeSystem="2.16.840.1.113883.3.26.1.1"/>
                        <!--definingMaterialKind indicates the Direct Marking Device Identifier-->
                        <!--code@code is the Direct Marking Device Identifier Number-->
                        <!--code@codeSystem 1.3.160, is the OID for GS1.  Note that this codeSystem
needs to be the same codeSystem as provided for the Primary Device Identifier, otherwise it will not
pass validation.)-->
                        <definingMaterialKind>
                           <code code="123456794" codeSystem="1.3.160"/>
                        </definingMaterialKind>
                     </asEquivalentEntity>
                     <!--Previous Device Identifier (optional) -->
                     <asEquivalentEntity>
                        <!--The Previous Device Identifier is provided with the asEquivalentEntity
element.-->
                        <!--code@code, C125195 is the code for a Previous Device Identifier)-->
                        <!--code@codeSystem, 2.16.840.1.113883.3.26.1.1 is the OID for NCIt-->
                        <code code="C125195" codeSystem="2.16.840.1.113883.3.26.1.1"/>
                        <!--definingMaterialKind indicates the Previous Device Identifier-->
                        <!--code@code is the Previous Device Identifier Number-->
```

```
                        <!--code@codeSystem 1.3.160, is the OID for GS1.-->
                        <definingMaterialKind>
                            <code code="12345678901234" codeSystem="1.3.160"/>
                        </definingMaterialKind>
                    </asEquivalentEntity>
                    <!--Package Hierarchy #1, Configuration #1: DI#201, Quantity in Package=4,
Package type=carton, Package Discontinue Date=9/1/2014, Contains base package
DI#10010010010011-->
                    <asContent>
                        <quantity>
                            <numerator value="100"/>
                            <denominator/>
                        </quantity>
                        <containerPackagedProduct>
                        <!--code@code is the device identifier value DI#= 201-->
                        <!--code@codeSystem is the OID for the issuing agency for the device
identifier, GS1 (1.3.160)-->
                        <!--name is the package type, "carton"-->
                        <!--capacityQuantity@value is the quantity per package, 4-->
                            <code code="201" codeSystem="1.3.160"/>
                            <name>carton</name>
                            <capacityQuantity value="4"/>
                            <asManufacturedProduct>
                                <subjectOf>
                                    <marketingAct>
                                        <!--effectiveTime.high@value is the Sponsor Package Commercial
Distribution End Date, 20140901-->
                                        <effectiveTime>
                                            <low/>
                                            <high value="20140901"/>
                                        </effectiveTime>
                                    </marketingAct>
                                </subjectOf>
                            </asManufacturedProduct>
                            <!--Package hierarchy #1, Configuration #2: DI#301, Quantity in Package=5,
Package type=case, Package Distribution End Date =9/1/2014, Contains DI#-201-->
                            <asContent>
                                <containerPackagedProduct>
                                <!--code@code is the device identifier value DI#= 301-->
                                <!--code@codeSystem is the OID for the issuing agency for the device
identifier, GS1 (1.3.160)-->
                                <!--name is the package type, "case"-->
                                <!--capacityQuantity@value is the quantity per package, 5-->
                                    <code code="301" codeSystem="1.3.160"/>
                                    <name>case</name>
                                    <capacityQuantity value="5"/>
                                    <asManufacturedProduct>
                                        <subjectOf>
```

