Presentation 1
Unlocking the value of UDI for healthcare and registries

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tga.gov.au

The importance of UDI

There is global demand for improved traceability of medical devices





- Australia – 2026 - 2030
- Canada
- Switzerland
- United Kingdom
- Japan
- Brazil – 2025 – 2028+
- Saudi Arabia – 2023 - 2024
- European Union – 2022 - 2027
- Singapore – 2022 - 2028
- China – 2021 - 2026
- South Korea – 2019 - 2022
- United States of America – 2014 - 2018

Why Australia introduced Unique Device Identification (UDI)

UDI is one of the key actions taken to improve patient safety outcomes and device identification and tracking

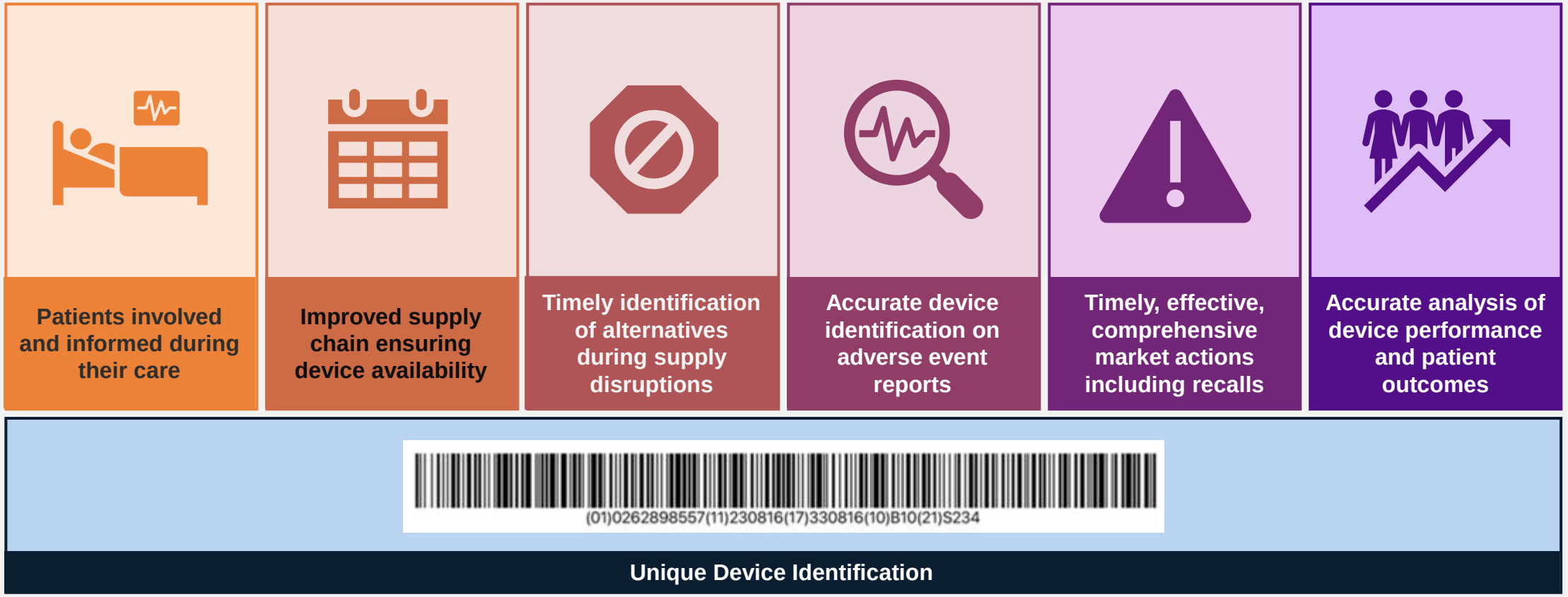
The Therapeutic Goods Administration (TGA) introduced UDI to support patient safety and to help improve the response to medical device crises such as:

- transvaginal mesh
- breast implants
- hip implants.



