Australian Government
Department of Health
Therapeutic Goods Administration

Recent and upcoming regulation changes

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TGA Health Safety Regulation

In this presentation

- Unique Device Identifier (UDI)
- Software as a medical device (SaMD)
- Repeal of 4.1 and change to 5.3
- Patient information materials
- Regulation 5.12
- Reclassification of certain medical devices

(not an exhaustive list of all the reforms……..)

UDI

- The Australian Government is strengthening patient safety through the establishment of a Unique Device Identification (UDI) system for medical devices.
- The system is an Australian first and (if adopted through the healthcare system) can assist tracking and tracing of medical devices that have been implanted in patients.
- It may enhance the ability for doctors to notify patients quickly if there is a safety issue with a medical device and strengthen Australia's post-market medical device adverse event system.
- The Australian Government has determined that the TGA will establish and maintain the Australian Unique Device Identification database (AusUDID).

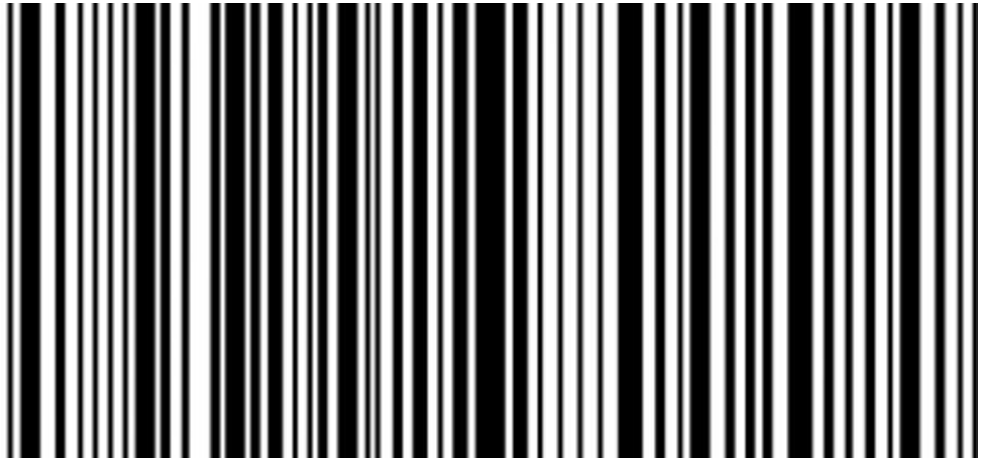
UDI continued

- We are in the early planning stages for the Australian implementation and have not yet defined the new regulations, regulatory dates or the transition approach.
- We understand that many manufacturers supply to multiple markets and already have USA UDIs in place and/or are preparing to meet the new European Union (EU) regulations.
- Australia does not plan to implement before the EU dates.
- Further information is available on our website, Unique Device Identification system

What is UDI?

- The unique device identifier (UDI) is a series of numeric or alphanumeric characters that is created through a globally accepted device identification and coding standard, and applied to a specific model of medical device.

- It is comprised of both device information and production information, and is applied to the device label and all levels of packaging for that device in both machine readable (such as a barcode) and human readable forms. It allows the clear identification of a specific model of medical device on the market.

