Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Unique Device Identification (UDI) Consultation 3

Detailed considerations for implementing the proposed Australian medical device UDI regulatory framework

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TGA Health Safety Regulation

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Introduction

The Australian Government is undertaking a significant program of reform to the regulation of therapeutic goods in Australia. The reforms will continue to improve the safety, performance, and quality of medical devices in Australia and improve health outcomes for patients who require medical devices. As part of the Australian Government Department of Health and Aged Care, the Therapeutic Goods Administration (TGA) regulates therapeutic goods, and is responsible for implementing the Government's reforms. The TGA has issued this consultation paper as part of the Government's reform program.

This consultation paper is the third consultation paper published by the TGA relating to the Australian implementation of a Unique Device Identification (UDI) System for medical devices. It builds on the two previous consultation papers, *Proposal to introduce a Unique Device Identification (UDI) system for medical devices in Australia*, and *Consultation: Exploring options for the introduction of an Australian Unique Device Identification (UDI) System.* Respondents may wish to consider those papers and the feedback / outcomes prior to responding to this current consultation.[1]

Changes to the *Therapeutic Goods Act 1989*[2] to allow for the establishment of the UDI database, and the introduction of related requirements, were passed by the Australian parliament in February 2021. For the system to be operational, there is a need to provide for the establishment of the UDI database, and for setting out of related requirements, in the *Therapeutic Goods (Medical Devices) Regulations 2002*[3] (the MD Regulations).

This third consultation relates to the details of the proposed regulatory framework, including seeking feedback on:

- the impact of accepting both European and USA compliant labels
- acceleration of delivered benefits through a phased implementation approach
- scope and exemptions in applying the UDI
- providing and maintaining data over the full life of the device
- UDI related fees and charges
- UDI labelling, and supporting documentation
- any potential regulatory burden
- adoption and use in the broader healthcare setting

This consultation is being undertaken in parallel with UDI Early Adopter Projects, to explore and validate adoption of the UDI in healthcare systems, and the release of a "sandpit" Australian UDI database for feedback on the technical aspects of the UDI database.

[1] Past consultation papers can be found at the TGA UDI Hub
[2] *Therapeutic Goods Act 1989*
[3] *Therapeutic Goods (Medical Devices) Regulations 2002*

Consultation paper intent and approach

The implementation of UDI is occurring globally, with many countries planning for, in the process of, or having implemented Unique Device Identifiers. The two countries of most relevance to Australia are the United States of America (USA) and the European Union (EU) – as the majority of medical devices imported into Australia are already certified from these countries. The EU UDI implementation is still in early stages, while the implementation in the USA commenced in 2013 and has provided many valuable learnings to the TGA from the perspective of the manufacturers, the adoption and use of UDIs in healthcare, and the regulatory and technical frameworks.

In addition, since 2020, the TGA has facilitated and published deliberations of working groups and open stakeholder engagement sessions, with input received from manufacturers, sponsors, issuing agencies authorised in other countries, through to hospitals, medical professionals, and clinical quality registries.

Two of the working groups established by the TGA have assisted in informing some matters covered in this consultation paper (e.g.: the scenarios under which a new UDI device identifier (UDI-DI) would be required, and technical aspects of UDI data interoperability – provision of data to the TGA, and adoption and use of that data - across the Australian healthcare system).

This consultation has been written to describe the intent (rather than proposed text for any future regulations).

UDI intent

The primary objective of UDI is to improve patient safety and post market surveillance. When fully adopted in supply chain, clinical and other health systems, the UDI enables easier and faster identification of patients who have been implanted with a device of concern (e.g.: a device with a safety incident or recall related to that device).

In addition, it will facilitate easier identification and removal of those devices from stocks, storage, and distribution to prevent any further devices of that model being implanted or used.

It will also enable patients, consumers, and health professionals to access information more easily about the devices that they use, including if there is a device safety incident or recall related to that device.

Other benefits include improved transparency and availability of device information, particularly for consumers and at the point of care (such as in hospitals).

When adopted and used in processes and IT systems, the UDI enables data for a model of device to be linked through manufacture, supply chain, distribution, patient use, billing, inventory, and stock management, and enables longitudinal device analysis.

Australian UDI data will augment the data already held by the TGA, noting that UDI data will be at the model of device level and that some of the existing data is at the “kind of device” level.

Under the regulations, medical devices, including In Vitro Diagnostic medical devices, are included in the Australian Register of Therapeutic Goods (ARTG) as a 'kind of medical device'. An application for inclusion in the ARTG must be made for a 'kind of medical device'.

Medical devices are taken to be of the same kind if they have the same:

- sponsor;
- manufacturer;
- classification; and
- Global Medical Device Nomenclature System Code (GMDN code)
- (for Class III, Class AIMD medical devices and Class 4 IVD medical devices, other than a Class 4 IVD that is an immunohaematology reagent) unique product identifier (UPI).

Class III and Class AIMD devices can have one or more variants[4] associated with a single Australian Register of Therapeutic Goods (ARTG) entry. This minimises the number of entries required in the ARTG, but still provides a sufficient level of identification of the products. Currently allowable variants include gauge, shape, volume, diameter[5].

In effect, this means that whilst a single ARTG inclusion may have many devices or variants, there will potentially be multiple UDI records linked to that ARTG inclusion - one UDI record for each device or variant.

Key principles

The Australian UDI system will be focused on two **primary principles**:

1. The implementation of the Australian UDI system is focused on patient safety and improved post-market surveillance
2. The Australian implementation aims to support a single global Device Identifier for a model of device

Whilst this is the aim, we understand that there are scenarios under which multiple UDIs will exist concurrently for the same device and we are not proposing to mandate a single UDI per device. For example, if a sponsor supplies the same device into the U.S. and the EU as well as Australia, the device may have a different UDI for each country. Or there may perhaps be scenarios where a device supply shortage means diverting devices meant for another market.

[4] A variant means a medical device, the design of which has been varied to accommodate different patient anatomical requirements (for example, relating to the shape, size, length, diameter, or gauge of the device), if the variation does not change the intended purpose of the device.

[5] Kind of medical device (TGA)

In addition to patient safety, the five key **underpinning principles** are:

1. Alignment with the International Medical Device Regulators Forum (IMDRF) UDI guidance and application guides[6]
2. The needs of all users will be considered, with priority given to accelerating adoption and use of the UDIs in clinical and hospital settings
3. The regulator will make core UDI data accessible to the public free of charge
4. Minimising the burden on manufacturers wherever feasible, many of which are required to comply with differing UDI regulations across many countries
5. UDI data held by the regulator
   - should be current, correct, and easy to access and maintain
   - should be high quality and be designed to maximise usage and value (including for example, comprehensive data validation, minimising use of free-text fields and providing values for drop down lists)

UDI alignment

We propose to align the Australian UDI system with the IMDRF framework. In our second consultation[7] we noted that the USA and EU requirements are both, at a high level, aligned with the IMDRF guidance, and we explored whether Australia should align with either the USA or EU requirements. The responses we received supported alignment but were split 50/50 on which to align with.

Given that the majority of devices in Australia will be supplied with USA or EU certification and noting that the underpinning medical device regulations do differ across all three, we propose to accept UDI labelling that complies with either USA or EU requirements. A number of manufacturers are already working towards a 'universal device label' for this purpose and/or are creating a 'core' set of UDI data and augmenting that with country-specific requirements to manage the provision of UDI data to multiple countries.

This consultation seeks feedback on the implications of that proposal for data providers and data users (such as hospitals), and as there are differences between the USA and EU data elements and therefore, whether the TGA should also accept and store both USA and EU compliant data.

Specific implementation challenges

A number of challenges have been identified by stakeholders that will require future consideration and do not form part of this consultation. These include:

- lack of harmonisation of UDI requirements between regulatory jurisdictions, which creates burden for global manufacturers and may lead to different UDIs for different countries which may dilute the benefits

[6] IMDRF UDI Guidance (IMDRF/UDI WG/N7FINAL:2013) IMDRF UDI Application Guide (IMDRF/UDI WG/N48FINAL:2019)
[7] UDI Consultation paper 2: Exploring options for the introduction of an Australian Unique Device Identification (UDI) System

- slower than anticipated adoption and use of UDI in hospitals and the health ecosystem more broadly, which means that real world experience and issues are still emerging
- staggered compliance dates across countries
- tracking and tracing small implantable devices such as spinal rods and screws, particularly those included in orthopaedic loan kits and are supplied unsterilised and may be processed before initial use. These devices do not usually have packaging
- emerging technology – areas such as Software as a Medical Device (SaMD) – is rapidly evolving but well suited to digital tracking through UDI. It will be important to have clear guidance about requirements for manufacturers (software developers and distributors)
- software that is included as part of a "configurable device" is also proving to be a challenge. There is a lack of consensus and alignment on how to identify this software and the device it is part of (or associated with)
- IMDRF work on harmonising guidance for personalised medical devices particularly in relation to medical device production systems and providing traceability for devices produced on those systems (including implantable devices)

Scope of the UDI system - regulatory context

Changes to the *Therapeutic Goods Act 1989*[8] to allow for the establishment of the UDI database, and the introduction of related requirements, were passed by the Australian parliament in February 2021. For the system to be operational, there is a need to provide for the establishment of the UDI database, and for setting out of related requirements, in the *Therapeutic Goods (Medical Devices) Regulations 2002*[9] (the MD Regulations).

The Australian Government will decide on the regulatory changes and make the regulations.

The TGA is now seeking detailed feedback to inform the Government's decision.

It is proposed that the Australian UDI system be implemented within the existing framework for the regulation of medical devices within Australia, principally through amendments to the Medical Device Regulations to:

- establish the database
- require the inclusion of UDIs and related information in the database (these requirements are proposed to be included as part of the Essential Principles)
- include related requirements in the Essential Principles, such as labelling

In Australia the sponsor is principally responsible for ensuring that the regulatory requirements are met for devices supplied in Australia. This may add complexity when a labeller is undertaking some activities on the sponsor's behalf (such as attaching a label to a device). In most instances the labeller will be the manufacturer or sponsor, but in some instances, it may be a specialist third party acting on behalf of the sponsor or manufacturer.

[8] *Therapeutic Goods Act 1989*
[9] *Therapeutic Goods (Medical Devices) Regulations 2002*

Australia is not proposing to add the role of 'labeller' as a regulated entity, however for the purposes of this paper, it will be used for ease of reading and understanding.

In recognition of the fact that the labeller will also in many cases manage the data elements associated with the UDI, we are exploring options to potentially allow the labeller to provide data to the TGA, where the labeller may not be the sponsor, or where a single model of device is supplied by multiple sponsors.

The content of this consultation paper is specific to medical devices that are for supply in Australia (i.e. not those that are only for export from Australia). It is important to note that other countries and/or the IMDRF may refer to these differently, have different risk classifications, or may include devices that are not recognised or regulated in the same way in Australia.

For ease of reading, we have provided descriptions for Australian definitions in Appendix 3 including the link to where these are defined in our regulatory framework.

References

We appreciate that as part of this paper we are requesting feedback in relation to comparing the proposed approach to establishing a UDI system in Australia with the implementation of UDI in other countries, as well as with work undertaken by the IMDRF. We have provided the core information in the body of this consultation paper; however, you may wish to read some of the following documents prior to preparing your response.

TGA resources

A range of TGA resources including the first two consultation papers, webinars and other information is on the TGA UDI hub.

IMDRF resources

The IMDRF has released a number of papers on UDI. The following two papers outline the base model for the UDI System:

- IMDRF/UDI WG/N7FINAL:2013 UDI guidance: Unique Device Identification (UDI) of medical devices
- IMDRF/UDI WG/N48 FINAL: 2019 Unique Device Identification (UDI) Application Guide

This document provides a comparison of data elements across the EU, U.S. FDA and IMDRF definitions (noting that there may have been changes to the EU data set since this document was published):

- IMDRF/UDI WG/N53 FINAL: 2019 Use of UDI Data Elements Across Different Jurisdictions

Other documents are available on the IMDRF website.

U.S. Food and Drug Administration (FDA) resources

This link is the home page for UDI:

- Unique Device Identification System (UDI System)

GUDID is the U.S. FDA UDI database. The data is publicly available and can be accessed here:

- AccessGUDID

EU resources

The EU has released a number of papers and guidance on the UDI implementation on the EU UDI home page.

The EU legislation is broken into two parts:

- Medical devices – REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017
- In vitro diagnostic medical devices – REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017

The European database on medical devices is EUDAMED.

Other resources

Overseas issuing agencies such as Global Standards One (GS1) and Health Industry Business Communications Council (HIBCC), as well as other countries such as Singapore and the UK also have UDI information available on their web sites.