Value of UDI

Accurate identification of medical devices throughout the device lifecycle



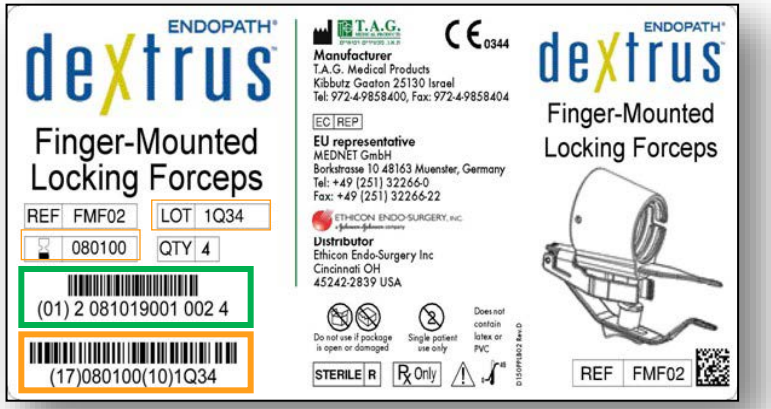
What makes up a UDI

UDI = UDI-DI + UDI-PI

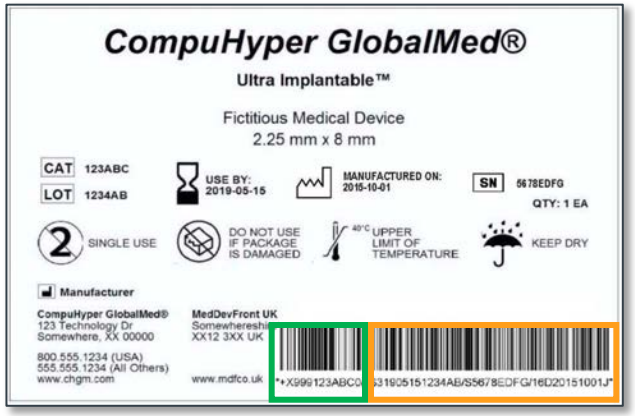
A UDI is made up of 2 parts:

1. UDI-Device Identifier (UDI-DI) – identifies the specific model or version of the device
2. UDI-Production Identifier (UDI-PI) – identifies the production run of the device through a serial number, lot number, batch number, manufacturing/expiry date.

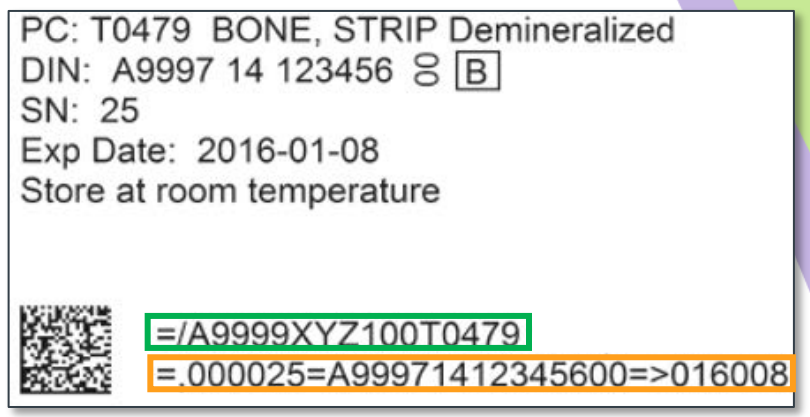
GS1 Australia



HIBCC GLOBAL



ICCBBA



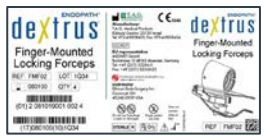
How UDI can help

Issuing Agency

(01) 2 081019001 002 4

UDI

Manufacturer



Device label



Medical device

Publicly accessible

Patients

Healthcare

Research

Consumers

Hospitals

Australian UDI Database
(AusUDID)

