



## TGA CONSULTATION RESPONSE:

Proposal to introduce a Unique Device Identification (UDI) system for medical devices in Australia

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## About Stryker

Established in 1941, Stryker is one of the world's leading medical technology companies. Stryker offers innovative products and services in Orthopaedics, Medical and Surgical, and Neurotechnology and Spine that help improve patient and hospital outcomes.

Stryker employs more than 33,000 people worldwide, and our products and services are available in over 100 countries. In the early 1970s, Stryker was established in Australia, where we now employ more than 600 people.

### Our mission

Together with our customers, we are driven to make healthcare better.

### Our values

- **Integrity:** we do what's right.
- **Accountability:** we what we say.
- **People:** we grow talent.
- **Performance:** we deliver.

## Contact

To discuss Stryker's response to the TGA consultation paper, please contact

[Redacted contact information]



## Introduction

The Australian Government is undertaking a significant program of reform to the regulation of therapeutic goods in Australia. As part of the Australian Government Department of Health, TGA regulates therapeutic goods, and is responsible for implementing the Government's reforms. The Therapeutic Goods Administration (TGA) has issued the consultation paper "Proposal to introduce a Unique Device Identification (UDI) system for medical devices in Australia" as part of the Government's reform program.

## Background

Demand is growing for improved traceability of medical devices in the supply chain. There is now worldwide recognition that, in the interests of patient safety and improved industry outcomes, the ability to unambiguously identify medical devices is essential. The development and implementation of the Unique Device Identification System (the UDI System) is widely acknowledged by the industry and regulators as an effective mean of ensuring timely access to complete, accurate and consistent information about medical devices.

The [International Medical Device Regulators Forum](#) (IMDRF) - a group of the major medical device regulators from around the world, including Australia - is working to advance and strengthen international medical device regulatory frameworks, including those governing Unique Device Identification (UDI). [IMDRF guidance documents](#) (IMDRF UDI Guidance) provide a framework within which regulatory authorities and manufacturers can develop and implement their own UDI systems. The aim is to secure 'a single, globally harmonized system for positive identification of medical devices'.

Several international regulatory authorities have already implemented the UDI System, commenced work on implementation, or introduced enabling legislation. This includes authorities from the USA, Europe, Japan, Brazil and some members of the [Asian Harmonization Working Party](#).

## This consultation

TGA are exploring the feasibility of introducing the UDI System in Australia, including options for development of the UDI database (AusUDID).

TGA proposes to build on the work and experience of the IMDRF, the U.S. Food and Drug Administration (U.S. FDA), the European Union (EU) and other jurisdictions to inform the principles and design of a UDI System for Australia.

TGA is seeking feedback on:

- the proposal to introduce a Unique Device Identification (UDI) system for medical devices in Australia
- whether the TGA or another body should be responsible for establishing and maintaining the Australian UDI database (AusUDID)
- the potential scope of regulatory and legislative amendments required to establish the UDI System in Australia.



## Stryker's response

Stryker, in essence, supports the MTAA's response, having significantly contributed to that submission.

Stryker is submitting this separate response in order to emphasise some aspects and provide any nuances that may be worth clarifying from our point of view.

### 1. The proposal to introduce a Unique Device Identification (UDI) system for medical devices in Australia

Stryker support the need to uniquely identify medical devices with complete, accurate and consistent information. We also support the ability to use this information for the purposes of traceability, for safety reasons as well as the ability to gather clinical data. The critical point to make is that these UDIs and the process of accreditation and recognition should be harmonised globally among regulators such as TGA, FDA and EU Notified Bodies. Rules must also align with international coding standards – both EU and US. Stryker uses only GTINs from GS1 but understand the need for other bodies such as HIBC to be accredited.

### 2. Should the TGA or another body should be responsible for establishing and maintaining the Australian UDI database (AusUDID)?

Stryker agrees with the MTAA that the AusDID database should be independently controlled, be publicly available at little or no cost, and also allow sponsors to update their own information free of charge. The TGA would be ideal as an independent authority, similar to the FDA, in performing the task, with some caveats: that TGA has both the expertise and resources to effectively perform the implementation and management of the AusDID in a timely and effective fashion. If any outsourcing were to be required, TGA must retain independent control over that function and the database itself. FDA has successfully implemented and utilized UDI and run the US UDI database without a 3<sup>rd</sup> party for the last 5 years with no known issues.

### 3. The potential scope of regulatory and legislative amendments required to establish the UDI System in Australia.

Again, it is important that there is harmonization with terminology and standards among regulators, and that appropriate resources are provided to maintain independent database control. Traceability would be further enhanced by the future inclusion of Global Location Numbering standard from GS1. Also, how will TGA treat products that do not have a UDI yet when placed on the ARTG? How can they, or should they, mandate this? Will there be the ability to include fields that are applicable to a supply chain but not specifically pertinent to regulatory requirements?

Stryker looks forward to continuing discussion with TGA in relation to the introduction of UDI to Australian regulations.