Definitions

Definitions used in this document are intended to align with the *Therapeutic Goods Act 1989* (the Act) and, where feasible, existing IMDRF definitions. However, in keeping with the 'plain English' approach to this paper, in some cases these have been reworded for clarity.

Further definitions are provided in Appendix 3.

Term	Description
Unique Device Identifier (UDI) (sometimes referred to as the full UDI) *The Act s3(1)*	Any combination of numbers, symbols and letters given to the **model** of device to enable identification of the device (whether or not that combination also allows identification of information relating to the device). The UDI is comprised of two elements—the Device Identifier and Production Identifier. Note: The word 'unique' does not imply serialization of individual production units, the UDI is unique to a model of device.
Device Identifier (UDI-DI)	A unique numeric or alphanumeric code specific to a **model** of medical device. The Device Identifier is used as the 'access key' to information stored in a UDI database, and is the data that allows the linking of device information across other systems. Examples of the UDI-DI include: • GS1's GTIN (Global Trade Item Number) • Health Industry Business Communications Council's (HIBCC's) HIBC-LIC (Health Industry Bar Code - Labeller Identification Code) • International Council for Commonality in Blood Banking Automation's (ICCBBA's) ISBT 128-PPIC (International Society of Blood Transfusion 128 - Processor Product Identification Code)
Production Identifier (UDI-PI)	A numeric or alphanumeric code that identifies the **unit of device production** (or how it is controlled). The Production Identifier may include the serial number, lot or batch number, software identification, date of manufacture or expiry date (or both of these dates). The Production Identifier will change from one production run to the next, and therefore it is considered the 'variable' element of the UDI, and it is not stored in the regulator's UDI database.

Term	Description
The Australian Unique Device Identification Database (AusUDID) *The Act s41CE*	**41CE Database of unique device identifiers of medical devices** (1) The regulations may make provision for and in relation to the Secretary causing a database to be established and maintained, to be known as: (a) the Australian Unique Device Identification Database; or (b) if another name is prescribed by the regulations—that other name. Note: The Essential Principles may include requirements in relation to the inclusion in the database of unique device identifiers of medical devices and related information: see subsection 41CA(3). *Personal information* (2) The regulations must provide that the database must not include personal information, unless the personal information: (a) is the name of a person in relation to whom a kind of medical device is included in the Register; or (b) is about an authorised representative of the manufacturer of a kind of medical device; or (c) is about an authorised representative of a person in relation to whom a kind of medical device is included in the Register. *Removal of information* (3) The regulations may provide for the removal of information from the database. *Corrections to information* (4) The regulations may provide for corrections to information in the database. *Making the database available* (5) The regulations may provide for the whole or a part of the database to be made: (a) available to specified persons, authorities or bodies; or (b) publicly available. (6) However, the regulations must provide that personal information covered by paragraph (2)(b) or (c) must not be made publicly available. *No limit on subsection (1)* (7) Subsections (2) to (6) do not limit subsection (1). *Database not a legislative instrument* (8) The database is not a legislative instrument.
Unique Device Identifier Carrier (UDI carrier)	The physical representation of the UDI on the device label (or in some cases on the device itself), usually in both a machine-readable (Automatic Identification and Data Capture (AIDC)) and human-readable (Human Readable Interpretation (HRI)) form. Machine-readable carriers can include linear barcodes, 2D data matrix, and radio-frequency identification (RFID).

Term	Description
Labeller	The labeller is the organisation that applies a label to a device, or who causes the label to be modified, with the intent that the device will be introduced into supply without any subsequent replacement or modification of the label. In most instances, the labeller will the manufacturer or sponsor, but in some instances the labeller may be a specialist third party, or a loan kit assembler. Adapted from UDI Final Rule 2013 (78 FR 58785) § 830.3
Issuing Agency	Organisations that maintain globally unique UDI coding systems using International Standards Organisation (ISO) or International Electrotechnical Commission (IEC) coding standards.
Sponsor *The Act ch1(3)*	***Sponsor***, in relation to therapeutic goods, means: (a) a person who exports, or arranges the exportation of, the goods from Australia; or (b) a person who imports, or arranges the importation of, the goods into Australia; or (c) a person who, in Australia, manufactures the goods, or arranges for another person to manufacture the goods, for supply (whether in Australia or elsewhere); But does not include a person who: (d) exports, imports or manufactures the goods; or (e) arranges the exportation, importation or manufacture of the goods; on behalf of another person who, at the time of the exportation, importation, manufacture or arrangements, is a resident of, or is carrying on business in, Australia.
Shipping Container	Shipping container is a container where the traceability is controlled by a process specific to logistics systems[10].

The Unique Device Identifier

The UDI should consist of a UDI-Device Identifier (UDI-DI) and UDI-Production Identifier (UDI-PI).

The UDI-DI should be a unique numeric or alphanumeric code specific to a model of medical device.

The UDI-DI should represent a mandatory fixed portion identifying a manufacturer's specific product and package configuration and be used as the "access key" to information stored in the Australian UDI database (AusUDID).

[10] IMDRF UDI Guidance (IMDRF/UDI WG/N7FINAL:2013) Section 5.

We anticipate that in the majority of cases, the manufacturer will be the labeller. Therefore, to reduce regulatory burden we propose to allow the provision of data by a labeller (which may or may not have an Australian presence) in addition to the sponsor.

See the section on UDI data and its provision and Question 5.

Issuing agencies

As we are proposing to accept both U.S. FDA and EU compliant labels, and as overseas issuing agencies (IAs) are both already required to manage UDI formats according to international standards, and to undertake a formal authorisation process in the U.S. and EU, we do not propose to create a formal framework for authorising IAs and managing their compliance.

Instead, the TGA proposes to have a process whereby IAs common to the U.S and EU. are in effect 'recognised' by the TGA. These are initially expected to be Global Standards One (GS1), Health Industry Business Communications Council (HIBCC) and the International Council for Commonality in Blood Banking Automation (ICCBBA).

Wherever feasible more than one IA will be named to provide a choice for labellers.

We do not anticipate the need for the TGA to become an IA.

The UDI carrier and labelling

The UDI carrier should represent the UDI in both machine-readable (scannable)[11] and human readable forms. This is to cater for the broad range of users of devices – from supply chain to clinical use, and over-the-counter use of devices by consumers.

The UDI carrier is an additional requirement to, and is not proposed to replace, any other, existing labelling requirements that apply under the Act or MD Regulations.

A UDI-DI must be applied to all levels of device packaging except the shipping container level. The labeller is responsible for considering UDI carrier placement on the label.

It is expected that when the machine-readable form of the UDI is scanned using an AIDC reader (for example a hand-held scanner), device data will be able to be read from the carrier, automatically captured, and stored in an electronic patient record or other computer system via an automated process.

There are many circumstances where scanning technology may not be available (such as over-the-counter devices, or in hospitals with paper-based systems), and so a human readable form of the UDI should also be included on the label along with the machine-readable form. The human readable form must be a legible interpretation of the data characters encoded in the UDI Carrier.

The TGA is not planning to restrict the machine-readable form to a specific symbology (for example a one-dimensional or linear barcode), noting that some symbologies may be more appropriate for specific settings or use (for example some formats like one-dimensional barcodes are more suited to supply-chain use).

[11] IMDRF UDI Guidance (IMDRF/UDI WG/N7FINAL:2013) Section 5.

Each issuing agency will have its own specifications including the carrier type, quality, and placement for example.

Where a label contains multiple symbologies (such as barcodes/QR codes), it is proposed that the UDI symbol (ISO 15223-1, UDI Graphical Symbol 5.7.10, 2021) be included on the label to avoid confusion as to the purpose of each of the symbologies.

Whilst the sponsor may not be the labeller in many cases, it is important to note that it is proposed that the UDI labelling requirements will mainly be included in the Essential Principles.

Where there is a single unpackaged device or one device in a package, the device UDI will be known as the 'base package' UDI-DI.

It is proposed that where there are multiple unpackaged and unlabelled devices within a single package (for example five syringes in one package), the device UDI-DI would be required to be different to the UDI-DI on the first layer of packaging (the base package), in this case the device UDI-DI will be known as the 'unit of use' UDI-DI.

It is expected that the sponsor would be principally responsible for ensuring that the UDI data for their medical devices is provided to the TGA and is in accordance with the relevant requirements in the Essential Principles (including that the carrier chosen is appropriate for the expected use).

Direct Marking

For devices that are intended for multiple uses, where it is reprocessed (for example cleaned and/or sterilised) between use on different patients, the original device packaging may not be available for each subsequent reuse, and the device would need to have the UDI carrier marked directly onto the device itself.

It is proposed that devices that are supplied non-sterile and without packaging and are sterilised, before being used on a patient should also be direct marked.

It is proposed that direct marking would not apply in circumstances where the manufacturer reasonably believes that any type of direct marking would interfere with the safety or performance of the device, or that it is not technologically feasible to use direct marking.

A range of factors may need to be considered in relation to direct marking, including the device materials, expected number of reprocesses, and so on.

There may be cases where the direct marking UDI-DI may be different to the base package UDI-DI for a device, for instance where a device is:

- packaged in both single and multiple packs
- provided both in sterile and non-sterile packaging
- provided in different sizes which are sold together

UDI data and provision

Sponsors are principally legally responsible for the supply of medical devices in Australia, whilst the IMDRF, the USA and EU note that, under their requirements, "manufacturers are responsible for the initial submission and updates to the information in the UDID"[12].

Whilst there are still some complexities to be resolved, the TGA is considering supporting UDI data provision by labellers (who are not sponsors), sponsors and regulatory agents.

It is possible for more than one sponsor to supply the same device in Australia.

We are exploring these complexities further in Question 4.

We recognise that some labellers and sponsors have complex, mature IT systems and others do not. Therefore, it is proposed that the Australian UDI database (AusUDID) will provide for the provision and maintenance of single device data through an online portal interface, and bulk entry through file upload and machine-to-machine interfaces.

At the time a sponsor receives final approval to supply a model of device in Australia, it is proposed that in most instances there must be a corresponding valid and complete UDI record for that device in the AusUDID.

Where a pre-market notification is not required (such as in circumstances where devices are aggregated into existing Australian Register of Therapeutic Goods (ARTG) inclusions) then it is proposed that a corresponding valid and complete UDI record for that device must exist in the AusUDID from the date the device is included on the ARTG.

Should devices that are regulated (i.e. must comply with the Essential Principles) but are not required to be included on the ARTG be required to comply with UDI regulations, it is proposed that the corresponding valid and complete UDI record must be in the AusUDID by the time the device is first supplied (imported into) in Australia.

When a device is no longer authorised for supply (which may occur for many reasons including a recall, sponsor cancellation), it is proposed that the UDI data for that device would be 'frozen' (in the AusUDID) as at the date commercial supply ceased, with no further changes allowed to be made to the database in respect of that device. Such 'frozen' device data would continue to be publicly available but could not be modified.

Under some circumstances, there may be a need to reactivate (or 'unfreeze') the device record. These may include:

- recall completed, or corrective actions implemented
- data entry error (incorrect commercial supply end date provided)

Changes to device data over time

Based on experience from other country implementations, we recognise there are many scenarios under which device data will change over time, including supply chain changes, correction of data errors, clinically relevant changes to the device, issuing agency requirements, and where a single device is supplied to multiple countries with different UDI requirements.

[12] IMDRF UDI Application Guide (IMDRF/UDI WG/N48FINAL:2019) Section 8.1.

Given the key principle of accurate and current device data, we are exploring ways to allow changes to the data, whilst maintaining the integrity of the data, without introducing significant additional administrative overheads. There are plans to capture an audit trail of changes to device data over time, and to allow the AusUDID to display versions of device records at points in time, showing the changes made between versions. Whilst a search for a device will only display the most current version, it is planned that users will be able to click to see the history.

This will provide benefits to long-term users of device data, including clinical quality registries who we anticipate will be able to undertake improved longitudinal device analysis once the UDI is adopted in hospitals and clinical quality registries.

It will also be important for those devices that might be implanted for many years before any safety issues emerge.

Changes to UDI-DIs and triggers

A UDI-DI 'trigger' is a scenario under which a new UDI-DI is required. The IMDRF UDI Guidance (IMDRF/UDI WG/N7FINAL:2013) provides that, "*at a minimum, a new UDI-DI is required whenever there is a change to the medical device that could lead to misidentification of the medical device, and/or ambiguity in its traceability".*

In such circumstances, it is proposed that the new UDI would be required to be reflected on the device label, and the new UDI-DI and any related data provided to the TGA, within a reasonable period of time (we would be grateful for views as to what this period should be). Entering the new UDI-DI in the database would result in a new record being created, which would be separate to the previous record held for that device, which would then be 'frozen'.

It is proposed to link the two UDI records for traceability (under certain circumstances).