UDI-DI: Model of device



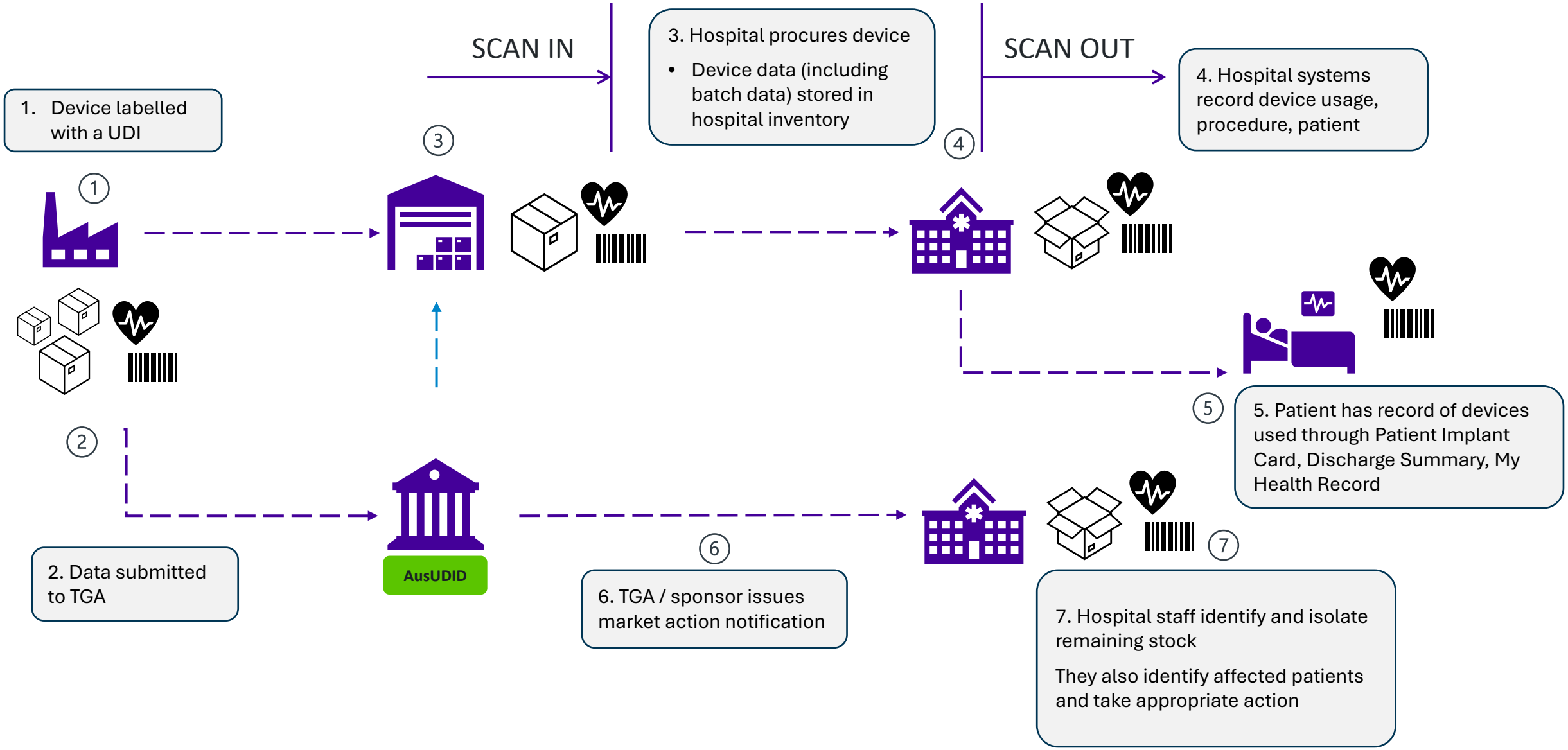
Australian Sponsor

Clinical Quality Registry



Hospital

UDI – from manufacture to healthcare to recall – the possibilities



TGA responsibilities

Multiple stakeholders must be involved to realise the full benefits of UDI



UDI system

- Oversee the Australian regulatory framework.
- Work with overseas regulators to harmonise the system.



Australian UDI Database (AusUDID)

- Maintain and administer the UDI database.



Device regulation

- Use UDIs to support regulatory decision making, post-market surveillance and recall management.