```
                                    <marketingAct>
                                        <!--effectiveTime.high@value is the Sponsor Package
Commercial Distribution End Date, 20140901-->
                                        <effectiveTime>
                                            <low/>
                                            <high value="20140901"/>
                                        </effectiveTime>
                                    </marketingAct>
                                </subjectOf>
                            </asManufacturedProduct>
                        </containerPackagedProduct>
                    </asContent>
                </containerPackagedProduct>
            </asContent>
            <!--Package Hierarchy #2, Configuration #3: DI#401, Quantity in Package=4,
Package type=carton, Package Distribution End Date=9/1/2014, Contains base package
DI#10010010010011-->
            <asContent>
                <quantity>
                    <numerator value="100"/>
                    <denominator/>
                </quantity>
                <!--code@code is the device identifier value DI#= 401-->
                <!--code@codeSystem is the OID for the issuing agency for the device
identifier, GS1 (1.3.160)-->
                <!--name is the package type, "carton"-->
                <!--capacityQuantity@value is the quantity per package, 4-->
                <containerPackagedProduct>
                    <code code="401" codeSystem="1.3.160"/>
                    <name>carton</name>
                    <capacityQuantity value="4"/>
                    <asManufacturedProduct>
                        <subjectOf>
                            <marketingAct>
                                <!--effectiveTime.high@value is the Sponsor Package Commercial
Distribution End Date, 20140901-->
                                <effectiveTime>
                                    <low/>
                                    <high value="20140901"/>
                                </effectiveTime>
                            </marketingAct>
                        </subjectOf>
                    </asManufacturedProduct>
                    <asContent>
                        <!--Package hierarchy #2, Configuration #4: DI#501, Quantity in
Package=5, Package type=case, Package Distribution End Date=9/1/2014, Contains DI#-401-->
                        <!--code@code is the device identifier value DI#= 501-->
```

```
                        <!--code@codeSystem is the OID for the issuing agency for the device
identifier, GS1 (1.3.160)-->
                        <!--name is the package type, "case"-->
                        <!--capacityQuantity@value is the quantity per package, 5-->
                        <containerPackagedProduct>
                           <code code="501" codeSystem="1.3.160"/>
                           <name>case</name>
                           <capacityQuantity value="5"/>
                           <asManufacturedProduct>
                              <subjectOf>
                                 <marketingAct>
                                    <!--effectiveTime.high@value is the Sponsor Package
Commercial Distribution End Date, 20140901-->
                                    <effectiveTime>
                                       <low/>
                                       <high value="20140901"/>
                                    </effectiveTime>
                                 </marketingAct>
                              </subjectOf>
                           </asManufacturedProduct>
                        </containerPackagedProduct>
                     </asContent>
                  </containerPackagedProduct>
               </asContent>
            </manufacturedProduct>
            <!--id@root, 1.2.36.1.2001.1005.84 is the OID for Australian TGA IDs-->
            <!--id@extension=AU TGA number for the Manufacturer Organization-->
            <manufacturerOrganization>
               <id root="1.2.36.1.2001.1005.84" extension="12345"/>
            <!-- Manufacturer Name must be the same as what is recorded in TBS -->
               <name>Manufacturer Name</name>
            </manufacturerOrganization>
            <!--Production Identifier on Label - Serial Number (required)-->
            <!--code@code, C101671 is the code for Controlled by Serial number-->
            <!--code@codeSystem, 2.16.840.1.113883.3.26.1.1 is the OID for NCIt-->
            <!--value@xsi:type is required to indicate the characteristic has a Boolean data type-
->
            <!--value@value is True or False -->
            <subjectOf>
               <characteristic>
                  <code code="C101671" codeSystem="2.16.840.1.113883.3.26.1.1"/>
                  <value xsi:type="BL" value="false"/>
               </characteristic>
            </subjectOf>
            <subjectOf>
               <!--Production Identifier on Label - Lot or Batch Number (required)-->
               <!--code@code, C101672 is the code for Controlled by Lot Number-->
               <!--code@codeSystem, 2.16.840.1.113883.3.26.1.1 is the OID for NCIt-->
```