Issuing Agencies may also have requirements relating to when a new UDI-DI is required.

Proposed UDI-DI triggers for Australia

The TGA Working Group on UDI Triggers, comprising of sponsors, global manufacturers with mature centralised UDI organisations, peak bodies, medical professionals, registries and issuing agencies – raised the following challenges related to triggers:

- different countries have different requirements relating to triggers
- global manufacturers may provide new UDI-DIs to all supplied markets if a trigger is mandated in one country but not all (for example, if a device is supplied to the EU and Australia and the EU mandates a trigger Australia does not, the manufacturer may also provide the new UDI-DI to Australia to keep the device UDI data aligned across countries)
- issuing agencies may also determine circumstances under which a new DI is required, in addition to regulatory requirements
- some triggers will be clinically relevant (such as a change to the clinically relevant size), others are likely not to be (such as manufacturer merger or acquisition)
- users of the data (including hospitals and registries) will need to account for and manage complex changes to device data including multiple UDI-DIs for a device where the device itself may not have changed

Based on the work of that group, we have broken down the changes to specifically highlight those that are clinically relevant, and which are not. It is proposed that changes to any of the following will require a new UDI-DI:

Changes that are proposed to be clinically relevant (and require a new UDI-DI)

- Software add/change features that result in change to intended purpose (new major version)
- Labelled as single use
- Critical warnings or contraindications:
  - Contains latex
  - Contains DEHP
  - MRI safety status
- Packaged sterile
- Need for sterilisation before use
- Clinical size (including volume, length, gauge, diameter)
- If the restricted number of reuses changes

Changes that are proposed to not be clinically relevant (and require a new UDI-DI)

- Brand name
- Device version or model
- Quantity of devices provided in a package (device count)

To accelerate the realisation of benefits from a hospital and registry perspective, and to reduce the administrative burden on those organisations that individually manage and track changes over time (such as hospitals), the TGA proposes to develop the following functionality as part of the AusUDID:

Field	Intent	Options
Reason for UDI-DI change	To enable data users to understand the underlying reason for the UDI-DI change	• Clinically relevant change • Regulatory compliance (for a country other than Australia) • Supply chain • Error fix • Other (Note: only one to be selected, the final wording, values and relationships with the change is to be agreed as part of database and data element work, including how to cater for divesture, acquisition or change in manufacturer)

Field	Intent	Options
Reason for UDI-DI change (notes/comments)	To provide any additional information relevant to users of the data in relation to the change	Single field, free text
Linked UDI-DI	This will provide linkages between UDI records over time, including UDI records that have changed through a UDI-DI trigger or other change	Must be a UDI-DI already in the AusUDID

It is proposed that new UDI-DI and data must be submitted to the TGA no later than the date the device is first labelled and supplied in Australia with the changed information. If the information does not appear on the label of a device, it is proposed that the updated information must be submitted prior to first supply in Australia.

It is not proposed that any recertification or audit is required as the result of these changes.

Scope of devices required to comply with UDI requirements

It is proposed that most kinds of medical devices would be required to comply with the UDI requirements, unless identified in the Essential Principles as kinds of devices for which a UDI is not required.

Note the following are proposed to be **in scope** and need to comply with the UDI requirements:

- medical devices in the emergency stockpile
- medical devices that are exempt from inclusion in the ARTG
- replacement parts where the original part was in scope

Class I devices

Globally, it is recognised that there are specific challenges relating to requiring UDIs for Class I devices, which are generally lower-risk kinds of medical devices.

The U.S. FDA for example, has recently released guidance relating to Class I (non life-supporting or life-sustaining) compliance dates, and requirements relating to Class I Consumer Health Products[13]. The guidance noted that "*As UDI implementation has progressed, FDA has gained further insight into the public health benefits and potential burdens of UDI requirements for class I devices, which generally pose the lowest risk*."

Considerations related to Class I devices include:

- will it be confusing for consumers if some devices are in the AusUDID and others are not?
- some Class I devices are both consumer health products and used in hospitals (such as specimen containers)

[13] U.S. FDA - UDI and Class I Devices Guidance (FDA-2017-D-6841)

- what might the challenges be in relation to procurement and hospital inventory systems if some devices have UDI and others do not – will two separate processes be required?
- should the TGA consider a grouping mechanism to reduce the number of UDI records that might be required?

We are seeking specific feedback on Class I devices in Question 3.

It should be noted that in Australia spectacle lenses and spectacle frames are excluded from the medical device regulatory framework, and the risk classifications for contact lenses are Class IIa and Class IIb.

Proposed exemptions

There are some kinds of medical devices that pose a lower risk to users and for which the risk profile may not justify inclusion in the UDI framework. There are also some kinds of medical devices for which other, similar regulatory oversight applies which may be more appropriate.

It is proposed that UDI requirements would not apply to the following kinds of medical devices:

Proposed out of scope Medical Devices and IVDs

Device	Comments
Class 1 General laboratory IVD medical devices (such as pipettes)	General laboratory ware IVD (CT 945). Other Class 1 IVD medical devices (such as instruments and analysers) are proposed to be in scope as they can be included in post-market surveillance and recalls.
Medical devices that are surgical loan kits (at the kit level)	Each device in the kit would already be subject to UDI requirements. It is proposed that UDIs for each device in the kit be made available to the hospital in a way that enables easy linking of the devices to a patient at the point of care.
Medical devices and IVD medical devices that are imported into and supplied in Australia under the Special Access Scheme (SAS) or Authorised Prescriber Scheme or any other exemption pathways (such as for Clinical Trials for example)	Even if these devices have UDIs from other countries we don't anticipate that the device data would be available in the Australian database which may be confusing to consumers and users.
Export only medical devices and IVDs	If they are not supplied in Australia, they are not required to comply with Australian UDI regulations, but may be

Device	Comments
	required to comply with UDI requirements for the target market.
Systems or Procedure Packs (SOPPs)	Individual single-use disposable devices, the uses of which are generally known to the persons by whom they are intended to be used, which are contained within a system or procedure pack, and which are not intended for individual use outside the context of the system or procedure pack, shall not be required to bear their own UDI carrier. Devices that are exempted from bearing a UDI carrier on the relevant level of packaging shall not be required to bear a UDI carrier when included within a system or procedure pack.
Custom made medical devices	
In-house IVDs	In-house IVDs are currently regulated but Class 1-3 in-house IVDs are exempt from inclusion on the ARTG provided the laboratory is accredited and complies with certain standards[14]. In-house IVDs are not commercially supplied. Manufacturers of in-house IVD medical devices need to notify the TGA of any new devices (once a year).

Specific medical device requirements

The following arrangements are proposed for specific types or classes of devices.

Implantable devices

The primary purpose of UDIs for implantable medical devices is to ensure that the full UDI (UDI-DI and UDI-PI) is identifiable to the implanting health care provider prior to implantation. As generally implantable devices are not reused across patients, it is not proposed that there be requirements for direct marking for implantable medical devices. However, the full UDI should be available for scanning at point-of-care (in an operating theatre prior to surgery for example).

In addition, it is proposed that the UDI-PI component of the UDI for an implantable medical device must have the following characteristics:

- serial number for active implantable devices
- serial number or lot number for other implantable devices (according to the manufacturer's quality management system) [15]

[14] *Therapeutic Goods (Medical Devices) Regulations 2002,* Schedule 4 Part 2 Item 2.10
[15] IMDRF UDI Guidance (IMDRF/UDI WG/N7FINAL:2013) Section 10.1, 2

Patient-matched medical devices

It is proposed that patient matched medical devices will require a UDI and be subject to UDI regulations.

Medical Device Production Systems and personalised medical devices produced using those systems

The IMDRF is currently undertaking additional work on technical documents for:

- validation of the specified design envelope for patient-matched medical devices
- validation of a Medical Device Production System (a relatively new framework for regulating point-of-care manufacture of Personalised Medical Devices[16])

We are proposing that the medical device production system itself requires a UDI. The UDI should be easily visible to the user of the system.

Personalised medical devices created by the MDPS are a device in their own right and as such also require a UDI. There should be some way to easily link the device to the MDPS it was produced on.

In the case of the UDI-DI for the personalised medical device, the user of the MDPS may provide linking information on the MDPS (including the MDPS UDI-DI). The user must also create a UDI-PI for the device and maintain this information in its records for traceability purposes.

Systems or procedure packs (SOPPs)

The TGA is currently moving to align with the EU for the regulation of Systems or Procedure Packs[17]. As such it is proposed that Australia aligns with the EU requirements:

- the system or procedure pack requires a UDI
- a system UDI-DI is allocated to defined groups of configurations
- a system UDI-PI is allocated to each individual system. A later change of a component, sub-systems or accessory of the system does not change the UDI-PI of the system
- the carrier of the System UDI should be put on the assembly that most likely does not get exchanged in its lifetime and should be identified as the 'Primary' UDI-DI

Spare or replacement parts

The TGA does not currently have a regulatory framework relating to replacement parts and is therefore not proposing any UDI requirements. It is proposed that in the scenario where a component of a device that is considered a device itself and has therefore assigned a UDI-DI is exchanged, the replacement part must also meet the UDI requirements.

[16] IMDRF Personalized Medical Devices (IMDRF/PMD WG/N58FINAL:2020)
[17] IMDRF UDI Guidance (IMDRF/UDI WG/N7FINAL:2013) Section 10.5

Accessories

It is proposed that an Accessory that has its own ARTG entry (for example a proprietary microscope slide that can only be read by an IVD instrument – the slide is needed for the instrument to achieve its intended purpose) – unless specifically exempted from UDI requirements, would need to comply with UDI requirements.

Software

It is proposed that medical devices that are software, including IVD medical devices, be required to meet the UDI requirements. It is proposed that Australia implements these requirements aligned to the U.S., in that:

- the version number should be easily visible regardless of whether the software is packaged or unpackaged (aligned with Essential Principle 13b)18
- the UDI should be displayed each time the software is started and/or via an "About" feature, user operated button, click-through, menu command or similar feature, this would apply equally to products that are a web service as well as downloadable software
- the UDI should be the same on the base package and the software, and consistent across other 'About' features
- the UDI should be searchable on the manufacturers' website
- for packaged software, the UDI should be included on the label and packaging in machine and human readable forms, as well as in the software itself
- for software distributed in non-packaged form, the UDI-PI should contain at a minimum the current version number, and where applicable, the build number

Surgical loan kits

There are recognised, global challenges in identifying devices in surgical loan kits, especially small implantable devices used in spinal, hand, and trauma surgery.

The TGA is undertaking separate consultation on surgical loan kits – especially in relation to repeated processing of implantable devices in loan kits.

In line with the TGA consultations and the IMDRF guidance[19], as each medical device within a kit is a medical device in its own right, it is proposed that the kit be exempt from requiring a UDI at the kit level.

Linking non-sterile orthopaedic implantable devices (such as for trauma kits or spinal surgeries) is a recognised challenge, as the implants are supplied without packaging.

It is proposed that the full UDI for each medical device in a kit be available for users of such kits and easily accessible at the point of care to allow the linking of medical devices to their implantation or use on patients.

[18] *Therapeutic Goods Act 1989* Part 4-2
[19] IMDRF UDI Guidance (IMDRF/UDI WG/N7FINAL:2013) Section 10.3, 2

In-Vitro Diagnostic medical devices

The Act[20] allows for grouping of multiple IVD medical devices under a single ARTG inclusion (based on being the same 'kind' of device which includes the GMDN collective term[21] (CT)). Certain Class 4 IVD medical devices must be included separately in the ARTG using the term name and unique product identifiers. It is proposed that each IVD must have a single assigned UDI, correct labelling and data provided to the TGA. It is proposed that a GMDN code, term name and description must be provided for each IVD.

Retention of data and records

No specific UDI requirements in addition to the existing obligations of manufacturers and sponsors.

UDIs in other regulatory processes

Patient Information Leaflets

There is no intent to require UDIs on Patient Information Leaflets (PILs).

However, it is important that consumers are provided as much information about a device, and this should have links with PILs – this link is explored in this consultation.

PILs are required to be supplied with implantable medical devices, providing patients with information about the device, its purpose, possible adverse events, and how to provide feedback if there are malfunctions. The Medical Device Regulations require that PILs are made available to the patient in hard copy or electronically; however, it is likely that hard copy PILs may be discarded, lost by patients over the course of time, or possibly not provided in a timely manner to allow patients to make an informed decision before being implanted with a device. Healthcare facilities are also reporting that they are overwhelmed with the delivery of patient information material for the provision to patients.

As such, the TGA is investigating options for the development of a PIL 'repository' that would provide patients with current medical device information in an easily accessible way. It is proposed participation would be voluntary for sponsors, with self-service functionality allowing sponsors to update their PILs quickly and easily. The sponsor would be responsible for ensuring the PIL is up to date.

