Information for NSW Health staff
TGA Medical Device Reforms
Unique Device Identification

The Therapeutic Goods Administration (TGA) has introduced the Medical Device Reforms to strengthen Australia's regulatory system for medical devices, ensure greater transparency of its systems and procedures, with a focus on patient safety.

This factsheet explains the Unique Device Identification (UDI) system, its components and implications for the Australian healthcare system under the TGA reforms. It will be updated as new information is provided by the TGA (see date of the factsheet at footer).

What is a UDI?

All medical devices registered for use in Australia will require a UDI – a unique combination of numbers, letters and symbols that contains information about the particular medical device associated with it. The UDI is applied to medical devices based on a globally accepted coding standard.

It consists of information to identify both the type of medical device and production information for that device and will permit identification of specific devices across both the supply chain and patient journey.

More specifically, the UDI-Device Identifier (UDI-DI) indicates the model of the medical device and the UDI-Production Identifier (UDI-PI) indicates the production-specific information (such as lot/batch number, expiry date and manufacturer). See samples provided in the pages that follow in this factsheet.

The UDI takes the form of a barcode (including QR code) and must also be supplied in human, readable format. Some examples are provided below.

Purpose: what is track and trace?

The UDI system is an Australian first. Within the NSW Health system, the UDI is being implemented into the supply chain system, procurement functions and medical record systems to allow improved tracking and tracing of medical devices. That is, if a medical device safety issue arises, the UDI can provide prompt identification of devices of concern, and help notify healthcare facilities, healthcare professionals and patients.

The TGA intends for the UDI to be the key identifier used in administrative and clinical transactions, such as in discharge summaries, patient records, registries, clinical notes and records, purchase orders, reimbursement or claims documentation, invoices and inventory maintenance/management.

What is the timeframe for implementation of the UDI system?

The system is being implemented in a staged manner. Currently, there is an indicative timeline for industry compliance. This means that industry must apply for a UDI for any new medical device being introduced, with retrospective application to existing medical devices occurring over the next 12 to 24 months. Additionally, the TGA has commenced work on UDI compliance dates and the UDI regulatory framework.

What is AusUDID?

The TGA is developing a database of the UDIs known as the Australian Unique Device Identifier Database (AusUDID). The AusUDID is a live, searchable database that will enable timely access to complete, accurate and consistent information provided by device manufacturers about their medical devices in use in Australia and includes the ability to access Patient Information Leaflets (PILs).

Approved UDI-issuing agencies

UDIs are issued by "issuing agencies", which are bodies recognised by the TGA. The issuing agencies ensure that every UDI is globally unique, and each complies with applicable international standards. These are three issuing agencies recognised in Australia:

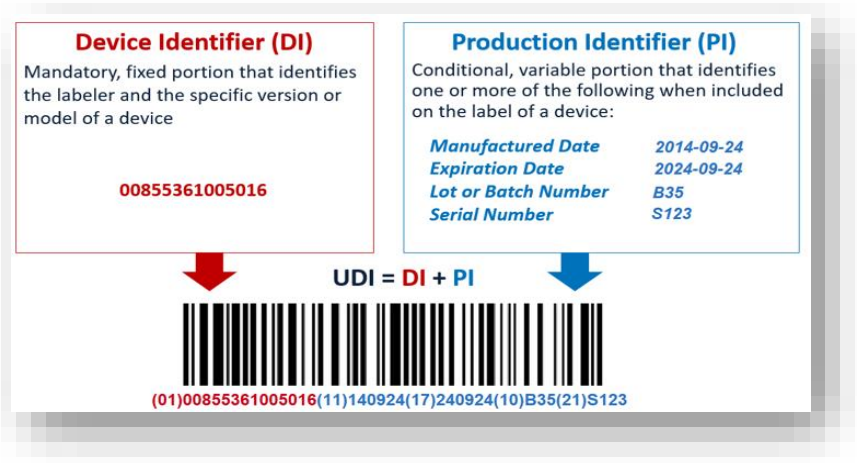
a. GS1
b. Health Industry Business Communications Council (HIBCC)
c. International Council for Commonality in Blood Banking Automation (ICCBBA).

