UDI – Proposed Consent to Supply process and fees

Formal Consultation – Information Session
17 December 2025

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UDI Program Lead, Devices Reforms Taskforce

Medical Devices and Product Quality Division

Acknowledgement of Country

I would like to acknowledge the Traditional Owners and Custodians of the lands on which we meet today and pay my respects to Elders past and present.

I would like to extend that acknowledgement and respect to any Aboriginal and Torres Strait Islander peoples here today.

TGA staff here today

Medical Devices Product Quality Division

Tracey Duffy

First Assistant Secretary

Devices Reforms Taskforce

Gary Pascoe

UDI Program Lead

Carolyn Wilson

Business Analyst

Medical Devices Authorisation Branch

Kylie Downes

Director

Devices Application and Triage Section

Denver Surrao

Assistant Director

Devices Application and Triage Section

UDI Consent to Supply - welcome

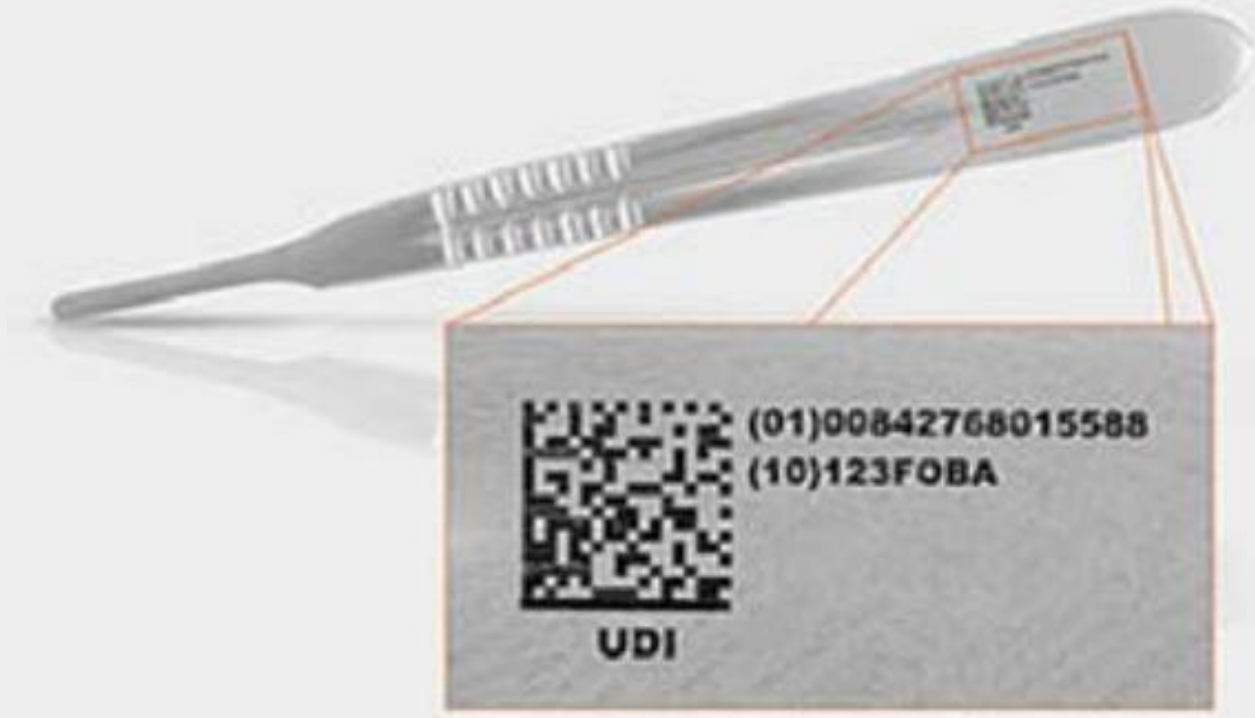
We are seeking feedback on a streamlined approach and change in fees for UDI Consent to Supply applications.