We are seeking feedback on how the TGA might implement a PIL repository – which could be linked to UDI or ARTG numbers. See Question 7.

[20] *Therapeutic Goods Act 1989* Section 41BE
[21] GMDN Agency

Instructions for Use

There is no intent to require UDIs on Instructions for Use.

Patient Implant Cards

Once the UDI is mandatory in Australia, it is proposed that the full UDI (UDI-DI and UDI-PI), in both machine and human readable form, will be a regulatory requirement that it must be included on the Patient Implant Card (PIC) for every implantable or active implantable medical device.
PICs are not required for a suture, staple, dental filling, dental brace, tooth crown, screw, wedge, plate, wire, pin, clip, or connector.

The card must include:

- the name of the device
- the model of the device
- the batch code, lot number or serial number of the device
- the unique device identifier of the device
- the manufacturer's name, address, and website

Recalls, Adverse Events and Incident Reports

Once the UDI is mandatory in Australia, it is proposed that for a medical device to which the mandatory recall procedures have been applied[22], the UDI may be included. For example, a sponsor may be required to inform the public of the UDI as part of informing the public of relevant information about the device's recall or provide UDI information to healthcare facilities).

The UDI is also proposed to be required for voluntary recalls of medical devices, adverse event reports and incident reports.

Device application process, and linking the ARTG and UDI

The Australian UDI implementation will also seek to link existing ARTG numbers.

Initially, whilst the UDI and ARTG are separate systems this may create some data integrity issues. In the future, for all new applications, at the time a sponsor receives approval to supply a model of device in Australia, it is proposed that there must be a corresponding valid and complete UDI record for that device in the AusUDID (with 30 days to upload data).

It is acknowledged that alignment and linkages will take time.

However, as the ARTG ID is one of the primary device identifiers in Australia, already used across supply chain, healthcare, and reimbursement systems, we anticipate linking every model of device in the AusUDID to the corresponding ARTG ID will have significant benefits for accelerating adoption. As such, the AusUDID, in the short term, will require one or more matching ARTG IDs for every UDI (there may be more than one ARTG ID if the same device is supplied by different sponsors).

[22] *Therapeutic Goods Act 1989* Section 41KA

Inspections and audits

Good Manufacturing Practice (GMP) inspections and Quality Management System (QMS) audits [23] undertaken are proposed to, where appropriate, include the assessment of whether a manufacturer is correctly assigning UDIs, storing and maintaining the data appropriately and ensuring that the data is consistent across the label, direct marking on the device itself (where applicable), QMS and other internal systems, PICs, and other information as required in the regulations.

Re-registration or re-certification

We are not proposing that re-registration or re-certification is required when labelling or other supporting documents are amended to meet the new UDI requirements.

Phased implementation approach

We are proposing a phased implementation approach that is aligned with other regulators whereby, high risk and implantable medical devices will be required to comply initially, prior to other classes of devices. This focus will accelerate the patient safety benefits but would not precede EU implementation dates.

Considerations

The following considerations for Australian implementation are based on feedback from stakeholders:

- a phased implementation based on risk classification starting with high-risk devices
- voluntary compliance framework from 1 January 2023, until a specified date on which compliance would be mandatory
- a minimum of twelve months for labellers and sponsors to prepare for compliance following the regulatory framework is in place
- global alignment where feasible to minimise the burden on industry stakeholders
- Australia to not precede EU implementation dates
- minimise the implementation burden where possible (manufacturers and TGA)

  recognition that a number of reforms and changes are occurring simultaneously, including for Australian reimbursement processes

[23] Good manufacturing practice inspections (TGA)

Proposed mandatory compliance dates

Noting: the scope of devices still to be finalised

Note it is proposed that the label/packaging for direct marked devices meet the earlier compliance date, the later date relates to the direct marking on the device itself, acknowledging the additional complexities involved in direct marking.

Australian Device Class	Devices	Label/Package to bear UDI, data to be provided to AusUDID	Direct Marking Compliance Date	Labels/packing not required to bear UDI for devices in transit to, or in Australia before	Direct marking not required for devices in transit to, or in Australia before*
Class III (including AIMD)	Included on the ARTG as at 30 June 2024, or supplied after 1 July 2024	1 July 2024	1 July 2024	1 July 2024	1 July 2024
Class II	Included on the ARTG as at 30 June 2024, or supplied after 1 July 2024	1 July 2024	1 July 2025	1 July 2024	1 July 2025
Class I	Included on the ARTG as at 30 June 2026	1 July 2026	1 July 2027	1 July 2026	1 July 2027
IVDs Class 2 IVDs Class 3 IVDs Class 4	Included on the ARTG as at 30 June 2026, or manufactured after 1 July 2026	1 July 2026	1 July 2027	1 July 2026	1 July 2027
IVDs Class 1	Included on the ARTG as at 30 June 2027, or manufactured after 1 July 2027	1 July 2027	1 July 2028	1 July 2027	1 July 2028
	Medical devices and IVD medical devices that are regulated (i.e. required to comply with the Essential Principles) but that are not required to be included on the ARTG	1 July 2027	1 July 2028	1 July 2027	1 July 2028

What does mandatory compliance mean?

In line with the phased implementation approach, and for those devices in scope, mandatory compliance means:

- UDIs, and related information, must be included in the database for all existing models of device, and labels and packaging must include the UDI
- devices are direct marked (where required)
- UDI data must be complete and correct (published) in the AusUDID for every model of device and the ARTG ID must also be provided for every UDI to allow for linking between the UDI and ARTG data sets
- UDI data must be kept up to date while the device is in commercial supply
- UDI must be included on the Patient Implant Card
- sponsors must include UDI on any notifications to the TGA, including adverse events, incident reports and recalls

Non-compliance

As the UDI requirements are proposed to be included in the Essential Principles, the main sanctions for non-compliance would include:

- suspension or cancellation from the Register
- the offences and civil penalties in Part 4-11, Division 1 of *the Act*
- infringement notices

However, as these requirements are proposed to form part of the Essential Principles, it would potentially also be open to sponsors that are not able to comply or meet the mandatory compliance date for UDI requirements for a device to request consent to import or supply a medical device that does not comply with one or more Essential Principles.[24]

Where consent to supply is granted for a medical device that is non-compliant with the Essential Principles ongoing regulatory responsibilities of the sponsor remain, including, but not limited to, undertaking recall action, and reporting of adverse events.

[24] Under sections 41MA and 41MAA of the *Therapeutic Goods Act 1989*. Under section 41MC of the Act, the consent of the Secretary may be given unconditionally or subject to conditions, or in respect of particular medical devices or kinds of medical devices.

Responsibilities

The Australian sponsor is responsible for compliance with UDI requirements.

Using UDIs in clinical and other systems

Overseas experience has highlighted a challenge for users of UDIs is in understanding which is the most appropriate DI to use, particularly in relation to linking a device to patient use or for billing or reimbursement purposes.

To facilitate that understanding, work has started to create a linking table (see below):

Device	Linking DI (for linking to specific patient use)	Linking DI (for billing and reimbursement purposes)
Device where there is more than one device in the base package or If there is a single item in a package that does not bear a complete UDI label	Unit of use DI	
Device which is direct marked with only one device in a package (or no packaging after the first use)	Direct mark DI	
Device where there is one device in the lowest level of packaging	Primary DI	
System or Procedure Pack	Primary DI	
Device included in a Surgical Loan Kit	Primary DI	
Software as a medical device		
Blood or product of human origin		

We are seeking feedback on whether AusUDID can make this easier for end-users without placing additional burden on labellers. See Question 10.

Global Medical Device Nomenclature (GMDN)

There are known complexities related to allocating the GMDN for devices included in the ARTG, including for IVDs. These have evolved over time for three main reasons:

- technical constraints in the TGA's systems
- the "kind of device" regulatory framework
- the application GMDN is valid for the life of the device, even if the GMDN Agency subsequently makes changes to that GMDN preferred term

In recognition of the importance of GMDN to post-market surveillance, for UDI, GMDN will be required for each model of device. We note that the GMDN Agency's position on alignment with the current code set is changing due to the increasing number of countries implementing UDI, and as such the TGA is now exploring options for a potential change to the way it uses GMDN and therefore a change in requirements in relation to GMDN for UDI specifically. We are seeking your feedback on the implications of requiring that the TGA GMDN data in the AusUDID be kept aligned with the GMDN Agency dataset. For example, if the GMDN Agency makes a code obsolete, any UDI records with that device code would need to have a new GMDN code provided by the sponsor or manufacturer.

We understand that this may mean that there are differences between the GMDN stored in the ARTG and AusUDID for the same model of device, which will need to be resolved.

See Question 8.

How to submit your feedback

Your input and feedback will help inform the planning and design of the Australian UDI implementation. In addition to the scope of this consultation, we will welcome other feedback on UDI, as well as feedback on our consultation process.

You can submit your feedback using our online survey tool the TGA Consultation Hub or via email by sending your response to udi@health.gov.au. Please direct any queries via email to udi@health.gov.au

This consultation closes on 11 October 2022.

Questions

It is important to carefully consider the questions – as some questions are applicable to only some stakeholders, whilst other questions are applicable to all stakeholders.

Question 1 – If Australia accepts both EU and USA compliant labels, what might the impact be?

We would appreciate feedback from both a labeller and UDI data user (such as a hospital or registry) perspective.

Question	
Which markets do you supply to or import from?	☐ Australia ☐ U.S. ☐ EU
Please provide more information	
If Australia is to accept labels and data from both the EU and U.S. what might the impact be for manufacturers/sponsors?	☐ There will be benefits ☐ There are no benefits ☐ It will increase the burden
If there are benefits, what are they?	
If the burden will increase, please provide more information	
If Australia is to accept labels and data from both the EU and U.S. what might the impact be for procurement and supply chain?	☐ There will be benefits ☐ There are no benefits ☐ It will increase the burden
If there are benefits, what are they?	
If the burden will increase, please provide more information	
If Australian is to accept labels and data from both the EU and U.S. what might the impact be for healthcare users (such as hospitals)?	☐ There will be benefits ☐ There are no benefits ☐ It will increase the burden
If there are benefits, what are they?	
If the burden will increase, please provide more information	
Are there any other benefits we should take into consideration?	☐ Yes ☐ No
If yes, what are they?	

Question	
Are there any other disadvantages we should consider?	☐ Yes ☐ No
If yes, what are they?	
Might this create a scenario where there is more than one UDI for the same model of device in Australia?	☐ Yes ☐ No
If yes, under what scenarios might a device have more than one Australian UDI?	
Might Australia need to cater for two complete data sets – both U.S. and the EU?	☐ Yes ☐ No
Please provide more information	

Question 2 – What should the phased implementation approach be?

We understand that many manufacturers who supply to multiple countries are managing complex changes and timings around UDI implementations, potentially at the same time as other changes. We would appreciate your feedback on the proposed implementation approach:

Question	
Do you plan to voluntarily comply with the UDI requirements prior to the mandatory compliance date (for assignment, labelling and provision of data)?	☐ Yes ☐ No
If yes, for which devices?	☐ All ☐ Class III ☐ Class II ☐ Class I ☐ Class 4 IVD ☐ Class 3 IVD ☐ Class 2 IVD ☐ Class 1 IVD
Is there anything the TGA could potentially do to accelerate the compliance/provision of data for existing devices (such as using GUDID data for example)?	☐ Yes ☐ No
If yes, what would that be?	

Question	
For existing devices, what might the complexities be in providing UDIs for each ARTG inclusion if there is more than one device for the inclusion?	
Do you envisage any related supply issues in meeting the UDI requirements?	☐ Yes ☐ No
If yes, please provide more information	
Are there any other Australia-based regulatory changes we should take into account in our considerations?	☐ Yes ☐ No
If yes, please provide more information	
Are there any other international regulatory changes we should take into account in our considerations?	☐ Yes ☐ No
If yes, please provide more information	
Is there anything else we should have taken into account for the proposed phased implementation that we have missed?	☐ Yes ☐ No
Please provide more information	
Do you have any other thoughts or suggestions on the implementation? If so, please provide them here	

Question 3 – Scope and exemptions

We would welcome your feedback in relation to the proposed scope of devices:

Question	
Should Class I medical devices be in scope for UDI?	☐ In scope ☐ Out of scope ☐ Voluntary
Please provide more information here, we are especially interested in the benefits and potential burden for data providers, data users (such as hospitals) and consumers	
Should Class I IVDs be in scope for UDI?	☐ In scope ☐ Out of scope ☐ Voluntary

Question	
Please provide more information here, we are especially interested in the benefits and potential burden for data providers, data users (such as hospitals) and consumers	
Should Australia adopt a similar approach to the U.S. for consumer health products (that is, the universal product code becomes the primary identifier and data is not included in the UDI database)? [25]	☐ Yes ☐ No
Should Australia adopt a similar approach to the EU in grouping Class I devices (such as the Master UDI-DI)?	☐ Yes ☐ No
Please provide more information	
Are there any additional devices that could be exempt?	☐ Yes ☐ No
If yes, which devices and why?	
Are there any devices we have proposed to be exempt that should not be?	☐ Yes ☐ No
If yes, which devices and why?	
Please provide any other feedback here	
Should there be special considerations for packages (which include medical devices) supplied free of charge to homeless or disadvantaged people? Should these packages as a whole be exempt from UDI requirements?[26]	☐ Yes ☐ No
Please provide any other feedback here	
Should the Australian system include ad-hoc requests for exemptions (as the U.S. does)?	☐ Yes ☐ No
Please provide any other feedback here	
Are there any complexities we should consider in linking ARTG ID to UDIs if some devices in an inclusion with multiple devices are exempt (from UDI requirements), and others are not?	☐ Yes ☐ No
If yes, please provide more information	

[25] U.S. FDA - UDI and Class I Devices Guidance (FDA-2017-D-6841)

[26] *Therapeutic Goods Regulations 1990* Schedule 5A Item 14

Question 4 – Who should provide and maintain the data where there are multiple sponsors for a device?