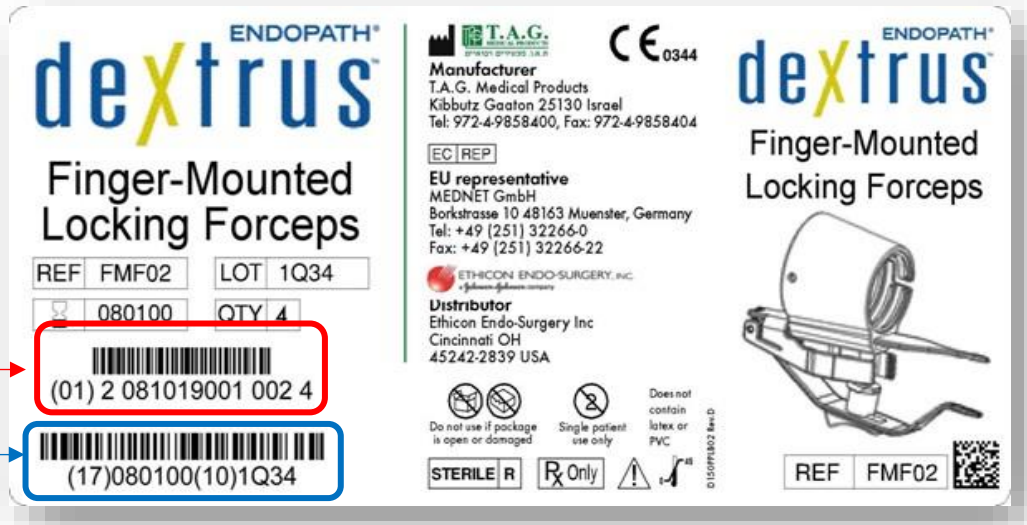
Will all medical devices have a UDI-DI and UDI-PI?

Every medical device will have a UDI-DI labelled on all applicable packaging, but some devices may either not have a UDI-PI or it will contain only certain components, such as the expiration date but not a batch number. Generally, low-risk medical devices, and point-of-care manufactured medical devices will not require a UDI.

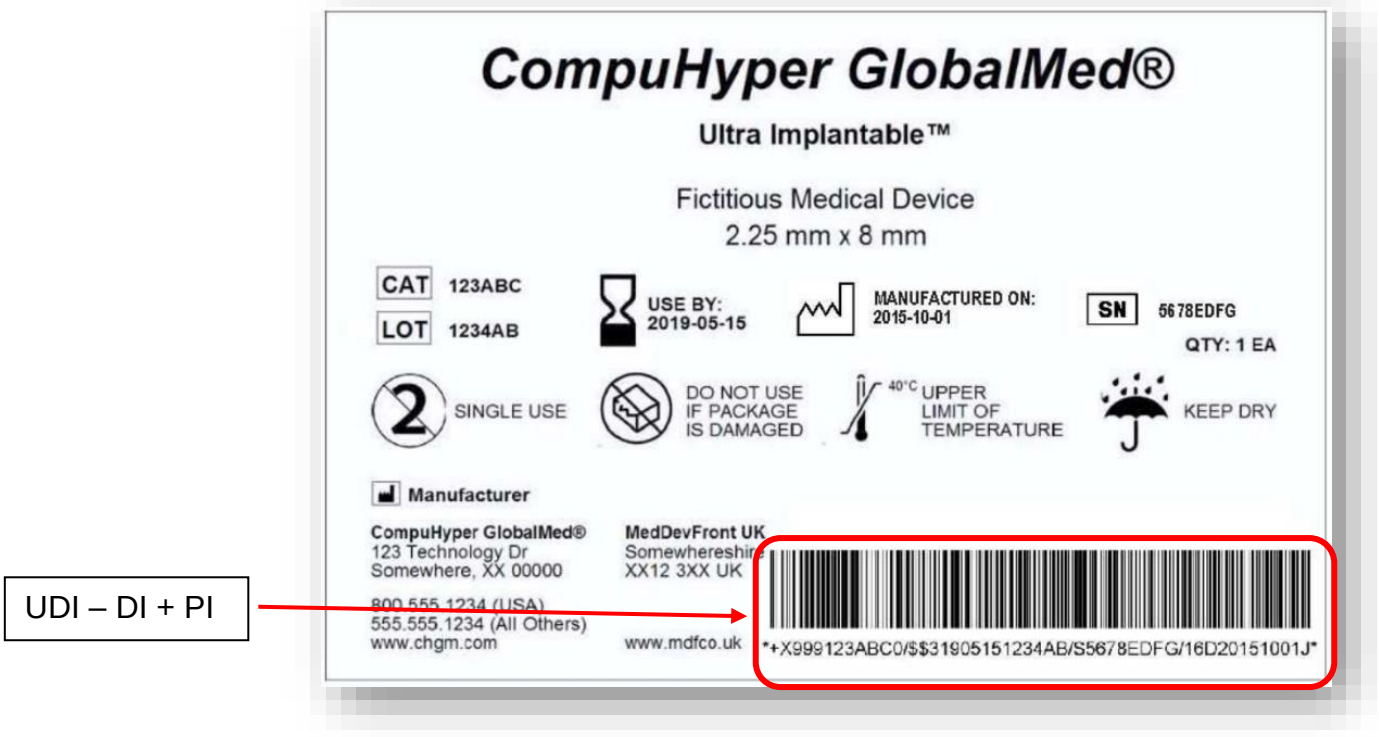
Below are samples of UDIs provided by the issuing agencies mentioned above (images sourced from the TGA).

