

Do you meet requirements for UDI?

Unique Device Identification for medical devices



The requirement to be able to uniquely identify products used within healthcare in order to support patient safety has been a strategic imperative for many countries around the world. Following recommendations from the International Medical Device Regulators Forum (IMDRF) an increasing number of regulations mandating Unique Device Identification (UDI) have emerged requiring use of global standards to identify medical devices.

UDI is expected to improve patient safety and healthcare business processes, and although Australia does not have any specific legislation in the area currently the same UDI standards can be utilised within our market to support improved healthcare.

GS1 standards for UDI



The GS1 system of standards supports all stakeholders to efficiently and effectively meet UDI requirements by enabling interoperability and compatibility within an organisation, between organisations and across borders.

GS1 has over 110 GS1 Member Organisations and more than 2,700 employees worldwide providing support to users on how to implement UDI in their local language and understanding the local requirements for implementation.

A single standard can ultimately accelerate implementation and increase compliance to the UDI regulations.

Unique Device Identification in GS1 terms

UDI regulatory requirements EU MDR and EU IVDR	GS1 standards Product Identification
Basic UDI-DI Device Identifier (DI)	GMN (Global Model Number) No Application Identifier (AI) for regulated medical devices
UDI-DI Device Identifier (DI)	GTIN Global Trade Item Number
UDI-PI Production Identifier (PI) <i>(if applicable)</i>	AI Application Identifier (AI) <ul style="list-style-type: none"> • Expiration date AI(17) - e.g. 141120 • Batch - lot AI(10) - e.g. 1234AB • Serial number AI(21) - e.g. 12345XYZ
<i>Production Identifier data will vary by medical device type and manufacturer current practice.</i>	
UDI-DI + UDI-PI = UDI	GTIN or GTIN + AI(s) = UDI

A few examples of Data Carriers across the supply chain

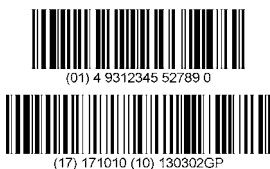
The Warehouse



GS1-128
'Concatenated' data



GS1-128
'Non-Concatenated' data



ITF-14



Data may be carried in a single 'concatenated' GS1-128 (best practice) or in two GS1-128s (allowed alternate).

The Hospital



GS1-128
'Concatenated' data



GS1-128
'Non-Concatenated' data



GS1 Data Matrix



(01) 0 9312345 52789 2
(10) 130302GP
(17) 171010

GS1 Data Matrix is particularly suited to small spaces on Single Unit or Multiple Unit Packages and Direct Part Marking (DPM) on Single Units.

Why GTINs change?

Some common reasons for a GTIN (DI) to change are listed below. Refer to the appropriate UDI regulation and the GS1 Healthcare GTIN Allocation Rules for complete details on regional influence for GTIN change:

- Change in quantity of a device package
- Change to package sterility
- Re-labelling of the original labeller's (manufacturer) device
- Change labelling languages for different global markets
- Change in certification mark, e.g., CE Mark

If you need to adhere to requirements for a specific regulation please refer to the appropriate regulation and the GS1 Healthcare GTIN Allocation Rules for complete details on regional influence for GTIN change.

Reference tools

- [GS1 General Specifications \(current version\)](#)
- [GS1 Healthcare GTIN Allocation Rules](#)
- [GS1 Healthcare AIDC Implementation Guidelines](#)

These tools can be found at www.gs1au.org/healthcare

For any questions regarding the use of GTINs, contact your GS1 Australia Healthcare team: healthcareteam@gs1au.org



The Point-of-Care



GS1-128
'Concatenated' data



(01) 1 9312345 52789 9 (17) 171010 (10) 130302GP

GS1 DataMatrix



(01) 0 9312345 52789 2
(10) 130302GP
(17) 171010
(21) 30072009CM

The Retail POS



EAN-13 and UPC do not encode 'Attribute Data' (Application Identifiers)

Where additional traceability is needed a GS1 DataMatrix may also be added to the product for this purpose

EAN 13



9 3 12345 527892

UPC-A



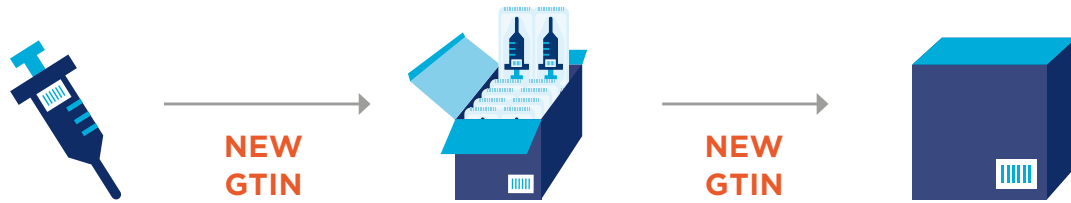
0 12345 67890 5

Whilst EAN-13 is most commonly used in Australian retail, UPC are used on some products where they originate from North America. Both contain Global Trade Item Numbers (GTIN).

Common industry practices

Packaging Levels - The GTIN (DI) & AIs (PIs) should be in barcode & in readable form on each applicable package level as defined by regulation. Each designated package level must have its own GTIN (DI).

Placement - Barcode symbols are to be positioned to allow ready access for scanning when the product is stored or stocked on shelves.



Single Unit Package	Multiple Unit Package	Case
GTIN A	GTIN B	GTIN C
09312345527892	19312345527899	49312345527890



Benefits

The implementation of UDI can enhance patient safety and improve efficiency in the healthcare supply chain. The system is expected to unambiguously identify medical devices throughout the global supply chain by providing precise information for healthcare professionals, thereby providing a secure global supply chain allowing for more accurate reports of adverse events, more effective management of medical device recalls and reduction of medical errors.

Interested in learning more about UDI?

<https://www.gs1au.org/for-your-industry/healthcare/>

For more information contact the GS1 Australia Healthcare Team:

healthcareteam@gs1au.org

About GS1 Healthcare

GS1 Healthcare is a global, voluntary user community bringing together all healthcare supply chain stakeholders, including manufacturers, distributors, healthcare providers, solution providers, regulatory bodies and industry associations. The mission of GS1 Healthcare is to lead the healthcare sector to the successful development and implementation of global standards by bringing together experts in healthcare to enhance patient safety and supply chain efficiencies.

GS1 Australia

Head Office, 8 Nexus Court, Mulgrave VIC 3170
 Locked Bag 2, Mt Waverley VIC 3149
T 1300 227 263 | **F** +61 3 9558 9551 | **ABN** 67 005 529 920
www.gs1au.org

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