In Australia it is possible for a single model of device to be supplied by multiple sponsors. ARTG inclusions are linked to an individual sponsor, and where the same device is supplied by more than one sponsor the same device will appear on multiple ARTG inclusions and therefore have multiple ARTG IDs.

For UDI the device data is proposed to be at the model of device level (regardless of how many different sponsors are authorised to supply the device). So even if one device is supplied by three different sponsors, it is proposed there is only one UDI record for that device.

We understand that this raises questions in relation to who 'owns' the data and who can change it, and we are seeking feedback on our proposed approach.

Note that under the regulatory framework the sponsor is legally responsible for the data in the AusUDID.

Question	
Should there be one UDI record per combination of model of device and sponsor? That is, if one model of device is supplied by three sponsors should there be three UDI records for the same device, one per sponsor?	☐ Yes ☐ No
Please provide any feedback here	
Where a model of device is supplied by more than one sponsor, should there be a single UDI record and single 'owner' of all device (i.e. non-sponsor) data in the AusUDID?	☐ Yes ☐ No
If yes, who should that be?	☐ Labeller/manufacturer ☐ First authorised sponsor ☐ Other
Please provide any feedback here	
Should the labeller be responsible for all of the data, including the sponsor details?	☐ Yes ☐ No
If yes, please provide any reasoning here	
Should the TGA limit access to specific data elements depending on role? For example should there be a 'labeller' role which can access all the data, but the 'sponsor' role can only add/amend sponsor details?	☐ Yes ☐ No
Please provide any feedback here	

Question	
Are there other approaches the TGA should consider?	☐ Yes ☐ No
If yes, please provide further information	
Might we need to allow for a scenario where a device that is supplied by multiple sponsors may have to allow for different commercial distribution statuses? That is, if two sponsors supply one model of device could it be in commercial distribution with one, but not the other?	☐ Yes ☐ No
If yes, please provide feedback on how we might cater for that	

Question 5 – Providing and maintaining data over the full life of the device

We have included the proposed data dictionary at Appendix 2.
We would appreciate your feedback on the proposed UDI data and its maintenance over the life of the device.

Question	
How many models of devices do you expect to provide data for (existing devices)?	☐ <10 ☐ 10-50 ☐ 51-100 ☐ >100
Which method do you plan to use to provide UDI data to the TGA?	☐ Bulk - Machine to Machine (e.g. HL7 SPL) ☐ Bulk – National Product Catalogue ☐ Bulk file upload ☐ Web based (using the online portal)
Do you foresee any challenges relating to the proposed triggers?	☐ Yes ☐ No
If yes, what might they be?	
Are there any data elements we have missed?	☐ Yes ☐ No
If yes, please provide more information	

Question	
Are there any data elements we have included that are not required?	☐ Yes ☐ No
If yes, please provide more information	
Are there any data elements we should not require for IVDs?	☐ Yes ☐ No
If yes, please provide more information	
Do you envisage you will make any changes to the ARTG as result of the introduction of UDI?	☐ Yes ☐ No
If yes, what might they be?	
Do you envisage any difficulties in keeping the data in the ARTG, Prostheses List and AusUDID aligned and current?	☐ Yes ☐ No
If yes, please provide more information	
Do you think the TGA should require that the GMDN code be kept aligned with the GMDN Agency code set while the device is in commercial supply?	☐ Yes ☐ No
Please provide more information	
Do you think there should be a 1:1 relationship between the catalogue number and the UDI? That is, if the catalogue number changes a new UDI-DI is required and vice versa	☐ Yes ☐ No
Please provide any feedback here	
Should the TGA consider additional fields for MRI Safety status?	☐ Yes ☐ No
If yes, is there a standard that the TGA should use for these fields? [27]	
Please provide any other data feedback here	

[27] Such as the U.S. FDA - Testing and Labelling Medical Devices for Safety in the Magnetic Resonance Guidance (FDA-2019-D-2837)

Question 6 – Fees and Charges

The costs associated with the Australian UDI system and database must be included in the fees and charges from 1 July 2024. We are seeking feedback on how this may be developed:

Question	
Do you have any feedback on what we should take into account when developing the UDI fees and charges model? In particular, considerations around current and correct data, and understanding that device data will change over time?	☐ Yes ☐ No
Please provide more details here	
Should the TGA consider moving to a fee structure which takes into consideration the number of changes to the UDI data over time?	☐ Yes ☐ No
Please provide more details here	
Should the TGA consider moving to an annual charge for UDI based on the number of UDI records?	☐ Yes ☐ No
Please provide more details here	
Is there anything else the TGA should consider in relation to determining the annual charge?	
What might make it easier for labellers to keep the data up to date in relation to fees and charges?	
What might the TGA consider in relation to fees and charges for machine to machine, NPC, or bulk transactions?	
Should the TGA include the cost of regular reviews and updates of the AusUDID to ensure it remains fit for purpose over time?	☐ Yes ☐ No
Please provide any other fees and charges feedback	

Question 7 – UDI labelling and supporting documentation

We would appreciate your feedback on the proposed UDI and labelling requirements.

Question	
Do you have any feedback on the composition of the UDI-PI for specific devices or scenarios?	☐ Yes ☐ No
If yes, please provide more information	
Do you have any feedback on direct marking requirements? Are there considerations or scenarios we haven't taken into account?	☐ Yes ☐ No
If yes, please provide more information	
Are there any considerations we should take into account for Patient Implant Cards?	☐ Yes ☐ No
If yes, please provide more information	
What would be your preferred method of providing Patient Information Leaflets (PILs) for your devices?	☐ As a PDF document ☐ As a link to an external website (i.e. sponsor or manufacturer website) where the PIL is hosted and publicly available for download ☐ Both a PDF copy and a link to an external website where the PIL is hosted ☐ Other
If other, please provide more information	
Do you foresee any issues or complications if the PIL repository was developed as part of the AusUDID database or the ARTG Search database on the TGA website?	☐ Yes ☐ No
If yes, please provide more information	
Are there complexities we should take into account if PILs are required for multiple devices in an ARTG inclusion?	☐ Yes ☐ No
If yes, please provide more information	
Do you think that there is a better platform other than the AusUDID or the ARTG Search, through which a PIL repository could be delivered?	☐ Yes ☐ No

Question	
If yes, please provide more information	
How might hospitals capture UDIs at the point of care for small implantable devices that cannot be direct marked and are unpackaged? Should labellers/kit providers provide additional information?	☐ Labellers or kit suppliers should provide additional information (say via a checklist or kit packing list) ☐ Labellers or kit suppliers should provide stickers ☐ Other
If other, please provide more information	

Question 8 – Global Medical Device Nomenclature

There are post-market surveillance benefits in having the device GMDN Term Name aligned with the most current GMDN Agency code set. We are seeking feedback on what the impact of this might be.

Question	
Can you foresee issues in having GMDN at kind of device in the ARTG, and model of device level in AusUDID?	☐ Yes ☐ No
If yes, what might they be and how might we overcome them?	
If the TGA was to require that the GMDN Term Name in the AusUDID is to remain aligned with the GMDN Agency code set over the life of the device, what might the impact be for manufacturers and sponsors?	
With the introduction of UDI in multiple countries, do you already have challenges in maintaining GMDN for your devices?	☐ Yes ☐ No
If yes, please provide more information	
For IVDs, do you foresee any issues in requiring collective terms (CT) for the ARTG inclusion and GMDN Term Name in AusUDID?	☐ Yes ☐ No
If yes, what might they be?	

Question 9 – Regulatory Burden

Please provide your feedback on the below questions.

Question	
Given the details provided in this paper, do you envisage that the introduction of the Australian UDI will increase the burden on manufacturers or sponsors over and above complying with other countries requirements?	☐ Yes ☐ No
If yes, what might those be?	☐ Additional cost ☐ Administrative overheads ☐ Data management overheads ☐ Other
If other, please provide more information	
Do you see the implementation of the Australian UDI requirements as a point at which you might review the products you supply into Australia?	☐ Yes ☐ No
If yes, please provide more information	

Question 10 – Adoption and use

As part of our consultations we have received feedback that one of the challenges relating to the adoption of UDIs in health systems is that there may be multiple identifiers for a single device, and it is not always clear which one is the correct one to assign to the patient.

Is it possible that there will be challenges at the point of care in working out which UDI-DI to assign to the patient? For example, it could be a Direct Marked-DI, Unit of Use-DI or Primary-DI.	☐ Yes ☐ No
If yes, please provide more information	
Would there be benefit in the AusUDID including a point of care DI "POC DI" in the AusUDID?	☐ Yes ☐ No
If yes, please provide more information, including if it is something that could be derived	
Should the same apply for UDIs used for billing purposes?	☐ Yes ☐ No

If yes, please provide more information	
Are there any specific considerations we should take into account from the data users' perspective?	☐ Yes ☐ No
If yes, please provide more information	

Question 11 – Any other feedback?

Please provide any other feedback that you might have below:

Free text area for feedback

Appendices

Appendix 1 – Guidance/guidelines

It is important to note that not all of the UDI requirements will be included in the regulations, some will be included in guidance documents and user manuals for example.

Specifically, the TGA is considering providing the following guidance in addition to the regulations:

Guidelines/guidance	Purpose
AusUDID System Guide for data owners *	Guide for users of the AusUDID system specifically focused on the provision of data to the AusUDID. • Data provision formats (such as HL7 SPL, JSON) • System rules • And so on
UDI for data users	Guide specifically focused on UDI data users such as hospitals
UDI for patients and health professionals	Guide focused on UDI for consumers and health professionals – including how to search for a device, etc.
Linking AusUDID device data over time	Indications based on experience in other countries is that Australian can expect that data will change frequently, and Australia will be the recipient of changes that are mandatory in other countries but may not be required in Australia. Guide for providers and users of data on how to link device data over time.
Guide for Sponsors	This guide will be specific to the needs of Australian sponsors, and their roles and responsibilities
Labelling and direct marking	Guidance related to specific labelling complexities and scenarios (for example, whether or not a long barcode can be split)

Appendix 2 Proposed UDI Data Dictionary

The following lists the proposed UDI Data elements with a description of each provided.

TGA specific requirements are provided in **green** for additional transparency. We are seeking feedback on data elements at Question 5.

