Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Consultation: Unique Device Identification (UDI) information in Certificates of Free Sale

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Introduction

The Australian Government is undertaking significant reforms to improve the regulation of medical devices in Australia. The Therapeutic Goods Administration (TGA) is the government authority responsible for evaluating and monitoring medical devices. To improve patient safety and enhance the ability to identify medical devices in a timelier way, the Government introduced the Australian Unique Device Identification (UDI) framework in March 2025, with mandatory compliance applying progressively from 1 July 2026 according to medical device risk classification.

More information regarding compliance with Unique Device Identification (UDI) requirements can be found on the TGA website: Unique Device Identification (UDI) hub | Therapeutic Goods Administration (TGA).

We are now seeking feedback on whether UDI information should be included with Certificates of Free Sale for medical devices.

Certificates of Free Sale provide an importing country with official evidence from the exporting country's regulator that the device is legally available for supply in its home market. In Australia, the TGA can issue a Certificate of Free Sale for a medical device that has a current inclusion in the Australian Register of Therapeutic Goods (ARTG) that allows the medical device to be supplied and sold within Australia and exported from Australia.

Certificates currently contain information drawn from the ARTG including:

- ARTG number
- medical device description
- GMDN code
- medical device class.

The introduction of the Australian UDI framework provides a means of identifying medical devices at a more granular level than the ARTG 'kind of device'. This raises the question of whether providing access to UDI information alongside Certificates of Free Sale would assist applicants or certificate recipients to identify the specific devices associated with a certificate.

We are considering how UDI information could interact with Certificates of Free Sale, including:

- whether access to UDI information would be useful to sponsors applying for certificates, overseas regulators or other certificate recipients
- whether providing this information could create additional administrative, financial or regulatory burden.

Purpose of this consultation

The purpose of this consultation is to understand the impact of including UDI information on Certificates of Free Sale.

We are particularly interested in:

- the benefits of including UDI information on Certificates of Free Sale
- whether applicants should have the option to provide UDI information in a schedule accompanying the certificate
- what UDI information would be useful if it were included
- whether including UDI information could create unintended regulatory burden, administrative or other practical consequences.

Your feedback will help us determine the most appropriate approach to providing access to UDI information while maintaining the purpose of Certificates of Free Sale.

Options being considered

There are 3 options being considered as follows:

Option 1: Do not include UDI information in the certificate

Under this approach, UDI information would **not** form part of the Certificate of Free Sale.

Instead, a reference or link to the Australian UDI Database (AusUDID) could be provided. This would allow certificate recipients to access current UDI information, where required and available.

This approach would maintain the distinction between information recorded in the ARTG and additional information available through the AusUDID.

Option 2: Allow UDI information in a schedule

Under this approach, applicants could provide relevant UDI information in a schedule accompanying their application.

The applicant would be responsible for providing accurate UDI information. This information will not be vetted by the TGA.

This would allow UDI information to accompany a certificate, without making it a standard component of every Certificate of Free Sale.

Option 3: Include UDI information on the certificate

Under this approach, UDI information would be a standard component presented on the Certificate of Free Sale.

This approach would require consideration of what UDI information is included and how it is represented.

Please note: This approach would not impose any additional UDI requirements. Eligibility for Certificates of Free Sale would remain tied to ARTG inclusion. Devices that are exempt from UDI requirements would remain exempt, and as such UDIs would not be included on certificates for those devices.

Key considerations

When considering the proposed options, you may wish to consider the following factors.

Potential value of UDI information

UDI information identifies medical devices at a more granular level than the ARTG 'kind of device'. Providing access to UDI information alongside a Certificate of Free Sale may therefore assist applicants or certificate recipients to identify the specific devices covered by the certificate.

We are interested in understanding whether this additional level of identification would be useful, including for overseas regulatory or import requirements, and how UDI information would be used in practice.

UDI information can change

A UDI – Device Identifier (UDI-DI) may change during the life of a medical device.

For example, a manufacturer may need to assign a new UDI-DI following a UDI Trigger scenario. A UDI-DI may also change following an Issuing Agency-led change that is not a UDI Trigger.

If UDI information is included on a certificate, a device change could mean the certificate no longer reflects the device's current UDI-DI.

This could result in applicants seeking replacement certificates when UDI information changes, creating additional administrative and financial burden.

A medical device may have multiple UDI-DIs

A device model may be associated with multiple UDI-DIs across different configurations or packaging levels. For example, different device variants, such as size or colour, may have different UDI-DIs, while higher packaging levels may also have their own Package DIs.

Therefore, including the UDI-DI of a medical device on a certificate will provide useful information but will not provide a full picture of the device's packaging hierarchy.

Including every relevant UDI-DI could make certificates or accompanying schedules significantly more complex.

The UDI encountered may differ from the UDI on a certificate

The UDI-DI included with a Certificate of Free Sale may not be the identifier visible to the recipient when the product is received. For example, the certificate may reference the UDI-DI assigned to the base package, while an importer or distributor encounters a higher packaging level carrying a different Package DI.

Not all devices will have a UDI

Most medical devices will be subject to UDI requirements, once implementation is complete.

However, certain medical devices and in vitro diagnostic (IVD) medical devices are exempt from Australian UDI requirements.

Some devices are also eligible for transitional arrangements or have Consent to Supply, meaning they are not yet UDI compliant.

Any approach that includes UDI information would need to accommodate devices where no UDI is required or available.

Accessing current UDI information

The AusUDID provides a source of UDI information for medical devices. Because UDI information may change over the life of a device, accessing the information directly from the AusUDID could allow certificate recipients to obtain current information rather than relying on information captured when a certificate was issued.

Consultation questions

We welcome feedback on the following questions via the Consultation Hub.

1. What is your preferred option?
    a. Option 1: Certificates of Free Sale do not include UDI information; recipients can access available information through AusUDID.
    b. Option 2: Applicants optionally provide UDI information in an accompanying schedule.
    c. Option 3: UDI information forms part of the standard Certificate of Free Sale.
2. Please provide any additional information on why you selected your preferred option.
3. If UDI information were provided, what information would be useful?
4. Could including UDI information create regulatory, administrative or practical impacts? Please provide examples.
5. Would directing the recipient to AusUDID meet user needs? Why or why not?
6. Is there anything else you would like to tell us about UDI information and Certificates of Free Sale?

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Device Reforms Taskforce	October 2026

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Reference/Publication #