- UDI amendments to **Medical Device Regulations took effect in March 2025** with mandatory compliance for Class III and Class IIb medical devices from 1 July 2026
- As UDI requirements are **reflected in the Essential Principles**, non-compliance with the UDI requirements has the potential to disrupt supply of medical devices
- The **safety risk from non-compliance with UDI requirements is low** – they are not changing the device approvals; UDI compliance provides for supplementary information that helps identify and track approved devices.

- We are seeking feedback via this formal consultation process on 2 matters:
    - A **streamlined approach** to TGA's review of a UDI Consent to Supply application
    - A **change in fees** for a sponsor applying for UDI Consent to Supply

Today’s Workshop Outline

1. **UDI Consent to Supply**
    - Background
    - Streamlined approach
    - Reduced Fees
    - Timeframe
    - Sample scenarios
2. **Open discussion**
3. **Next Steps**



UDI Consent to Supply - overview

Non-compliance with UDI requirements is not expected to directly impact the safety or performance of the medical device – although it could have implications for timely market actions such as recalls, corrections and adverse event reporting.

The UDI Consent to Supply (CTS) process aims to provide a streamlined UDI-specific path that:

- Supports non-compliance with only the UDI-related Essential Principles
- Incurs reduced fees
- Leverages the existing Consent to Supply processes and systems
- Minimises administrative burden for sponsors and the TGA.

UDI Consent to Supply – UDI-related Essential Principles

Sponsors can apply to the TGA to seek approval for continued supply of their device if they are non-compliant with one or more UDI-related Essential Principles.

13A.2 – Patient Implant Cards

UDI on Patient Implant Card

13.5 – Device identifier and production identifier are provided with the device

13.6 – Packaging identifiers are provided with the device

13C.1 – Identifiers are issued by recognised Issuing Agencies

UDI on the device label

13C.2 – Identifiers are in the Australian Unique Device Identification Database

13C.3 – Other device-related data is in the Australian Unique Device Identification Database

13C.4 – Australian Unique Device Identification Database information is accurate and up to date

UDI and device data in AusUDID

13C.5 – Device identifier and production identifier are direct marked on the device

UDI on the device itself

UDI Consent to Supply – approach

The UDI CTS approach utilises the existing IT solution and involves a streamlined review process.

The proposed UDI Consent to Supply process:

- Supports new applications for inclusion and and existing ARTG inclusions
- Uses the existing CTS system – changes are underway to add new Essential Principles
- Allows for breach of UDI-related Essential Principles only, when combined with non-UDI EPs the streamlined approach and reduced fees do not apply
- Supports a single strategy to rectify non-compliance (Device Group)
- Is for a maximum 2 year duration
- Allows an unlimited number of ARTG inclusions on a single Consent to Supply application.

UDI Consent to Supply – phases

The TGA is seeking to maximise UDI compliance for each device class. UDI CTS can only be submitted in the year prior to the applicable mandatory compliance date.

- From 1 April 2026 to 30 June 2026 (submission of CTS for Class III and IIb)
- From 1 July 2026 to 30 June 2027 (submission of CTS for Class IIa)
- From 1 July 2027 to 30 June 2028 (CTS for Class Is, Class 4, Class 3 + MDD: Class III and IIb)
- From 1 July 2028 to 30 June 2029 (CTS for Class 2, Class 1 + MDD: Class IIa, Class Is, Class 4, Class 3)
- From 1 July 2029 to 30 Dec 2030 (CTS for MDD: Class 2, Class 1)

UDI Consent to Supply – streamlined review of applications

The TGA's review of the UDI CTS application will be streamlined to support timely TGA approval.

- UDI CTS applications will be approved if all the following applies:
  - For UDI-related Essential Principles only
  - Does not request non-compliance with **13C.1 Identifiers are issued by recognised Issuing Agencies** or **13C.3 Other device-related data is in the Australian Unique Device Identification Database**
  - Only lists ARTG inclusions for device classes that are due to become compliant in the next 12 months
  - For a period of 2 years, or less
  - Not for export only devices.
- UDI CTS applications that do not meet the criteria above will require additional time to review and may not be granted.
- Where implementation plans have specific dates for achieving full UDI compliance, our review processes may also monitor achievement of these.