Industry responsibilities

Where devices are in scope of UDI requirements, several requirements of the UDI system will be evident in healthcare



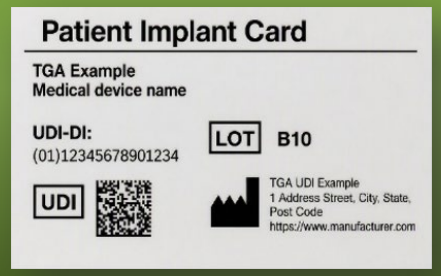
Labelling

- Include the UDI on the device label and higher levels of packaging
- Directly mark the UDI on certain types of devices such as reusable devices.

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AusUDID

Australian UDI Database (AusUDID)

- Maintain device data in the AusUDID including linking to relevant Australian Register of Therapeutic Goods (ARTG) entries.



Regulatory

- Include the UDI on patient implant cards.
- Include the UDI in reporting to the TGA for adverse events and market actions.

TGA responsibilities

Multiple stakeholders must be involved to realise the full benefits of UDI



Capture and use

- Integrate UDI across systems and processes
- Use AusUDID as a device data source
- Share UDI data with clinical quality registries



Safety and traceability

- Build workforce capability and understanding of UDI
- Include UDI in adverse event reporting
- Use UDI to identify stock and patients in response to market actions



Improvement and regulation

- Provide feedback on usability, data or readability discrepancies

Consider manufacturer or sponsor obligations for point-of-care manufacturing

Scope

Currently - UDI requirements apply to some types of medical devices

- UDI applies to:

Medical devices	In vitro diagnostic (IVD) devices
• Class III (hernia mesh) • Class IIb (lung ventilator) • Class IIa (digital thermometer) • Class Is (surgical gown)	• Class 4 (blood screening for HIV) • Class 3 (cancer diagnostic test) • Class 2 (pregnancy test) • Class 1 (Software or Instrument/Analyser only)

- UDI does **not** apply to:
  - Class I (nonsterile non-measuring) or Class Im (measuring) medical devices
  - Class 1 IVDs (remainder)
  - In-house IVDs
  - Devices **not** included on the ARTG
  - Devices exempt under the Special Access Scheme (SAS) or Authorised Prescriber (AP) Scheme.

Timeframes

Timeframes for compliance are phased over several years

Requirement	Medical devices				In vitro diagnostic medical devices			
	Class III	Class IIb	Class IIa	Class Is	Class 4	Class 3	Class 2	Class 1
UDI on the label	1 July 2026		1 July 2027	1 July 2028	1 July 2028		1 July 2029	
Data submitted								
Direct Marked	1 Jan 2028	1 Jan 2029			1 July 2029		1 July 2030	

- **Existing devices -** manufactured and labelled before their UDI compliance date. They do not need to meet UDI requirements even if supplied after the compliance date.
- **Consent to Supply -** allows TGA approval for a sponsor to supply devices that are non-compliant with UDI requirements for an agreed period.

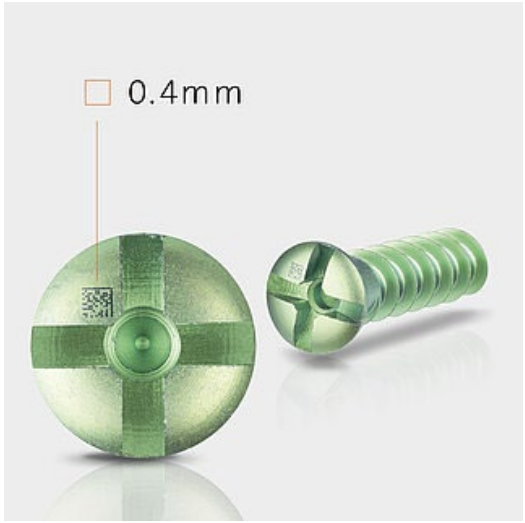
Formats and feasibility

UDI requirements do not prescribe the format of the UDI Carrier used to convey the UDI

- UDIs can be provided in **different formats** – 2D barcodes, linear barcode, stacked barcode
- UDIs can be shown in **different places** - on labels, directly marked on the device, on stickers and tabs







- **Exemptions** mean not every label can include a UDI and not every reusable device will have direct marking. Exemptions can apply to small devices or labels, if it is not technically feasible, if it could impact performance of the device.