Device Identifiers

Data Element Name	Description	Type	Mandatory ?	Look up Values	Publicly Available?	Trigger?	Comment /
Primary DI	The Primary Device Identifier (DI) is the DI portion of the UDI assigned to the lowest package level (base package). The primary DI is the main (primary) lookup for a medical device and meets the requirements to uniquely identify a device through its distribution and use. Is also known as the base package DI, System DI	String	Yes		Yes	Yes	IF Device IS Packaged Primary DI = DI portion of the UDI on the lowest package level OR IF Device is NOT Packaged Primary DI = DI on the label of the device itself, or if no label could be DM DI The data provided for Primary DI will be validated to ensure it complies with the relevant coding rules of the UDI code Issuing Agency.
Issuing Agency	Organisations approved to manage UDI format and structures according to international standards, and issue those to labellers	List	Yes	GS1 HIBCC ICCBBA	Yes	Yes	Will reflect TGA's decision on the Issuing Agencies, currently anticipated as GS1, HIBCC, ICCBBA This may change over time.
Device Count	Number of medical devices in the base package	Numeric	Yes		Yes	Yes	Must be equal to or greater than 1

Data Element Name	Description	Type	Mandatory ?	Look up Values	Publicly Available?	Trigger?	Comment /
Unit of Use DI	A virtual identifier assigned to an individual device when a UDI is not labelled on the individual device. Most likely because there is more than one device in the base package and the devices themselves are not directly marked. Its purpose is to associate the use of a device to/on a patient.	String	No*		Yes	No	Is different to the Primary DI *Mandatory if Device Count is greater than 1 If a value is entered, the Device Count must be greater than 1. Must use the same Issuing Agency as Primary DI The data provided for Unit of Use DI will be validated to ensure it complies with the relevant coding rules of the UDI code Issuing Agency. The Unit of Use DI does not appear on the label of the device.
Direct Marked DI	The DI portion of the UDI is permanently marked directly on the medical device itself if the device is intended to be used more than once (on different patients) and is intended to be reprocessed between uses.	String	No*		Yes	Yes	*Mandatory if device is intended to be reused (see validation rule) and value for *'Direct Marked DI Different from Primary DI'* is yes The Direct Marked DI may be identical to or different from the Primary DI. Must use the same Issuing Agency as Primary DI The data provided for Direct Marked DI will be validated to ensure it complies with the relevant coding rules of the UDI code Issuing Agency.
Secondary DI	An identifier that is issued from a different issuing agency than that used for the Primary DI. The DI is an alternate (secondary) lookup for a medical device	String	No		Yes	No	Must be able to enter multiple Secondary DI numbers for a UDI (a maximum of one per Issuing Agency) The data provided for Secondary DI will be validated to ensure it complies with the relevant coding rules of the UDI code Issuing Agency.

Data Element Name	Description	Type	Mandatory ?	Look up Values	Publicly Available?	Trigger?	Comment /
	Only one device identifier from any accepted issuing agency may be used.						A secondary DI from the same issuing agency as the primary DI is permitted. Where the Primary DI represents a device which has been manufactured using a Medical Device Production System, one of the Secondary DIs must be the DI for the MDPS.
ARTG ID	**The ARTG ID (if the device is included on the ARTG)**	**String**	**No***		**Yes**	**No**	***Mandatory if the device is included on the ARTG.**
Previous DI	Where a new DI has been created for a device and the device has not changed from a clinical perspective this is the previous Primary DI for that device.	String	No		Yes	No	Allows linking of device records over time where a new DI has had to be created, where there is no change to the device itself. Particularly benefits longitudinal device analysis and assists clinical quality registries where the data for a device might change many times over the life of the device. A change may arise from scenarios such as a merger of manufacturers, a supply chain change or the UDI regulations of another country requires a change in the DI.
Brand Name	The trade/proprietary name assigned by the manufacturer, and under which the device is sold, distinguished from other similar devices, and recognised by the user or purchaser.	String	Yes		Yes	Yes	A brand name is often registered and/or protected by a trademark. For devices that do not have a brand name “NA” (or similar) to be entered

Data Element Name	Description	Type	Mandatory?	Look up Values	Publicly Available?	Trigger?	Comment
Model or Version	The version or model found on the device (not software – see software version number below) label or accompanying packaging used to identify a category or design of a device. The version or model identifies all devices that have specifications, performance, size, and composition within limits set by the labeller.	String	Yes		Yes	Yes	For devices that do not have a model or version number "NA" (or similar) to be entered, or could include the catalogue number
Catalogue Number	The catalogue, reference, re-order, or product number used by the Sponsor (Manufacturer) for business and clinical transactions to identify a particular product; this number may be found on the device label or labelling	String	Yes		Yes	No	To include a model or version number if no catalogue or reference number exists for the device
Device Class	**Medical device or IVD medical device Class as per Australian regulatory framework**	**List**	**N**	**Yes**			**Proposed additional TGA specific field to assist with device identification and adoption and use** **Look up list as per Australian regulatory framework** **Noting this is mandatory for devices that are included on the ARTG.**

Data Element Name	Description	Type	Mandatory?	Look up Values	Publicly Available?	Trigger?	Comment
Is the medical device software or does it incorporate software?	**To identify if this is software**	**List**	**Y**	**SaMD device** **Software in a medical device** **No**	**Yes**		**Set to No by default**
Software Version Number	**Software version number**	**String**	**No**		**Yes**	**Yes**	**The TGA is considering this additional field noting that it is variable data and therefore there may be an overhead for labellers in providing this to the TGA.** **Please provide feedback at Question 5.**
Additional Information URL	Uniform Resource Locator (web address) for additional information provided by manufacturer	URL string	No		Yes	No	
PIL URL	**Uniform Resource Locator (web address) for Patient Information Leaflet**	**URL string**	**No**		**Yes**	**No**	**The TGA is considering this additional field** **Please provide feedback at Question 5.**

Data Element Name	Description	Type	Mandatory?	Look up Values	Publicly Available?	Trigger?	Comment
Kit or combination product?	Indicates that the device is a kit or that includes a medical device and a medicine or product of human origin.	Boolean	Yes	Yes Combination Product Companion IVD Class 4 IVD Kit No	Yes	Yes	
Human Cell, Tissue or Cellular or Tissue-Based Product (HCT/P)	Indicates that the product contains or consists of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient	Boolean	No	Yes No	Yes	No	If no data is provided, 'No' is stored
Device Description	Additional information about the device that is not already captured as a distinct UDID data element	String	No		Yes	No	

Data Element Name	Description	Type	Mandatory?	Look up Values	Publicly Available?	Trigger?	Comment
Commercial Distribution End Date	Indicates the date the device is no longer offered for commercial distribution by the Sponsor. Note the device may or may not still be available for purchase in the marketplace.	Date	No	NA (In house IVD) In Commercial distribution Not in commercial distribution	Yes	No	There are additional complexities as if there are multiple sponsors there may be different supply dates and therefore this field may need to be at the sponsor level. Please provide feedback at question 5. If distribution end date is <blank> or after today "In Commercial Distribution" is displayed to user, otherwise "Not in Commercial Distribution" is displayed
Device Exempt from Direct marking requirements ?	The device is exempt from Direct Marking requirements	Boolean	*No	Yes No	Yes	Yes	*Conditionally required if device is intended to be reused (see validation rule) and value for *'Direct Marked DI Different from Primary DI'* is yes
Direct Marking DI Different from Primary DI?	Indicates that the Direct Marking DI Number is different than the Primary DI Number	Boolean	*No	Yes No	Yes	Yes	* Conditionally required if device is intended to be reused if device intended to be reused (see validation rule)

Data Element Name	Description	Type	Mandatory?	Look up Values	Publicly Available?	Trigger?	Comment
GMDN Code	Global Medical Device Nomenclature (GMDN)Nomenclature Preferred Term Code - the unique five-digit code assigned to the device by the manufacturer	Value Selection	Yes	Yes GMDN Agency	No	No	Is a valid and active GMDN Preferred Term Code that has been issued by the GMDN Agency To comply with the relevant formatting rules of the GMDN Agency. • Must be able to enter multiple GMDN Codes for a UDI • GMDN preferred term codes to be included for IVDs as well (i.e. different to the 'collective terms' used in ARTG inclusions) • Note the system will automatically also store the Preferred Term Name and Description in the record
GMDN Preferred Term Name	GMDN Preferred Term name linked to the GMDN Code at the date it was provided (or changed) to the TGA		Yes		Yes		System generated
GMDN Preferred Term Description	GMDN Preferred Term description linked to the GMDN Code at the date it was provided (or changed) to the TGA		Yes		Yes		System generated
Additional documents	The ability to upload one or more documents for additional information (for example a Patient Information Leaflet as a PDF)	Document	No		Yes	No	A document can be one of these file types: '.pdf', '.doc', '.docx', '.xls', '.xlsx', '.rtf', '.png', '.jpg', '.jpeg', '.bmp', '.gif', '.txt', '.csv', '.avi', '.mkv', '.zip' Each file must be less than 50MB in size

Clinical Characteristics

Data Element Name	Description	Type	Mandatory?	Look up Values	Publicly Available?	Trigger?	Comment
MRI Safety Status	Indicates the Magnetic Resonance Imaging safety information, if any, that is present on the device labelling. See the ASTM F2503-13 standard for more information.	Value Selection	Yes	Labelling does not contain MRI safety information; MRI Conditional; MRI Safe; MRI Unsafe	Yes	Yes	
Intended for single Use?	Indicates that the device is intended for one use or on a single patient during a single procedure	Value selection	Yes	Yes No N/A	Yes	Yes	We propose to add the value "N/N" for such devices as IVD reagents that are consumed during use and the smallest trade item comprises a maximum number of tests >1.
Restricted Number of Uses	**Number of reuses if restricted**	**Numeric**	**No**		**Yes**	**Yes**	
Contains DEHP?	Flag to indicate if the device contains Bis(2-ethylhexyl) phthalate (DEHP)	Boolean	No	Yes No	Yes	Yes	
Prescription Use?	Indicates that the device requires a prescription to use	Boolean	No	Yes or No	Yes	No	If no data is provided, 'No' is stored
Over the Counter (OTC)	Indicates that the device does not require a prescription to use and can be purchased over the counter (OTC)	Boolean	No	Yes or No	Yes	No	If no data is provided, 'No' is stored

Data Element Name	Description	Type	Mandatory?	Look up Values	Publicly Available?	Trigger?	Comment
Device required to be labelled as containing natural rubber latex or dry natural rubber?	Indicates that the device or packaging contains natural rubber that contacts humans.	Boolean	No	Yes No	Yes	Yes	Choosing 'Yes' indicates that the device label or packaging contains one of the following statements: (1) "Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions" (2) “This Product Contains Dry Natural Rubber" (3) “Caution: The Packaging of This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions" (4) "The Packaging of This Product Contains Dry Natural Rubber"
Device labelled as "Not made with natural rubber latex"	Indicates that natural rubber latex was not used as materials in the manufacture of the medical product and container and the device labelling contains this information.	Boolean	No	Yes No	Yes	No	If no data is provided, 'No' is stored Only applicable to devices not subject to the requirements under the Australian medical device regulations. Not all medical products that are NOT made with natural rubber latex will be marked.
Device Packaged as Sterile?	Indicates the medical device is free from viable microorganisms. See ISO/TS 11139.	Boolean	Yes	Yes No	Yes	Yes	Must be able to enter multiple ‘Device Packaged as Sterile’ values for a UDI
Requires Sterilisation Prior To Use?	Indicates that the device requires sterilisation prior to use	Boolean	Yes	Yes No	Yes	Yes	Must be able to enter multiple ‘Device Requires Sterilisation Prior To Use’ for a UDI

Data Element Name	Description	Type	Mandatory?	Look up Values	Publicly Available?	Trigger?	Comment
Sterilisation Method(s)	Indicates the method(s) of sterilisation that can be used (by the user) this device prior to device use on the patient	Value Selection	*No	Refer to List of Values (LOV)	Yes	No	Conditionally Required* *if *'Requires Sterilisation Prior to Use'* is marked 'Yes' Must be able to enter multiple Sterilisation method(s) recommended prior to use for a UDI
Clinical Size Type	Dimension type for the clinically relevant measurement of the medical device	Value Selection	* No	Refer to List of Values (LOV)	Yes	Yes	Conditionally Required* *If device is available in more than one size Must be able to enter multiple Size Type for a UDI
Clinical Size Value	Numeric value for the clinically relevant size measurement of the medical device	Numeric	*No	Refer to List of Values (LOV)	Yes	Yes	Conditionally Required* *Required if device is available in more than one size, with value to align with selected Clinical Size Type Must be able to enter multiple Clinical Size Value for a UDI
Clinical Size Unit of Measure	The unit of measure associated with each clinically relevant size	String	*No	Refer to List of Values	Yes	Yes	Conditionally Required* *Required if device is available in more than one size, with value to align with selected Clinical Size Type Must be able to enter multiple Clinical Size Unit of Measure for a UDI

Data Element Name	Description	Type	Mandatory?	Look up Values	Publicly Available?	Trigger?	Comment
Clinical Size Type Text	Additional undefined device size not represented in the UDID Size Type LOV	String	*No	Refer to List of Values	Yes	Yes	Conditionally Required* *Required if 'Size Text, specify' is selected above Must be able to enter multiple Clinical Size Type Text for a UDI
Storage and Handling Type	Indicates storage and handling requirements that are required for the device including temperature, humidity, and atmospheric pressure	Value Selection	No	Refer to List of Values (LOV)	Yes	No	Must be able to enter multiple Storage and Handling Type for a UDI
Storage and Handling Special Conditions	Indicates any special storage requirements for the device	String	*No	Refer to List of Values (LOV)	Yes	No	Conditionally Required* *Required if 'Special Storage Conditions' is selected above with value to align with selected Storage and Handling Type Must be able to enter multiple Storage and Handling Special Conditions for a UDI
Storage and Handling Unit of Measure	The unit of measure associated with the storage and handling conditions	Value Selection	*No	Refer to List of Values (LOV)	Yes	No	Conditionally Required* *Required if Storage and Handling Type is added to the device record with the value to align with the selected Storage and Handling Type Must be able to enter multiple Storage and Handling Unit of measure for a UDI
Storage and Handling Low Value	Indicates the low value for storage and handling requirements	Numeric	*No	Refer to List of Values (LOV)	Yes	No	Conditionally Required* *One value (Low or High) is required if Storage and Handling Type is added to the device record Must be able to enter multiple Storage and Handling Low Value for a UDI