```
                <!--value@xsi:type is required to indicate the characteristic has a Boolean data
type-->
                <!--value@value is True or False -->
                <characteristic>
                  <code code="C101672" codeSystem="2.16.840.1.113883.3.26.1.1"/>
                  <value xsi:type="BL" value="false"/>
                </characteristic>
              </subjectOf>
              <subjectOf>
                <!--Production Identifier on Label - Expiration Date (required)-->
                <!--code@code, C101670 is the code for Controlled by Expiration Date-->
                <!--code@codeSystem, 2.16.840.1.113883.3.26.1.1 is the OID for NCIt-->
                <!--value@xsi:type is required to indicate the characteristic has a Boolean data
type-->
                <!--value@value is True or False -->
                <characteristic>
                  <code code="C101670" codeSystem="2.16.840.1.113883.3.26.1.1"/>
                  <value xsi:type="BL" value="false"/>
                </characteristic>
              </subjectOf>
              <subjectOf>
                <!--Production Identifier on Label - Manufacturing Date (required)-->
                <!--code@code, C101669 is the code for Controlled by Manufacturing Date-->
                <!--code@codeSystem, 2.16.840.1.113883.3.26.1.1 is the OID for NCIt-->
                <!--value@xsi:type is required to indicate the characteristic has a Boolean data
type-->
                <!--value@value is True or False -->
                <characteristic>
                  <code code="C101669" codeSystem="2.16.840.1.113883.3.26.1.1"/>
                  <value xsi:type="BL" value="false"/>
                </characteristic>
              </subjectOf>
              <subjectOf>
                <!--Production Identifier on Label - Donation Identification Number (required)-->
                <!--code@code, C113843 is the code for Donation Identification Number-->
                <!--code@codeSystem, 2.16.840.1.113883.3.26.1.1 is the OID for NCIt-->
                <!--value@xsi:type is required to indicate the characteristic has a Boolean data
type-->
                <!--value@value is True or False -->
                <characteristic>
                  <code code="C113843" codeSystem="2.16.840.1.113883.3.26.1.1"/>
                  <value xsi:type="BL" value="false"/>
                </characteristic>
              </subjectOf>
              <subjectOf>
                <!--Clinically Relevant Size is a characteristic that can either be sent with a CV or
as free text.-->
                <characteristic>
```

```
                        <!--code@code, C96684 is the code for longest diameter; clinically-relevant-size-type are available for several known size measures.  For testing, only select values are available in the controlled vocabulary.  Additional size types may be added in the future.-->
                        <!--code@codeSystem, 2.16.840.1.113883.3.26.1.1 is the OID for NCIt-->
                        <!--value@xsi:type is required to indicate the characteristic has a Physical Quantity data type-->
                        <!--value@value is the measurement value -->
                        <!--value@unit is the unit of measurement -->
                        <code code="C96684" codeSystem="2.16.840.1.113883.3.26.1.1"/>
                        <value xsi:type="PQ" value="3" unit="m"/>
                     </characteristic>
                  </subjectOf>
                  <subjectOf>
                     <!--Clinically Relevant Size - free text-->
                     <!--code@code, C106041 is the code for providing a free-text clinically-relevant-size.  For testing, this should be used when size-types are not available in the controlled vocabulary.-->
                     <!--code@codeSystem, 2.16.840.1.113883.3.26.1.1 is the OID for NCIt-->
                     <!--value@xsi:type is required to indicate the characteristic has a String data type-->
                     <!--value element should include the free-text between the value tags, as shown -->
                     <characteristic>
                        <code code="C106041" codeSystem="2.16.840.1.113883.3.26.1.1"/>
                        <value xsi:type="ST">Size text</value>
                     </characteristic>
                  </subjectOf>
                  <subjectOf>
                     <!--Storage and Handling Requirements (Provide as many as necessary)-->
                     <!--code@code, C101707 is the code for Storage Environment Temperature; storage-handling-conditions are available.  For testing, only select values are available in the controlled vocabulary.  Additional storage and handling conditions may be added in the future.-->
                     <!--code@codeSystem, 2.16.840.1.113883.3.26.1.1 is the OID for NCIt-->
                     <!--value@xsi:type is required to indicate the characteristic has a Physical Quantity Interval data type-->
                     <!--value.low@value is the measurement value; provide when temperature has a range, provide when the value is less than this value or if the value is exactly this temperature (note- same value will be entered in high@value)-->
                     <!--value.low@unit is the unit of measurement -->
                     <!--value.high@value is the measurement value; provide when temperature has a range, provide when the value is greater than this value or if the value is exactly this temperature (note- same value will be entered in low@value)- -->
                     <!--value.high@unit is the unit of measurement -->
                     <characteristic>
                        <code code="C101707" codeSystem="2.16.840.1.113883.3.26.1.1"/>
                        <value xsi:type="IVL_PQ">
                           <low value="0" unit="Cel"/>
                           <high value="10" unit="Cel"/>
```