Allocation of new UDIs

Changes that require a new UDI can result in multiple UDI records for what ‘seems to be’ the same model of device

Certain changes to a device are considered UDI Triggers, which require:

- a new UDI-DI to be allocated
- a new UDI record to be submitted to the AusUDID.

Australian Trigger Data Elements

- Brand name
- Clinical size
- Labelled as single use
- Change to restricted number of reuses
- Packaged sterile
- Need for sterilisation before use
- Critical warnings or contraindications:
  - Contains latex
  - MRI safety status
- Device version or model (including software features that change intended purpose / major version number)
- Number of devices in a base package

TGA Action ID	RC-2025-RN-00667-1
Type of Product	Medical Device
Product Name/Description	**PrisMax V2 and PrisMax V3 Control Unit and TherMax Blood Warmer Unit** **Product Codes: 955558, 955725, 955515** **All serial numbers**
ARTG Number	311561, 311562
Unique Device Identifier (UDI)	07332414124359, 07332414126025, 07332414123925
Action Type	Product Correction
Action Level	Hospital
Hazard Classification	Class II
Reason for the Action	Vantive has identified three problems affecting the PrisMax Systems and TherMax Blood Warmer Units: 1. PrisMax System alarm T2309: Air Detected in Prime may be raised after priming with a low liquid level in the deaeration chamber. 2. PrisMax System alarm T0830: Blood Leak Detected may be raised when no blood leak is present, or the operator may have difficulty normalising the Blood Leak Detector (BLD) leading to PrisMax System alarms T1313: BLD Normalise Failed, T0853: Normalisation Failed, or T1205: BLD Self-Test Failure. 3. Thermax System may be unable to detect the presence of a bag on the Thermax Blood Warmer Unit leading to difficulty setting up therapy, or PrisMax System alarm T2284: Thermax Disposable Not Inserted. The occurrence of these three problems may result in delays or interruptions to therapy, and in certain circumstances, could lead to blood loss.
Instructions for Customers/Users	Customers are to: · Continue using the PrisMax Systems and TherMax Blood Warmer Units in accordance with the Operator’s Manuals and on-screen instructions, as safe operation is maintained. · Expect contact from a local Vantive representative once corrections become available, to determine the appropriate correction plan and schedule the necessary updates for impacted devices.
Action Commencement Date	7/08/2025

Specific device types

Some devices are exempt from certain requirements or have additional requirements







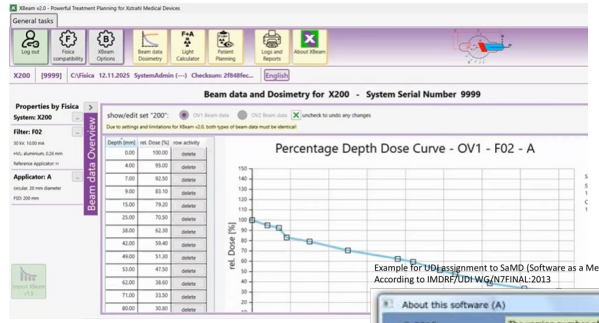




Specific requirements exist for:

- devices principally sold in retail
- software
- system or procedure packs
- single use devices
- reusable devices
- surgical loan kits
- capital equipment
- refurbished devices
- systems that are medical devices
- medical device accessories
- replacement parts or spare parts
- boundary and combination products
- co-packaged medical devices.