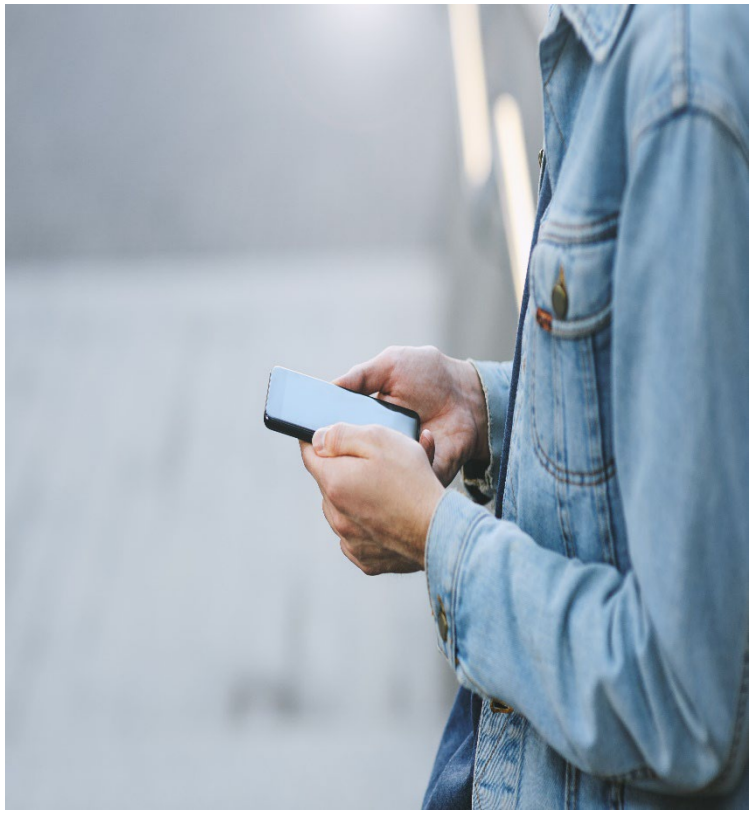


What is UDI?

- It is used as the ‘access key’ to information stored in a UDI database and is the data that may allow the linking of device information across other systems – if the UDI is included in systems such as registries, in electronic medical records or in patients’ My Health Record. Globally harmonised (where possible), core data about those devices will be publicly available through the Australian UDI Database (AusUDID).

Software as a medical device

- On 25 February 2021, reform changes commenced including:
  - clarifying the boundary of regulated software products (including ‘carve outs’)
  - introducing new classification rules
  - providing updates to the essential principles to more clearly express the requirements for software-based medical devices.



Software as a medical device

- Helpful flowcharts are available to determine is my software regulated?
- Guidance is available on how the TGA regulates software based medical devices.
- Guidance, including examples are available of regulated and unregulated (excluded) software based medical devices.
- Further information on the regulation of software based medical devices is available on our website, including:
  - Classification of active medical devices (including software-based medical devices)

Intended to be used for…	Rules that may apply	Possible Classifications
Detecting, diagnosing, screening, monitoring, investigation	Rule 4.3 Active medical devices for diagnosis (includes monitoring)	Class IIa Class IIb
	Rule 4.5 Diagnosis or screening for a disease or condition	Class IIa Class IIb Class III
	Rule 4.6 Monitoring the state or progression of a disease or condition	Class I Class IIa Class IIb
	Rule 4.7 Specifying and recommending treatment or intervention	Class IIa Class IIb Class III
Therapy	Rule 4.2 Active medical devices for therapy	Class IIa Class IIb
Administering and removing medicines or other substances from a patient's body	Rule 4.4 Active medical devices intended to administer or remove medicines, etc from a patient's body	Class IIa Class IIb
Information-based therapy	Rule 4.8 Providing therapy through the provision of information	Class IIa
Recording patient images and anatomical models	Rule 5.4 Medical devices that record patient images or that are anatomical models etc	Class IIa
Implantable devices	Rule 5.7 Active implantable medical devices	Class III AIMD
Other active medical device	Rule 4.1 Active medical devices—general	Class I

Repeal of Regulation 4.1

- On 23 July 2021, the Australian Government made a decision to repeal Regulation 4.1 and amend Regulation 5.3 of the *Therapeutic Goods (Medical Devices) Regulations 2002*.
- From 28 July 2021, the range of applications for inclusion in the Australian Register of Therapeutic Goods (ARTG) that can rely on conformity assessment documents issued by European notified bodies was expanded.
  - Before the change, under regulation 4.1, sponsors of such devices could only rely on conformity assessment certification by the Therapeutic Goods Administration (TGA) for inclusion in the Australian Register of Therapeutic Goods (ARTG) for these types of devices.
  - Now sponsors can provide conformity assessment documents issued by notified bodies designated by a member state of the European Union to support an application for inclusion in the ARTG.