```
                        </value>
                    </characteristic>
                </subjectOf>
                <subjectOf>
                    <!--Special Storage Condition Text (provide as many as necessary)-->
                    <!--code@code, C101704 is the code for providing a free-text special-storage-condition.  For testing, this element should be used when storage-requirements are not available in the controlled vocabulary.-->
                    <!--code@codeSystem, 2.16.840.1.113883.3.26.1.1 is the OID for NCIt-->
                    <!--value@xsi:type is required to indicate the characteristic has a String data type-->
                    <!--value element should include the free-text between the value tags, as shown -->
                    <characteristic>
                        <code code="C101704" codeSystem="2.16.840.1.113883.3.26.1.1"/>
                        <value xsi:type="ST1">keep out of sunlight</value>
                    </characteristic>
                </subjectOf>
                <subjectOf>
                    <!--Sterilization - Is the product packaged as sterile? (required)-->
                    <!--code@code, C101676 is the code for Packaged as Sterile-->
                    <!--code@codeSystem, 2.16.840.1.113883.3.26.1.1 is the OID for NCIt-->
                    <!--value@xsi:type is required to indicate the characteristic has a Boolean data type-->
                    <!--value@value is True or False -->
                    <characteristic>
                        <code code="C101676" codeSystem="2.16.840.1.113883.3.26.1.1"/>
                        <value xsi:type="BL" value="true"/>
                    </characteristic>
                </subjectOf>
                <!--Sterilization Method - Requires sterilization prior to use -->
                <!--If sterilization method code (e.g., C101712- Dry Heat) is provided and matches the sterilization values - the question - requires  sterilization prior to use will be marked "True". -->
                <!--If this element is not present, requires sterilization prior to use will be marked "False". -->
                <!--code@code, C84382 indicates the package needs to be sterilized prior to use-->
                <!--code@codeSystem, 2.16.840.1.113883.3.26.1.1 is the OID for NCIt-->
                <subjectOf>
                    <characteristic>
                        <code code="C84382" codeSystem="2.16.840.1.113883.3.26.1.1"/>
                        <!--value@xsi:type is required to indicate the characteristic has a Coded data type-->
                        <!--value@code, C101676 is the code for Sterilization Method. sterilization-method values are available as per the regulations.  Below the sample has C101712- Dry Heat as an example-->
                        <!--value@codeSystem, 2.16.840.1.113883.3.26.1.1 is the OID for NCIt-->
                        <value xsi:type="CD" code="AU1009" codeSystem="1.2.36.1.2001.1005.85" displayName="Beta Radiation Sterilization"/>
```

```
                    </characteristic>
                </subjectOf>
                <subjectOf>
                    <!--Labeled as Containing Natural Rubber Latex (required)-->
                    <!--code@code, C101673 is the code for Labeled as Containing Natural Rubber
Latex-->
                    <!--code@codeSystem, 2.16.840.1.113883.3.26.1.1 is the OID for NCIt-->
                    <!--value@xsi:type is required to indicate the characteristic has a Boolean data
type-->
                    <!--value@value is True or False -->
                    <characteristic>
                        <code code="C101673" codeSystem="2.16.840.1.113883.3.26.1.1"/>
                        <value xsi:type="BL" value="true"/>
                    </characteristic>
                </subjectOf>
                <subjectOf>
                    <!--Not Made with Natural Rubber Latex-->
                    <!--code@code, C106038 is the code for -->
                    <!--code@codeSystem, 2.16.840.1.113883.3.26.1.1 is the OID for NCIt-->
                    <!--value@xsi:type is required to indicate the characteristic has a Boolean data
type-->
                    <!--value@value is True or False -->
                    <characteristic>
                        <code code="C106038" codeSystem="2.16.840.1.113883.3.26.1.1"/>
                        <value xsi:type="BL" value="true"/>
                    </characteristic>
                </subjectOf>
                <subjectOf>
                    <!--Single Use (required) -->
                    <!--code@code, C53602 is the code for Single Use-->
                    <!--code@codeSystem, 2.16.840.1.113883.3.26.1.1 is the OID for NCIt-->
                    <!--value@xsi:type is required to indicate the characteristic has a Coded data
type-->
                    <!--value@code is the coded answer Yes - C49488, No - C49487, N/A - C48660--
>
                    <!--value@codeSystem, 2.16.840.1.113883.3.26.1.1 is the OID for NCIt-->
                    <characteristic>
                        <code code="C53602" codeSystem="2.16.840.1.113883.3.26.1.1"/>
                        <value xsi:type="CD" code="C49487"
codeSystem="2.16.840.1.113883.3.26.1.1"/>
                    </characteristic>
                </subjectOf>
                <subjectOf>
                    <!--MRI Safety Status (required) -->
                    <!--code@code, C106044 is the code for MRI Safety-->
                    <!--code@codeSystem, 2.16.840.1.113883.3.26.1.1 is the OID for NCIt-->
                    <!--value@xsi:type is required to indicate the characteristic has a Coded data
type-->
```