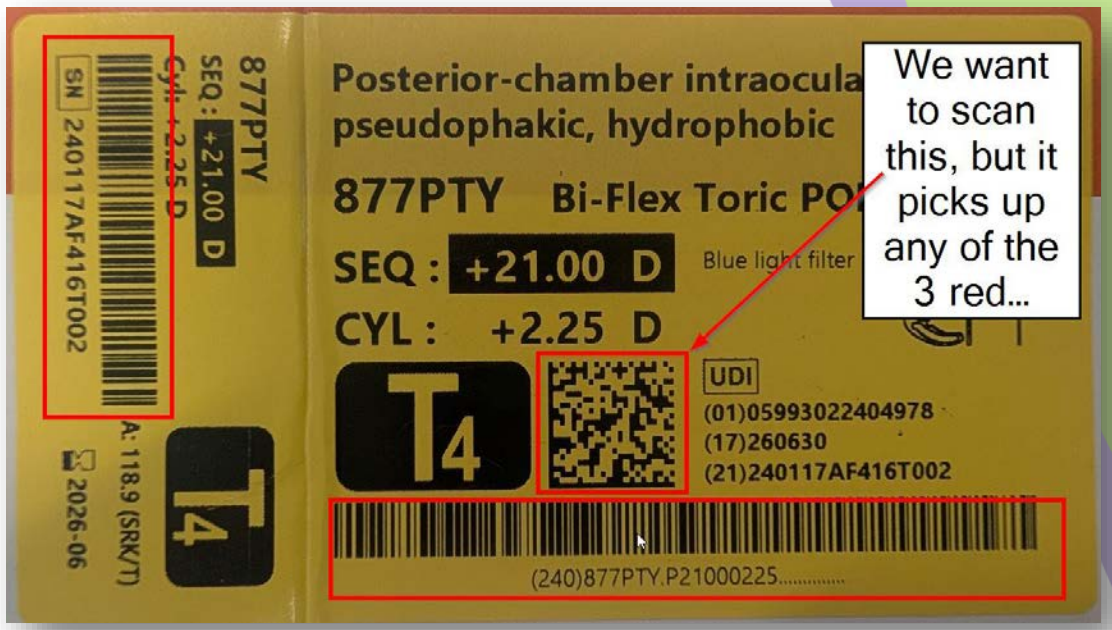
Example for UDI assignment to SaMD (Software as a Medical Device)
According to IMDRF/UDI WG/N7FINAL:2013

Ease of use and scanning

Readability and scan-ability of barcodes can be impacted by many factors

Readability and scanning can be impacted by:

- ink quality and colour
- printing directly on corrugated box
- printing on shiny surfaces
- outer packaging such as plastic wrap
- shipping labels that are prone to fading and smudging
- multiple barcodes on the pack
- stacked barcodes requiring two scans
- multiple barcode types with the same or different information
- deterioration over time.



Digital capability and data sharing

Underpinning digital capability and data sharing/governance arrangements are key to support device data moving through the ecosystem



Digital Capability

Variation in digital maturity across hospitals and health services creates uneven capacity to collect, manage, and integrate device data effectively



Data Sharing and Governance

The complexity of establishing data-sharing agreements limits seamless information exchange

The Australian UDI Database (AusUDID)

The Australian UDI Database maintained by the TGA contains up to date medical device data

- Data is publicly available at no cost
- Includes UDI-DI
- Does **not** include UDI-PI
- Does **not** include any patient information
- Data remains indefinitely to support future adverse event reporting and market actions
- Currently holds over 310 000 records

