

UDI – Proposed Consent to Supply process and fees

Formal Consultation

December 2025



Australian Government

Department of Health, Disability and Ageing
Therapeutic Goods Administration

tga.gov.au

Dear Sponsor,

Unique Device Identification (UDI) requirements were introduced into the *Therapeutic Goods (Medical Devices) Regulations 2002* in March 2025. The first mandatory compliance date for Class III and IIb devices is 1 July 2026. We understand that some Sponsors may be unable to meet all UDI requirements so we are finalising details on how the Consent to Supply process can be used to support continued device supply until full compliance can be achieved.

This is the formal consultation process for:

- A **streamlined approach** to review of UDI Consent to Supply (see [Slides 5 and 6](#) for details)
- A proposed **change in fees** for an application for UDI Consent to Supply (see [Slide 7](#) for details)

Upon finalisation, the ***User guide for completing an application for consent to import, supply, or export a medical device that does not meet the Essential Principles*** will be updated to reflect the final details of the UDI Consent to Supply process.

ACTION: I am seeking your feedback on the proposed fees and streamlined UDI Consent to Supply process as described in this deck.

Your response by 23 January 2026 would be appreciated.

Kind regards

Tracey Duffy
First Assistant Secretary
Medical Devices Product Quality Division

UDI Consent to Supply - overview

Non-compliance with UDI requirements is expected not to directly impact the safety or performance of the actual medical device – although could have implications for timely post market and/or recall actions.

The UDI Consent to Supply (CTS) process aims to:

- Be specific to UDI-related Essential Principles
- Incur reduced fees
- Provide a streamlined UDI-specific path that leverages the existing process
- Minimise 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 will utilise the existing IT solution but offers a streamlined review process.

The streamlined UDI Consent to Supply process will support both new applications and existing ARTG inclusions and will:

- Be completed using the existing CTS system
- Allow for non-compliance with UDI-related Essential Principles only (if combining with other non-UDI-related Essential Principles the standard Consent to Supply process and fees will apply)
- Allow a single strategy to rectify non-compliance (Device Group) even if some remediation actions will be completed during the period of consent
- Allow for 2 years of non-compliance, this cannot be extended however a new CTS can be submitted
- Allow for an unlimited number of ARTG inclusions in a single CTS application in the 12-month period prior to their mandatory compliance date:
 - From 1 April 2026 to 30 June 2026 (submission of UDI CTS for Class III and IIb)
 - From 1 July 2026 to 30 June 2027 (submission of UDI CTS for Class IIa)
 - From 1 July 2027 to 30 June 2028 (submission of UDI CTS for Class I, Class 4, Class 3 + MDD: Class III and IIb)
 - From 1 July 2028 to 30 June 2029 (submission of UDI CTS for Class 2, Class 1 + MDD: Class IIa, Class I, Class 4, Class 3)
 - From 1 July 2029 to 30 Dec 2030 (submission of UDI CTS for MDD: Class 2, Class 1).

UDI Consent to Supply – streamlined review

UDI CTS application review will be streamlined to allow timely TGA approval. Applications may be sampled using a risk-based approach and additional information requested if required.

- UDI CTS applications will be approved if all of the following applies:
 - They are for UDI-related Essential Principles only
 - They do not request breach of **13C.1 Identifiers are issued by recognised Issuing Agencies or 13C.3 Other device-related data is in the Australian Unique Device Identification Database**
 - They only list ARTG inclusions for device classes that are due to become compliant in the next 12 months
 - They are for a period of 2 years or less
 - They are not for export only devices.
- UDI CTS applications that do not meet the criteria above will require additional time to review and/or may not be granted.
- The TGA may use a risk-based approach and review a selection of plans to ensure they contain all the relevant information as required and seek additional information from sponsors. Where implementation plans have specific dates for achieving full UDI compliance, our review processes may also monitor the achievement of these.

UDI Consent to Supply – reduced fees

UDI CTS proposed fee options offer a reduction to existing Consent to Supply fees. This reflects the proposed streamlined approval process (and effort by the TGA).

- 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.

	Option 1	Option 2	Option 3
Description	Standard fee for each ARTG inclusion	Standard fee for first ARTG inclusion, lower cost for additional inclusion	Standard fee for each UDI CTS application
Cost Basis	\$32 per ARTG	\$80 for first ARTG \$10 for 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



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