```
                    <!--value@code is the coded answer -->
                        <!--C113844 Labeling does not contain MRI Safety Information -->
                        <!--C106046 MR Conditional -->
                        <!--C106045 MR Safe -->
                        <!--C106047 MR Unsafe -->
                    <!--value@codeSystem, 2.16.840.1.113883.3.26.1.1 is the OID for NCIt-->
                    <characteristic>
                        <code code="C106044" codeSystem="2.16.840.1.113883.3.26.1.1"/>
                        <value xsi:type="CD" code="C106046"
codeSystem="2.16.840.1.113883.3.26.1.1"/>
                    </characteristic>
                </subjectOf>
                <!--Kit-->
                <!--code@code, C50021 is the code for Kits-->
                <!--code@codeSystem, 2.16.840.1.113883.3.26.1.1 is the OID for NCIt-->
                <!--value@xsi:type is required to indicate the characteristic has a Boolean data type-
->
                <!--value@value is True or False -->
                <subjectOf>
                    <characteristic>
                        <code code="C50021" codeSystem="2.16.840.1.113883.3.26.1.1"/>
                        <value xsi:type="BL" value="false"/>
                    </characteristic>
                </subjectOf>
                <!--DM Exempt-->
                <!--code@code, C101679 is the code for DM Exempt-->
                <!--code@codeSystem, 2.16.840.1.113883.3.26.1.1 is the OID for NCIt-->
                <!--value@xsi:type is required to indicate the characteristic has a Boolean data type-
->
                <!--value@value is True or False -->
                <subjectOf>
                    <characteristic>
                        <code code="C101679" codeSystem="2.16.840.1.113883.3.26.1.1"/>
                        <value xsi:type="BL" value="false"/>
                    </characteristic>
                </subjectOf>
                <!--Device Software-->
                <!--code@code, AU1007 is the code for Device Software-->
                <!--code@codeSystem, 1.2.36.1.2001.1005.85 is the OID for Australian Code
System-->
                <!--value@xsi:type is required to indicate the characteristic has a Coded data type--
>
                <!--value@code is the coded answer-->
                <!--value@codeSystem, 2.16.840.1.113883.3.26.1.1 is the OID for NCIt-->
                <subjectOf>
                    <characteristic>
                        <code code="AU1007" codeSystem="1.2.36.1.2001.1005.85"/>
```

```
                        <value xsi:type="CD" code="AU1018" codeSystem="1.2.36.1.2001.1005.85"
displayName="Software as a medical device"/>
                    </characteristic>
                </subjectOf>
                <!--Restricted Number of Reuses-->
                <!--code@code, AU1004 is the code for Restricted Number of Reuses-->
                <!--code@codeSystem, 1.2.36.1.2001.1005.85 is the OID for Australian Code
System-->
                <!--value@xsi:type is required to indicate the characteristic has a Integer data type--
>
                <!--value@value is the integer and must be greater than 1 if present-->
                <subjectOf>
                    <characteristic>
                        <code code="AU1004" codeSystem="1.2.36.1.2001.1005.85"/>
                        <value xsi:type="INT" value="5"/>
                    </characteristic>
                </subjectOf>
            </manufacturedProduct>
        </subject>
    </section>
</component>
</structuredBody>
</component>
</document>
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Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Devices Reforms Taskforce	Month Year
V1.1	Revisions for multiple sponsor and other editorial changes	Devices Reforms Taskforce	March 2025

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Reference/Publication #