Data Element Name	Description	Type	Mandatory?	Look up Values	Publicly Available?	Trigger?	Comment
Storage and Handling High Value	Indicates the high value for storage and handling requirements	Numeric	*No	Refer to List of Values (LOV)	Yes	No	Conditionally Required* *One value (Low or High) is required if Storage and Handling Type is added to the device record Must be able to enter multiple Storage and Handling High Value for a UDI

Manufacturer and sponsor information

Data Element Name	Description	Type	Mandatory?	Look up Values	Publicly Available?	Trigger?	Comment
Sponsor Name	Sponsor Name	Text Box	Yes		Yes	No	Value is auto populated using the Sponsor's details that have been recorded in the TGA Business Systems (TBS). Must be able to record multiple Sponsors for a UDI
Sponsor Phone	Phone number for the Customer contact; to be used by patients and consumers for device-related questions	Text Box	No		Yes	No	Value is auto populated using the Sponsor's details that have been recorded in the TGA Business Systems (TBS). Must be able to record multiple Sponsors for a UDI
Sponsor Email	Email for the Customer contact; to be used by patients and consumers for device-related questions	Text Box	No		Yes	No	Value is auto populated using the Sponsor's details that have been recorded in the TGA Business Systems (TBS). Must be able to record multiple Sponsors for a UDI

Data Element Name	Description	Type	Mandatory?	Look up Values	Publicly Available?	Trigger?	Comment
Sponsor Address	Company physical address	Text Box	No			No	Value is auto populated using the Sponsor's details that have been recorded in the TGA Business Systems (TBS).
Manufacturer Name	Company name of the manufacturer	Text Box	Yes		Yes	No	
Manufacturer Address	Company physical address of the manufacturer	Text Box	Yes		Yes	No	
Manufacturer Customer Service Contact Name	Name of the manufacturer's customer contact; to be used by patients and consumers for device related questions. Able to enter multiple contact details for a manufacturer. If customer contact details are supplied: must supply, at a minimum, a name and phone number, or a name and an email address.	Text Box	*No		Yes	No	Conditionally Required* *Required if entering manufacturer contact information Able to enter multiple contact names and details
Manufacturer Customer Service Contact Phone	Phone number of the manufacturer's customer contact; to be used by patients and consumers for device related questions. Able to enter multiple contact details for a manufacturer. If customer contact details are supplied: must supply, at a minimum, a name and phone number, or a name and an email address.	Text Box	*No		Yes	No	Conditionally Required* *Required if entering manufacturer contact information and email address has not been supplied Able to enter multiple contact names and details

Data Element Name	Description	Type	Mandatory?	Look up Values	Publicly Available?	Trigger?	Comment
Manufacturer Customer Service Contact email	Email address of the manufacturer's customer contact; to be used by patients and consumers for device related questions. Able to enter multiple contact details for a manufacturer. If customer contact details are supplied: must supply, at a minimum, a name and phone number, or a name and an email address.	Text Box	*No		Yes	No	Conditionally Required* * Required if entering manufacturer contact information and phone number has not been supplied Able to enter multiple contact names and details

Package data

Data Element Name	Description	Type	Mandatory?	Look up Values	Publicly Available?	Trigger?	Comment
Package DI	The device identifier for the package	String	No		Yes	Yes	New packaging configurations will require a new UDI DI Whenever a new device package is created, you must assign a new device identifier to the new device package. Conditionally Required* *If device is available in higher levels of packaging The Issuing Agency must be the same Issuing Agency as the Primary DI The data provided for Package DI will be validated to ensure it complies with the relevant coding rules of the UDI code Issuing Agency. Must be able to enter multiple Package DI numbers for a UDI

Data Element Name	Description	Type	Mandatory?	Look up Values	Publicly Available?	Trigger?	Comment
Package Type	Text to describe the outer packaging of the product and enables users to understand higher level packaging configurations.	String	No		Yes	No	Must be able to enter multiple Package Types for a UDI
Package Contains DI	The Primary DI for the base package or the Package DI for any lower-level package configuration contained within a given package configuration.	String	Yes		Yes	No	Conditionally Required* *If Package DI is entered The data provided for Package Contains DI will be validated to ensure it complies with the relevant coding rules of the UDI code Issuing Agency and exists in the UDI database Must be able to enter multiple Package Containing DI numbers for a UDI
Quantity per Package	The number of packages with the same Primary DI or Package DI within a given packaging configuration.	Value Selection	No	Depends on the number of devices	Yes	No	Conditionally Required* *If Package DI is entered Must be able to enter multiple Quantity per Package for a UDI
Package Commercial Distribution End Date	Indicates the date the package is no longer offered for commercial distribution by the Sponsor. Note the device may or may not still be available for purchase in the marketplace.	Date	No		Yes	No	

Production data (how the device is controlled)

Note, while individually they are not mandatory, at least one of the below must be set to Yes for each device.

Data Element Name	Description	Type	Mandatory?	Look up Values	Publicly Available?	Trigger?	Comment
Lot or Batch Number on the label?	Set to yes if a lot or batch number is included on the label. Lot or batch number is the number assigned to one or more device(s) that consist of a single type, model, class, size, composition, or software version that are manufactured under essentially the same conditions and that are intended to have uniform characteristics and quality within specified limits.	Boolean	No	Yes No	Yes	No	If a lot number or batch number appears on the label, it should be part of the UDI-PI and this field should be set to "Yes" A value is required to be part of the UDI when included on the label in order to provide the means to track the device back to its manufacturing source or otherwise allow the history of the device manufacturing, packaging, labelling, distribution and use to be determined.
Manufactured Date on the label?	Set to yes if the date on which a device is manufactured is included on the label.	Boolean	No	Yes No	Yes	No	If there is a manufacturing date on the label it should be part of the UDI-PI and this field should be set to "Yes". This date is required to be part of the UDI when included on the label in order to provide the means to track the device back to its manufacturing source or otherwise allow the history of the device manufacturing, packaging, labelling, distribution and use to be determined. We would appreciate your feedback at question 5 on whether this should be for data that is on the label, or how the device is controlled. We understand there may be circumstances where the data is on the label but is not used to control the device.

Data Element Name	Description	Type	Mandatory?	Look up Values	Publicly Available?	Trigger?	Comment
Serial Number on the label?	Does the label include a number that allows for the identification of a device, indicating its position within a series?	Boolean	No	Yes No	Yes	No	If a serial number appears on the label it should be part of the UDI-PI and this field should be set to “Yes”. This number is required to be part of the UDI when included on the label in order to provide the means to track the device back to its manufacturing source or otherwise allow the history of the device manufacturing, packaging, labelling, distribution and use to be determined. We would appreciate your feedback at question 5 on whether this should be for data that is on the label, or how the device is controlled. We understand there may be circumstances where the data is on the label but is not used to control the device.
Expiration Date on the label?	Does the label include the date by which the device must or should be used?	Boolean	No	Yes No	Yes	No	If an expiration date appears on the label it should be part of the UDI-PI and this field should be set to “Yes”. This date is required to be part of the UDI when included on the label in order to provide the means to track the device back to its manufacturing source or otherwise allow the history of the device manufacturing, packaging, labelling, distribution and use to be determined. We would appreciate your feedback at question 5 on whether this should be for data that is on the label, or how the device is controlled. We understand there may be circumstances where the data is on the label but is not used to control the device.

Data Element Name	Description	Type	Mandatory?	Look up Values	Publicly Available?	Trigger?	Comment
Donation Identification Number on the label?	The Donation Identification Number (DIN) is applicable to devices that are also regulated as Human Cells, Tissues, and Cellular and Tissue-Based Products and is a number that is assigned to each donation.	Boolean	No	Yes No	Yes	No	If DIN appears on the label it should be part of the UDI-PI and this field should be set to "Yes". This number/code is required to be part of the UDI when included on the label in order to provide the means to track the device back to its manufacturing source or otherwise allow the history of the device manufacturing, packaging, labelling, distribution and use to be determined.

Other data that the AusUDID might include (including data derived from data provided by manufacturers):

Data Element Name	Description	Type	Mandatory?	Look up Values	Publicly Available?	Trigger?	Comment
Record Status	Indicates the status of the UDI record in the Australian database and used to help manage the changes to the UDI record and controlling access to UDI records.	Value Selection	Yes	Draft Unpublished Published	No	No	Draft - a record with a status of "Draft" indicates the UDI data is still being added and updated. The record and updated data are only visible to the user working on the record. Published – a record with a status of "Published" indicates the UDI data has been approved by the owner and is publicly available. Unpublished – a record with a status of "Unpublished" indicates UDI data has been approved by the owner of the data. The data is not available to consumers of the UDI data, until the published date is passed. Note once commercial distribution has ceased the record cannot be amended (i.e. it is 'frozen').

Data Element Name	Description	Type	Mandatory?	Look up Values	Publicly Available?	Trigger?	Comment
Package Distribution Status	Indicates whether the package is in commercial distribution	String	No	In Commercial Distribution Not in Commercial Distribution	Yes	No	Field is auto populated based on the Package Discontinued Date. If Package DI and related elements are entered and no Package Distribution End Date is entered, the status is 'In Commercial Distribution.' If Package DI and related elements are entered and Distribution End Date is entered and is not before today's date, the status is "In Commercial Distribution" If Package DI and related elements are entered, Distribution End Date is entered and before the current date the status is "Not In Commercial Distribution" Must be able to select multiple Package Distribution Status for a UDI
Primary DI Commercial Status	Indicates whether the device is in commercial distribution.	Derived String	Yes	In Commercial Distribution Not in Commercial Distribution	Yes	No	Field is auto populated based on the Primary DI Discontinued Date. If Primary DI Discontinued Date is not entered, the status is 'In Commercial Distribution.' If Primary DI Discontinued Date is entered and is not before today's date, the status is "In Commercial Distribution" If Primary DI Discontinued Date is entered and before the current date the status is "Not In Commercial Distribution"

System specific data

Data Element Name	Description	Type	Mandatory?	Look up Values	Publicly Available?	Trigger?	Comment
UDI Record Published Date	Date this version of the UDI record was published / committed to the Australian UDI database	Date	Yes (System Allocated)		Yes	No	System allocated
UDI Record Version Number	Number to track updates to a device record		Yes (System Allocated)		Yes	No	System derived, visible in record history
UDI Record Version Status	Status of a device record associated with a version change		Yes (System Allocated)		No	No	System derived

Lists of proposed values

Sterilisation methods

Value		
ClO_2 Sterilisation	High-Level Disinfectant Sterilisation	Peracetic Acid Sterilisation
Cobalt-60 Gamma Radiation Sterilisation	Hydrogen Peroxide (H_2O_2) Sterilisation	Plasma Sterilisation
Cold Fluid Sterilisation	Liquid Chemical Sterilisation	Radiation Sterilisation
Dry Heat Sterilisation	Microwave Radiation Sterilisation	Sound Waves Sterilisation
Electron Beam Irradiation Sterilisation	Moist Heat or Steam Sterilisation	Steam Sterilisation
Ethylene Oxide Sterilisation	Moist Heat Sterilisation	Supercritical Carbon Dioxide Sterilisation
Formaldehyde Gas	Nitrogen Dioxide Sterilisation	Ultraviolet Light Sterilisation
Gamma Radiation Sterilisation/ γ ray Sterilisation	Non-sterile	
High Intensity Light or Pulse Light Sterilisation	Ozone (O_3) Sterilisation	

Clinical size types

Group	Value
Angle	Angle
Area	Area / Surface Area
Device Size Text	Device Size Text, specify
Gauge - Needle	Needle Gauge
Gauge French	Catheter Gauge
Gauge French	Crossing Profile
Gauge French	Guidewire Compatibility
Gauge French	Introducer Sheath Compatibility
Length Size	Atherectomy Cutter Diameter
Length Size	Atherectomy Cutter Length
Length Size	Atherectomy Device Tip Length
Length Size	Atherectomy Rotating Component Diameter
Length Size	Atherectomy Rotating Component Length
Length Size	Balloon Catheter Tip Length
Length Size	Balloon Diameter
Length Size	Balloon Length
Length Size	Balloon Proximal Outer Diameter (OD)
Length Size	Catheter Inner Diameter
Length Size	Catheter Length
Length Size	Catheter Working Length
Length Size	Circumference
Length Size	Depth
Length Size	Guidewire Diameter