ausudid.tga.gov.au

An example – Medical device

ACE Catheter Set

ITEMS		VALUE
Product Name		Ace Catheter Set
Type		Single, Dual Type
Catheter Length		50, 70, 100cm
Catheter Hole		2.5cm(8 hole), 5.0cm(10 hole), 6.5cm(15 hole), 10cm(20 hole), 12.5cm(25 hole), 15cm(30 hole), 20cm(40 hole), 30cm(60 hole)
Specification	Single	1. 2.5cm Catheter(8 hole), Introduce Needle 18G, 0.2μm Filter, 5cc Syringe, Catheter Securement(Ace Lock) 2. 5.0cm Catheter(10 hole), Introduce Needle 18G, 0.2μm Filter, 5cc Syringe, Catheter Securement(Ace Lock) 3. 6.5cm Catheter(15 hole), Introduce Needle 18G, 0.2μm Filter, 5cc Syringe, Catheter Securement(Ace Lock) 4. 10cm Catheter(20 hole), Introduce Needle 18G, 0.2μm Filter, 5cc Syringe, Catheter Securement(Ace Lock) 5. 12.5cm Catheter(25 hole), Introduce Needle 18G, 0.2μm Filter, 5cc Syringe, Catheter Securement(Ace Lock) 6. 15cm Catheter(30 hole), Introduce Needle 18G, 0.2μm Filter, 5cc Syringe, Catheter Securement(Ace Lock) 7. 20cm Catheter(40 hole), Introduce Needle 18G, 0.2μm Filter, 5cc Syringe, Catheter Securement(Ace Lock) 8. 30cm Catheter(60 hole), Introduce Needle 18G, 0.2μm Filter, 5cc Syringe, Catheter Securement(Ace Lock)
	Dual	1. 2.5cm Catheter(8 hole), Introduce Needle 18G, 0.2μm Filter, 5cc Syringe, Catheter Securement(Ace Lock), Y-Connector LIne 2. 5.0cm Catheter(10 hole), Introduce Needle 18G, 0.2μm Filter, 5cc Syringe, Catheter Securement(Ace Lock), Y-Connector LIne 3. 6.5cm Catheter(15 hole), Introduce Needle 18G, 0.2μm Filter, 5cc Syringe, Catheter Securement(Ace Lock), Y-Connector LIne 4. 10cm Catheter(20 hole), Introduce Needle 18G, 0.2μm Filter, 5cc Syringe, Catheter Securement(Ace Lock), Y-Connector LIne 5. 12.5cm Catheter(25 hole), Introduce Needle 18G, 0.2μm Filter, 5cc Syringe, Catheter Securement(Ace Lock), Y-Connector LIne 6. 15cm Catheter(30 hole), Introduce Needle 18G, 0.2μm Filter, 5cc Syringe, Catheter Securement(Ace Lock), Y-Connector LIne 7. 20cm Catheter(40 hole), Introduce Needle 18G, 0.2μm Filter, 5cc Syringe, Catheter Securement(Ace Lock), Y-Connector LIne 8. 30cm Catheter(60 hole), Introduce Needle 18G, 0.2μm Filter, 5cc Syringe, Catheter Securement(Ace Lock), Y-Connector LIne

ARTG Public Summary

Summary for ARTG Entry: 327940 Teleflex Medical Australia Pty Ltd - Autoinfuser - Elastomeric infusion pump kit

ARTG entry for Medical Device Included Class IIb

Sponsor Teleflex Medical Australia Pty Ltd

Postal Address Suite 3 Level 7 Building 3 Corporate Connect Centre, 189 O'Riordan Street, Mascot, NSW, 2020 Australia

ARTG Start Date 19/12/2019

Product Category Medical Device Class IIb

Status Active

Approval Area Medical Devices

Conditions

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Manufacturers

Name	Address	Location Id
Ace Medical Co Ltd	33 Naeyu-gil 124beon-gil Deogyang-gu Goyang-si, Gyeonggido, 10264 Korea - Republic of	103993

Products

1 . Autoinfuser - Elastomeric infusion pump kit

Product Type Medical device system **Effective Date** 19/12/2019

GMDN 47190 Elastomeric infusion pump kit

Intended Purpose Disposable balloon infuser intended for continuous and/or intermittent infusion of medication for general infusion use including chemotherapy and pain management therapies.



AusUDID

Brand name	Model or version	Manufacturer	ARTG ID	Primary DI
Ace Catheter Set	TBD-2.5	Ace Medical Co Ltd	**Teleflex Medical Australia Pty Ltd** 327940	08806139650268
Ace Catheter Set	TBD-5.0	Ace Medical Co Ltd	**Teleflex Medical Australia Pty Ltd** 327940	08806139650275
Ace Catheter Set	TBD-6.5	Ace Medical Co Ltd	**Teleflex Medical Australia Pty Ltd** 327940	08806139650282
Ace Catheter Set	TBD-10	Ace Medical Co Ltd	**Teleflex Medical Australia Pty Ltd** 327940	08806139650299
Ace Catheter Set	2TBD-2.5	Ace Medical Co Ltd	**Teleflex Medical Australia Pty Ltd** 327940	08806139650404
Ace Catheter Set	2TBD-5.0	Ace Medical Co Ltd	**Teleflex Medical Australia Pty Ltd** 327940	08806139650411
Ace Catheter Set	2TBD-6.5	Ace Medical Co Ltd	**Teleflex Medical Australia Pty Ltd** 327940	08806139650428
Ace Catheter Set	2TBD-10	Ace Medical Co Ltd	**Teleflex Medical Australia Pty Ltd** 327940	08806139650435