Medical devices now included:

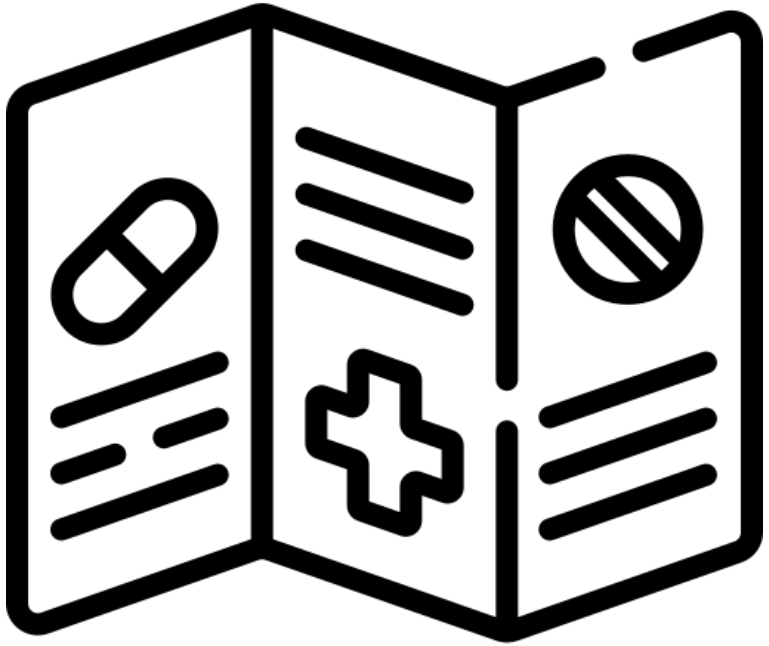
- Those containing medicines or materials of animal, microbial, recombinant or human origin
- Class 4 in vitro diagnostic (IVD)

Change to Regulation 5.3

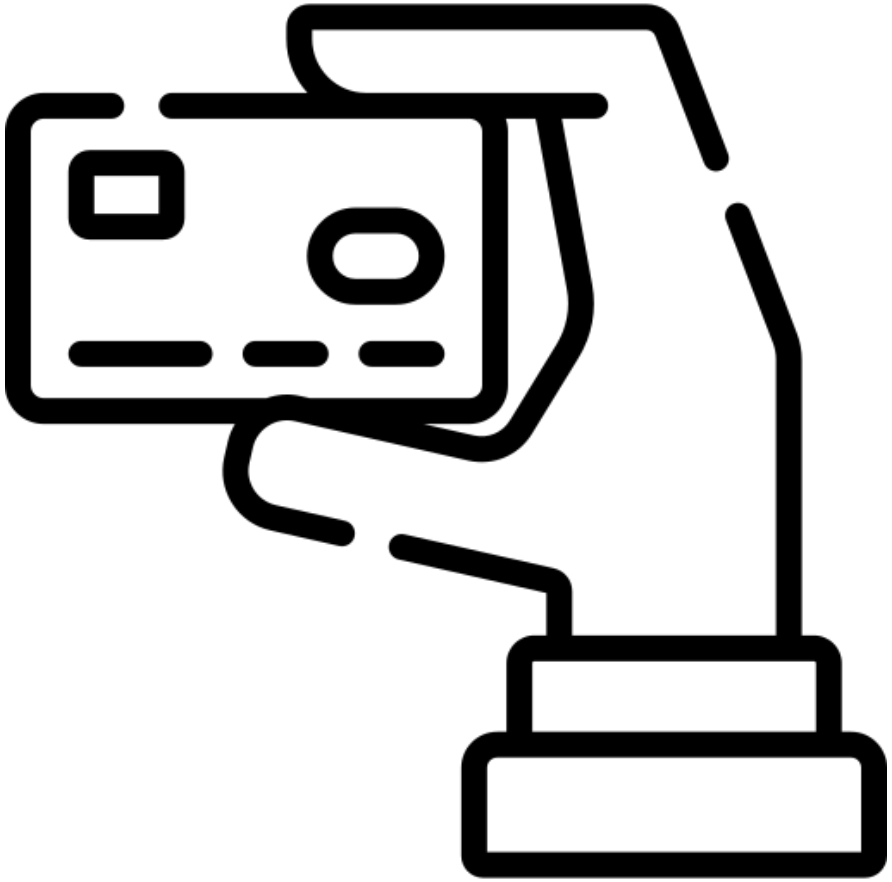
- The amendment to Regulation 5.3 allows the TGA to audit applications, including those previously requiring TGA conformity assessment
  - Audits are mandatory (and audit fees apply) for
    - Class III, AIMD, a number of specified Class IIb medical devices
    - Class 4 IVDs and a number of specified Class 3 IVDs
    - **unless supported by a conformity assessment from TGA, or Australian conformity assessment body, or issued under the European MDR / IVDR**
  - Any device may be selected for audit (no audit fee applies for discretionary audit)
- This is to ensure the device meets the Australian regulatory requirements prior to approval for supply in Australia.