Applications may be sampled using a risk-based approach and additional information requested if required.

UDI Consent to Supply – reduced fees

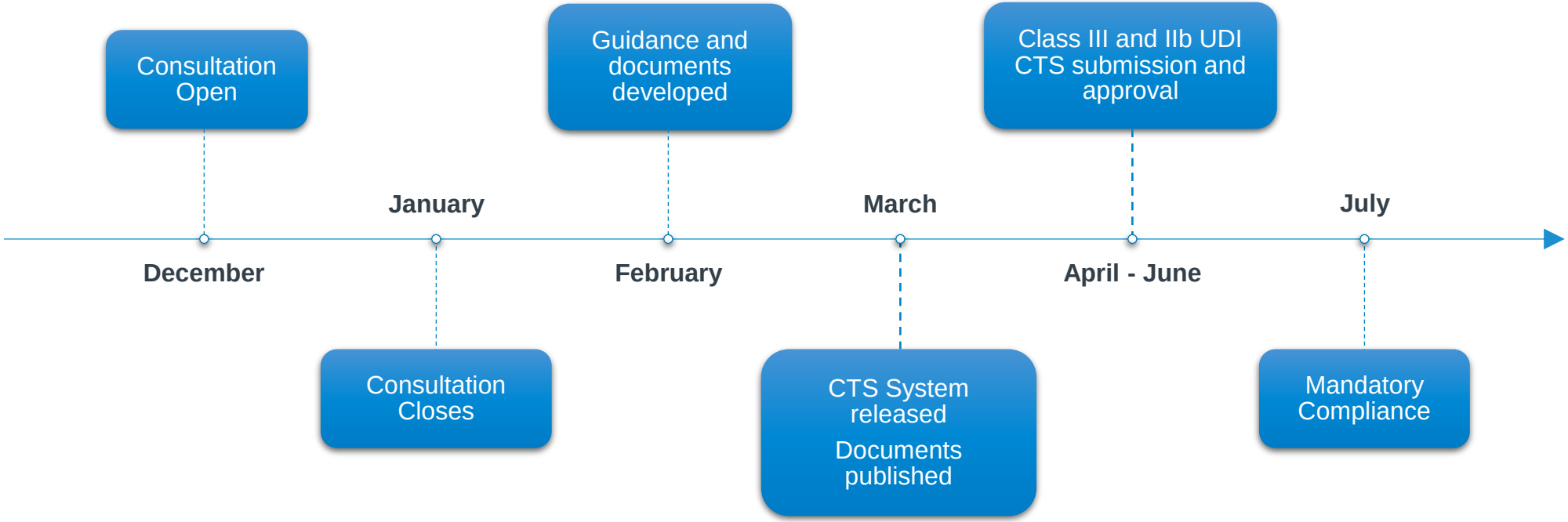
The proposed streamlined approval process (and reduced effort for the TGA) results in a reduction to the Consent to Supply fees for a UDI CTS.

- Our modelling considers estimated numbers of ARTG inclusions and sponsors potentially requiring UDI Consent to Supply
- The proposed fee options are based on recovering costs for TGA staff to complete the streamlined review process
- **Current CTS Fees:** $583 first ARTG, $117 each additional; $32 per ARTG (breach of 13A EU transition only).