Group	Value
Length Size	Guidewire Length
Length Size	Height
Length Size	Length
Length Size	Lumen / Inner Diameter
Length Size	Maximum Stent Diameter
Length Size	Outer Diameter
Length Size	Pore Size
Length Size	Shaft length
Length Size	Stent Diameter
Length Size	Stent Length
Length Size	Tapered Stent Larger Diameter
Length Size	Tapered Stent Length
Length Size	Tapered Stent Smaller Diameter
Length Size	Tip Bend Radius
Length Size	Width
Pressure Units of Measure	Balloon Nominal (Inflation) Pressure
Pressure Units of Measure	Balloon Rated Burst Pressure
Pressure Units of Measure	Pressure
Volume Units of Measure	Total Volume
Weight Units of Measure	Weight

Clinical size units

Group	Value	Abbreviation
Angle	Degree	deg
Area	Square centimetre	cm^2
Area	Square foot	sqft
Area	Square inch	sqin
Area	Square metre	m^2
Area	Square millimetre	mm^2
Gauge - Needle	Gauge	G
Gauge French	French	ch
Length Size	Centimetre	cm
Length Size	Decimetre	dm
Length Size	Feet	ft
Length Size	Femtometre	fm
Length Size	Inch	in
Length Size	Kilometre	km
Length Size	Metre	m
Length Size	Micrometre	um
Length Size	Millimetre	mm
Length Size	Nanometre	nm
Length Size	Picometer	pm
Length Size	Yard	yd
Pressure Units of Measure	Atmosphere	ATM
Pressure Units of Measure	Hertz	hz
Pressure Units of Measure	Kilopascal	kPa
Pressure Units of Measure	Millibar	mbar
Pressure Units of Measure	Pound per Square Inch	PSI
Volume Units of Measure	Centilitre	cl
Volume Units of Measure	Cubic Inch	cu
Volume Units of Measure	Cup	cup
Volume Units of Measure	Decilitre	dl
Volume Units of Measure	Femtoliter	fl
Volume Units of Measure	Fluid Ounce	floz

Group	Value	Abbreviation
Volume Units of Measure	Gallon	gal
Volume Units of Measure	Kilolitre	kl
Volume Units of Measure	Litre	L
Volume Units of Measure	Microliter	µL
Volume Units of Measure	Millilitre	ml
Volume Units of Measure	Nanolitre	nL
Volume Units of Measure	Picolitre	pL
Volume Units of Measure	Pint	pt
Volume Units of Measure	Quart	qt
Weight Units of Measure	Gram	g
Weight Units of Measure	Kilogram	kg
Weight Units of Measure	Metric Ton	MT
Weight Units of Measure	Microgram	mcg
Weight Units of Measure	Milligram	mg
Weight Units of Measure	Pound	lb
Weight Units of Measure	Ton	ton

Storage handling types

Value
Handling Environment Atmospheric Pressure
Handling Environment Humidity
Handling Environment Temperature
Special Storage Conditions
Storage Environment Atmospheric Pressure
Storage Environment Humidity
Storage Environment Temperature

Storage handling units

Value
Degrees Celsius
Degrees Fahrenheit
Degrees Kelvin
Kilo Pascal
Millibar
Percent (%) Relative Humidity

MRI safety statuses

Value
Labelling does not contain MRI Safety Information
MR Conditional
MR Safe
MR Unsafe

Appendix 3 - Australian device definitions

Device	Definition
Implantable medical device (IMD)	Implantable medical device (IMD) means a medical device (other than an active implantable medical device) that is intended by the manufacturer: (a) to be, by surgical intervention, wholly introduced into the body of a human being, and to remain in place after the procedure; or (b) to replace, by surgical intervention, an epithelial surface, or the surface of an eye, of a human being, and to remain in place after the procedure; or (c) to be, by surgical intervention, partially introduced into the body of a human being, and to remain in place for at least 30 days after the procedure. *Therapeutic Goods (Medical Devices) Regulations 2002* Part 1, 1.3
Medical device production system (MDPS)	Medical device production system (MDPS) means a system that consists of raw materials and main production equipment (whether or not the system also consists of software), where the system is intended by the manufacturer to be used (whether or not with ancillary inputs or equipment) by a health professional, or suitably qualified person within a healthcare facility, to produce a particular medical device for use in relation to a patient of the health professional or healthcare facility. *Therapeutic Goods (Medical Devices) Regulations 2002* Part 1, 1.3
System or Procedure Packs (SOPP)	Two or more goods (including at least one medical device) are a system or procedure pack if: (a) all of the goods are to be interconnected or combined for use in a medical or surgical procedure; or (b) all of the goods are packaged together for use in a medical or surgical procedure. *Therapeutic Goods Act 1989* Section 41BF
Surgical loan kit (SLK)	Medical device that is a surgical loan kit, where: (a) the kit is intended by its manufacturer to be supplied to hospitals in Australia; and (b) the kit is intended by its manufacturer to be used in a surgical procedure; and (c) the kit contains 2 or more reusable surgical instruments and the only other therapeutic goods (if any) in the kit are either or both of the following: (i) one or more implantable medical devices; (ii) one or more Class I, Class IIa, Class IIb or Class III medical devices; and (d) each of the medical devices in the kit is included in the Register *Therapeutic Goods (Medical Devices) Regulations 2002*, Part 2 Item 2.16
In-vitro diagnostic medical device (IVD)	In vitro diagnostic medical device (IVD) means a medical device that is: (a) a reagent, calibrator, control material, kit, specimen receptacle, software, instrument, apparatus, equipment, or system, whether used alone or in combination with another diagnostic product for in vitro use; and (b) intended by the manufacturer to be used in vitro for the examination of a specimen derived from the human body, solely or principally for: (i) giving information about a physiological or pathological state or a congenital abnormality; or (ii) determining safety and compatibility with a potential recipient; or (iii) monitoring therapeutic measures; and (c) not a product that is: (i) intended for general laboratory use; and

Device	Definition
	(ii) not manufactured, sold or presented for use as an IVD medical device. *Therapeutic Goods (Medical Devices) Regulations 2002* Part 1, 1.3
In-house IVD medical device	In-house IVD medical device means an IVD medical device that is: (a) within the confines or scope of an Australian laboratory or Australian laboratory network: (i) developed from first principles; or (ii) developed or modified from a published source; or (iii) developed or modified from any other source; or (iv) used for a purpose, other than the intended purpose assigned by the manufacturer; and (b) not supplied for use outside that laboratory or laboratory network. *Therapeutic Goods (Medical Devices) Regulations 2002* Part 1, 1.3
Software as a medical device	Software (including mobile apps) is a medical device if it fits within the definition of a medical device in section 41BD of the Act, unless otherwise excluded. *Therapeutic Goods Act 1989* Section 41BD
Custom-made medical device (CMD)	Custom-made medical device (CMD) means a medical device that: (a) is intended by the manufacturer to be for: (i) the sole use of a particular patient (the intended recipient); or (ii) the sole use of a particular health professional (the intended recipient) in the course of the health professional's practice; and (b) is manufactured by the manufacturer in accordance with a written request of a health professional (the requesting health professional) and with particular design characteristics specified by that health professional in the request (even if the design is developed in consultation with the manufacturer), where those design characteristics are intended to address: (i) either or both of the anatomical and physiological features of the intended recipient; or (ii) a pathological condition of the intended recipient; and (c) the requesting health professional has determined is necessary to address the matters covered by paragraph (b) because there is no kind of medical device included in the Register to address those matters or to address those matters to an appropriate level. However, a custom-made medical device does not include a patient-matched medical device, an adaptable medical device or other mass-produced medical device. *Therapeutic Goods (Medical Devices) Regulations 2002* Part 1, 1.3
Ancillary medical device	Ancillary medical device means an implantable medical device that: (a) consists of screws, plates or wedges; or (b) is intended by the manufacturer to be used to: (i) provide stability for an implantable medical device that is intended to (either alone or together with one or more other implantable medical devices) replace the shoulder joint, hip joint or knee joint; or (ii) provide bone substitution in relation to, or additional fixation for, any such device; or (iii) otherwise assist any such device; where the individual requirements of a patient make it appropriate to do so.

<table>
<tr><th>Device</th><th>Definition</th></tr>
<tr><td></td><td>Therapeutic Goods (Medical Devices) Regulations 2002 Part 1, 1.3</td></tr>
<tr><td>Patient-matched medical device (or Personalised medical device) PMD</td><td>Patient-matched medical device (PMD) means a medical device that:
(a) is manufactured by the manufacturer, within a specified design envelope, to match:
(i) either or both of the anatomical and physiological features of a particular individual; or
(ii) a pathological condition of a particular individual; and
(b) is designed by the manufacturer (even if the design is developed in consultation with a health professional); and
(c) is manufactured using production processes that are capable of being:
(i) either or both validated and verified; and
(ii) reproduced.
Therapeutic Goods (Medical Devices) Regulations 2002 Part 1, 1.3</td></tr>
<tr><td>Patient information leaflet (PIL)</td><td>Patient information leaflet (PIL) has the meaning given by clause 13A.3 of Schedule 1.
13A.3 Patient information leaflets etc. for implantable devices
(1) Either:
(a) a leaflet (a patient information leaflet) that includes the information covered by subclauses (2) and (3) and that satisfies subclause (4) and clause 13A.4 must be made available for provision to the patient concerned; or
(b) information covered by subclauses (2) and (3) that is in electronic form and that satisfies subclause (4) and clause 13A.4 must be made available in a way that is readily accessible by the patient concerned.
(2) The information covered by this subclause is the following information:
(a) information identifying the device, or the kind of device;
(b) the intended purpose of the device;
(c) information explaining how to use the device safely;
(d) other information about the device that the manufacturer considers would be useful for patients.
(3) The information covered by this subclause is the information in the following table.
Information to be made available for provision to patient
Item | Information
1 | (a) the name of the device; and (b) the model of the device
2 | (a) the intended purpose of the device; and (b) the kind of patient on whom the device is intended to be used
3 | Any special operating instructions for the use of the device
4 | (a) the intended performance of the device; and (b) any undesirable side effects that could be caused by use of the device
5 | Any residual risks that could arise due to any shortcomings of the protection measures adopted as mentioned in subclause 2(2)
6 | (a) warnings about risks that could arise from the interaction of the device with other equipment; and (b) precautions and other measures that, because of those risks, should be taken by the patient or a health professional
Example 1: The risk of electrical interference from electro-surgical devices.</td></tr>
</table>

Device	Definition
	Example 2: The risk of magnetic field interference from magnetic resonance imaging devices. 7 (a) the nature and frequency of regular or preventative examination, monitoring or maintenance of the device that should be undertaken; and (b) symptoms that could indicate that the device is malfunctioning; and (c) precautions and other measures that should be taken by the patient if the performance of the device changes or the patient experiences any of the symptoms mentioned in paragraph (b); and (d) the expected device lifetime; and (e) anything that could shorten or lengthen the device lifetime; and (f) precautions and other measures that should be taken at, or near, the end of the expected device lifetime; and (g) other circumstances in which the patient should contact a health professional in relation to the operation of the device 8 (a) the materials and substances included in the device; and (b) any manufacturing residuals that could pose a risk to the patient 9 (a) a notice that any serious incident that occurs in relation to the device should be reported to the manufacturer and to the Therapeutic Goods Administration; and (b) the address of the Therapeutic Goods Administration's website (4) The information covered by subclauses (2) and (3) must be written in a way that is readily understood by patients. *Therapeutic Goods (Medical Devices) Regulations 2002* Schedule 1, Clause 13A.3
Kits	(1) If a package contains one or more goods, the package and each of the goods in the package together constitute a kit for the purposes of this Act if: (a) the package and each of the goods are for use as a unit; and (b) the package and the goods do not constitute a composite pack; and (c) at least one of the goods is therapeutic goods; and (d) each item of the therapeutic goods consists of goods that are: (i) registered or listed; or (ii) exempt goods in relation to Part 3-2; or (iii) included in the Register under Part 3-2A; or (iv) exempt under subsection 32CA(2) or section 32CB. (2) A package and therapeutic goods in the package together constitute a composite pack if: (a) the therapeutic goods are of 2 or more kinds; and (b) the package does not contain any medical devices; and (c) the therapeutic goods are for administration as a single treatment or as a single course of treatment; and (d) it is necessary that the therapeutic goods be combined before administration or that they be administered in a particular sequence. (3) To avoid doubt, it is declared that a kit constitutes therapeutic goods. *Therapeutic Goods Act 1989* Section 7B

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Medical Devices Surveillance Branch	31/08/2022

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