a. GS1




UDI - DI
UDI - PI
ENDOPATH
dextrus
Finger-Mounted Locking Forceps
REF FMF02
LOT 1Q34
080100
QTY 4
(01) 2 081019001 002 4
(17)080100(10)1Q34
T.A.G.
CE 0344
Manufacturer
T.A.G. Medical Products
Kibbutz Gaaton 25130 Israel
Tel: 972-4-9858400, Fax: 972-4-9858404
EC REP
EU representative
MEDNET GmbH
Borkstrasse 10 48163 Muenster, Germany
Tel: +49 (251) 32266-0
Fax: +49 (251) 32266-22
ETHICON ENDO-SURGERY, INC.
Distributor
Ethicon Endo-Surgery Inc
Cincinnati OH
45242-2839 USA
Do not use if package is open or damaged
Single patient use only
Does not contain latex or PVC
STERILE R
Rx Only
ENDOPATH
dextrus
Finger-Mounted Locking Forceps
REF FMF02

b. HIBCC


UDI – DI + PI
CompuHyper GlobalMed®
Ultra Implantable™
Fictitious Medical Device
2.25 mm x 8 mm
CAT 123ABC
LOT 1234AB
USE BY: 2019-05-15
MANUFACTURED ON: 2015-10-01
SN 5678EDFG
QTY: 1 EA
2 SINGLE USE
DO NOT USE IF PACKAGE IS DAMAGED
40°C UPPER LIMIT OF TEMPERATURE
KEEP DRY
Manufacturer
CompuHyper GlobalMed®
123 Technology Dr
Somewhere, XX 00000
800.555.1234 (USA)
555.555.1234 (All Others)
www.chgm.com
MedDevFront UK
Somewhereshire
XX12 3XX UK
www.mdfco.uk
+X999123ABC0/$$31905151234AB/S5678EDFG/16D20151001J

c. ICCBBA

Which devices will need a UDI?

The tables below outline the device classifications and the corresponding UDI requirements (tables sourced from the TGA).

For medical devices:

Class	Risk	Examples	UDI Required
Class I	Low	Face shield, tongue depressor, non-sterile gauze, incontinence pants, otoscope	No
Class Im (measurable)	Low-medium	Oral syringe, surgical drill guide, ECG recording paper	No
Class Is (sterile)	Low-medium	Surgical gown, sterile glove, medical drape equipment, basic IV set	Yes
Class IIa	Low-medium	Digital or infrared thermometer, surgical glove, automated blood pressure cuff, suction tip	Yes
Class IIb	Medium-high	Hypodermic needle, surgical laser, lung ventilator, external defibrillator	Yes
Class III	High	Aortic heart valve, major joint replacement prostheses, catheter guide wire, hernia mesh, absorbable sutures	Yes

For in vitro diagnostic (IVD) devices:

Class	Risk	Examples	UDI Required
Class 1	No public health risk or low personal risk	Microbiological culture media Cleaning solutions Glucose meter	Partial (See below)
Class 2	Low public health risk or moderate personal risk	Pregnancy and fertility self-testing kits Tests to detect rotavirus or adenovirus infections Cholesterol test	Yes
Class 3	Moderate public health risk or high personal risk	Sexually transmitted disease test, e.g. herpes, chlamydia, HPV Human genetic test, e.g. Cytomegalovirus, Cystic Fibrosis Cancer diagnostic test Rapid antigen test for SARS-COV-2 virus	Yes
Class 4	High public health risk	Blood screening tests for HIV, syphilis Test for Ebola	Yes

The following Class 1 IVD categories must adhere to the UDI regulations:

- instrument/analyser IVDs (Global Medical Device Nomenclature (GMDN) Collective Term 943)
- Software IVDs (GMDN Collective Term 944).

Are there any differences between a Global Trade Item Number (GTIN) and a UDI?

Yes. A GTIN is used by a company for unique identification of its trade items. The UDI, on the other hand, is intended to be used in business and clinical transactions throughout the wider healthcare system.

What does the UDI mean for healthcare?

As outlined above, the main purpose of the UDI system is to improve the tracking and tracing of medical devices across their lifecycle. The TGA is also making it a mandatory requirement for the UDI to be included in adverse event reporting.

The TGA is working with the Australian Commission for Safety and Quality in Health Care (ACSQHC) to implement accreditation standards and/or guidelines for UDI in the National Safety and Quality Health Service (NSQHS).

Healthcare organisations across Australia are encouraged to start preparing for UDI adoption early. For example, ensuring that the UDI is:

- provided with all adverse event reports (including near misses), which comes into effect from 1 March 2025
- appropriately recorded in the patient's medical records
- included in discharge summaries and My Health Record (MHR)
- documented on Patient Implant Cards (PICs).

This factsheet will be updated as new information is provided by the TGA (see date at footer).

More information is available from the TGA's UDI hub at https://www.tga.gov.au/how-we-regulate/manufacturing/manufacture-medical-device/unique-device-identification-udi-hub

The **Clinical Excellence Commission** is supporting NSW Health staff through the reforms. Visit its dedicated page at www.cec.health.nsw.gov.au/keep-patients-safe/medical-device-governance-program. Email enquiries to cec-medicaldevicegovernance@health.nsw.gov.au