	Option 1	Option 2	Option 3
Description	**Standard fee for each ARTG inclusion**	**Standard fee first ARTG inclusion, lower cost each additional inclusion**	**Standard fee for each UDI CTS application**
Cost Basis	**$32 per ARTG**	**$80 first ARTG $10 each additional ARTG**	**$170 per UDI CTS**
Sponsor A – 2 ARTGs	$64	$90	$170
Sponsor B – 12 ARTGs	$384	$190	$170
Sponsor C – 32 ARTGs	$1,024	$390	$170

UDI Consent to Supply – timeframe

Changes are required to IT systems and regulations



UDI Consent to Supply – scenarios

13A.2 – Patient Implant Cards

13.5 – Device identifier and production identifier are provided with the device
13.6 – Packaging identifiers are provided with the device
13C.1 – Identifiers are issued by recognised Issuing Agencies

13C.2 – Identifiers are in the Australian Unique Device Identification Database
13C.3 – Other device-related data is in the Australian Unique Device Identification Database
13C.4 – Australian Unique Device Identification Database information is accurate and up to date

13C.5 – Device identifier and production identifier are direct marked on the device

You have **Class III devices with EU MDD certificates,** they will not be UDI compliant by 1 July 2026.

You do not need CTS as the UDI regulations provide extended times for compliance for EU MDD and EU IVDR devices

You have voluntarily applied UDIs to your device labels and added data to the AusUDID in advance of the mandatory compliance date. However you are unable to meet a specific UDI requirement, e.g. add direct marking or meeting UDI requirements on the PIC.

You can apply for CTS and nominate the specific EPs that will apply. For example:
- 13C.5 for direct marking
- 13A.2 for PIC requirements

You have a Class IIa product that is transitioning to being an exempt product and do not wish to meet UDI requirements for these.

You can apply for CTS for 13.5, 13.6, 13C.1, 13C.2, 13C.3, 13C.4.

You just acquired a company and all their devices. There will be a 12-month delay while you relabel devices and submit new data to the AusUDID.

You apply for CTS for 13.5, 13.6, 13C.2, 13C.4

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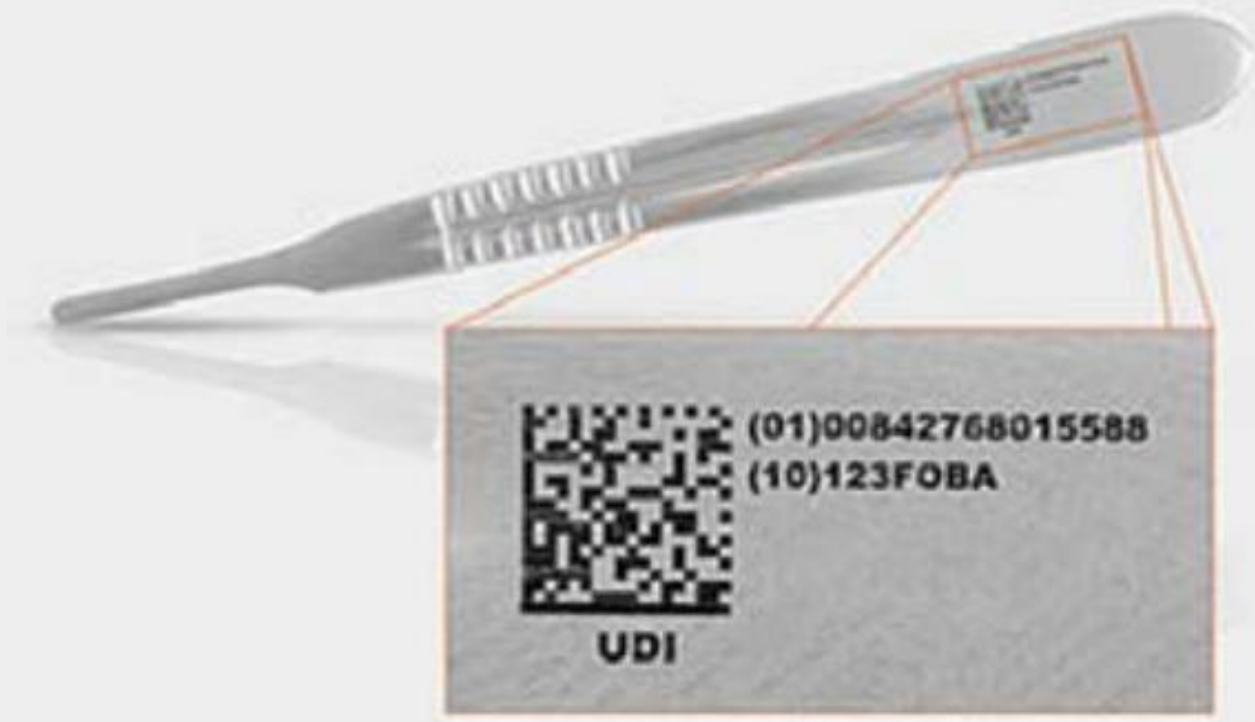