Patient information materials

- From 1 December 2021, all implantable and Active Implantable Medical Devices (AIMD) are required to have patient information materials available (unless specifically excluded from these requirements), in the form of both:
  - Patient Information Leaflets (PILs)
  - Patient Implant Cards (PICs)
- Information to be included in PILs and PICs are detailed in Essential Principle 13A.



Patient information materials



- Sponsors who do not have compliant patient information materials need to apply for consent to import, supply, or export a medical device that does not comply with the Essential Principles. The application form is available on the TGA Business Services (TBS) portal. More information is available on the Essential Principles - consent for non-compliance web page.
- More information is available in our guidance on medical device patient information leaflets and implant cards.

Regulation 5.12

- Under Regulation 5.12, from 25 November 2021, Class IIb spinal fusion devices will need to have specific information in the ARTG entry about the devices that are supplied under the ARTG entry. This includes product names of all devices under each ARTG entry, before those devices can be imported, supplied or exported.
- For new applications, Class IIb application forms have been updated to provide space to include this information.
- More information is available in our guidance on reclassification of spinal implantable medical devices: guidance on the transitional arrangements and obligations of sponsors and manufacturers

Reclassification of certain medical devices

- On 25 November 2021, the reclassification of certain medical devices came into effect. To continue to supply your device you must notify the TGA by 25 May 2022 that you have an inclusion to be reclassified.

Reform	Old classification	Revised classification
Active medical devices for therapy with diagnostic function	IIa or IIb	III
Spinal implantable medical devices	IIb	IIb or III
Devices used in direct contact with the heart, central circulatory system (CCS), or central nervous system	IIa	III
Medical devices that administer medicines or biologicals by inhalation	I or IIa	IIa or IIb
Active implantable medical devices (AIMD)	AIMD	III
Medical devices that are substances introduced into the body via body orifice or applied to the skin	I or IIa	IIa, IIb or III

Reclassification of certain medical devices – transition period

- A transition period is available for existing medical devices:
  - **included in the ARTG prior to 25 November 2021**. You will need to notify the TGA before 25 May 2022 that you have an inclusion to be reclassified.
  - **with applications for inclusion in the ARTG lodged before 25 November 2021**. Your application will be assessed, and the device included in the ARTG under the old classification rules. You will need to notify the TGA that you have an inclusion to be reclassified by whichever is the later date, before 25 May 2022 or within 2 months of the start date of your ARTG entry.

- Applications for medical device inclusions submitted on or after 25 November 2021 must be submitted according to the new classification rules.

- Further information, including guidance and notification forms for each certain medical device are available on our website, Medical devices reforms: Reclassification of certain medical devices

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