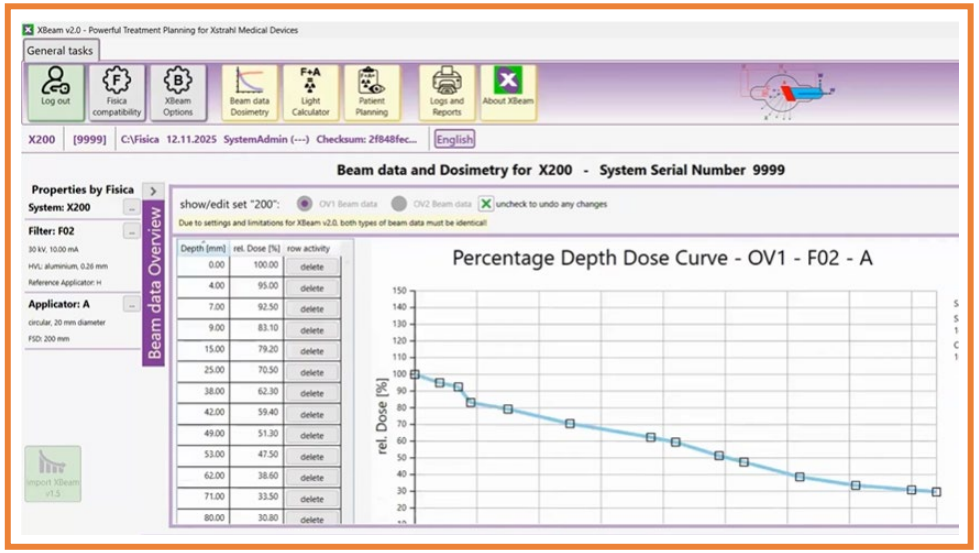
An example – Medical device incorporating software

Device that generates X-ray beams used in the treatment of various types of cancers. There are multiple models of device including floor and ceiling mounted models with Xbeam Software incorporated to support treatment.









AusUDID

Brand name	Model or version	Manufacturer	ARTG	Primary DI	Published
Xstrahl	Xstrahl 150 X-ray System - Floor	Xstrahl Ltd	**Oxford Scientific Pty Ltd** 313981	05060494200022	20 January 2026
Xstrahl	Xstrahl 200 X-ray system - Floor	Xstrahl Ltd	**Oxford Scientific Pty Ltd** 313981	05060494200046	20 January 2026
Xstrahl	Xstrahl 300 X-ray System - Ceiling	Xstrahl Ltd	**Oxford Scientific Pty Ltd** 313981	05060494200077	20 January 2026
Xstrahl XBeam Software	v1.5.5	Xstrahl Ltd	**Oxford Scientific Pty Ltd** 313981	05060494200169	22 January 2026
Xstrahl	Xstrahl 100 X-ray System	Xstrahl Ltd	**Oxford Scientific Pty Ltd** 313981	05060494200015	20 January 2026
Xstrahl	Xstrahl 150 X-ray System - Ceiling	Xstrahl Ltd	**Oxford Scientific Pty Ltd** 313981	05060494200039	20 January 2026
Xstrahl	Xstrahl 200 X-ray System - Ceiling	Xstrahl Ltd	**Oxford Scientific Pty Ltd** 313981	05060494200053	20 January 2026
Xstrahl	Xstrahl 300 X-ray System - Floor	Xstrahl Ltd	**Oxford Scientific Pty Ltd** 313981	05060494200060	20 January 2026

Find more information on the UDI Hub or contact the UDI Support Team

TGA UDI Hub

UDI Support Team: UDI@health.gov.au

ausudid.tga.gov.au

You can access the AusUDID here: TGA AusUDID.