Open Discussion

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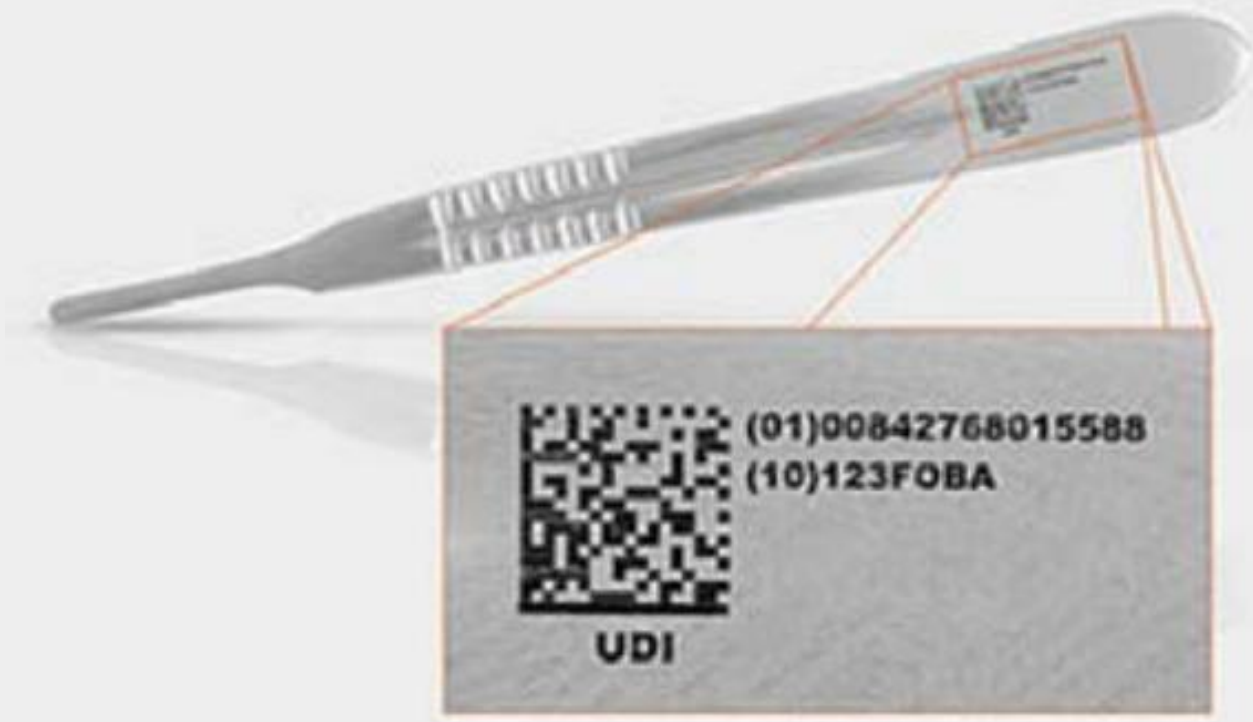

Next steps – including feedback on consultation process

Have your say!

Provide feedback through the TGA Consultation Hub:

https://consultations.tga.gov.au/tga/b598ed31

Email us with any questions:

UDI Support Team
UDI@health.gov.au

Australian Government

Department of Health, Disability and Ageing

Therapeutic Goods Administration