Are you ready for UDI?

Unique Device Identification for medical devices

Introduction

The United States Food and Drug Administration (FDA), the European Commission and other regulators have made patient safety a strategic priority by developing legislation for Unique Device Identification (UDI).

UDI is expected to improve patient safety and Healthcare business processes. A single, global system of standards is fundamental to enable an efficient and effective implementation of UDI by all Healthcare stakeholders worldwide.

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

GS1 has over 110 GS1 Member Organisations and more than 2,000 employees worldwide providing support to users on how to implement UDI in their local language and understanding the local requirements for implementation.

Unique Device Identification in GS1 terms

UDI Unique Device Identification	GS1 Standards Product Identification
DI Device Identifier (DI)	GTIN Global Trade Item Number
PI Production Identifier (PI) (if applicable)	AI Application Identifier (AI) • Expiration Date AI(17) - e.g. 141120 • Lot/Batch AI(10) - e.g. 1234AB • Serial Number AI(21) - e.g. 12345XYZ
Production Identifier data will vary by medical device type and manufacturer current practice.	
DI + PI = UDI	**GTIN or GTIN + AI(s) = UDI**

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

Reference tools

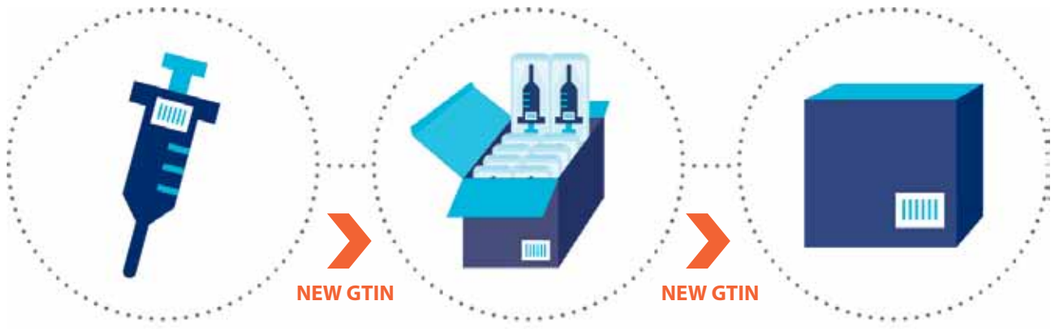
- GS1 General Specifications (current version)
- GS1 Healthcare GTIN Allocation Rules
- GS1 US Healthcare Provider & Supplier GTIN Tool Kits

For any question regarding the use of GTINs contact your local GS1 Member Organisation: http://www.gs1.org/contact

Common industry practices

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

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



NOTE: GTINs below for illustration only

Single Unit Package	Multiple Unit Package	Case
GTIN A	GTIN B	GTIN C
00857674002010	10857674002017	40857674002018

A few examples of Data Carriers across the supply chain

The Warehouse

GS1-128 "Concatenated" data

(01)10857674002017(17)141120(10)1234AB

GS1-128 "Non-Concatenated" data

(17)141120(10)1234AB

(01)10857674002017

ITF-14

18931234567894

The Hospital

GS1-128 "Concatenated" data

(01)10857674002017(17)141120(10)1234AB

GS1-128 "Non-Concatenated" data

(01)10857674002017

(17)141120(10)1234AB

GS1 DataMatrix

(01)10857674002017
(17)141120
(10)1234AB

The Point-of-Care

GS1-128 "Concatenated" data

(01)10857674002017(17)141120(10)1234AB

GS1 DataMatrix

(01)10857674002017
(17)141120
(10)1234AB

The Retail POS

EAN 13

4 512345 678906

UPC-A

0 12345 67890 5

ITF-14

18931234567894

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

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

U.P.C. is used primarily in North America. EAN-13 is used throughout the world on Secondary (retail) packaging.

U.P.C., EAN-13 and ITF-14 do not encode "Attribute Data" (Application Identifiers).

ITF-14 usually seen at POS by "warehouse" retailers and commonly in the warehouse on cases.

All data carriers are for illustration only, not to scale and not in proportional size to one another. Please refer to GS1 General Specifications for detailed & up-to-date GS1 System information. UDI requirements may vary by geography -please refer to regional UDI regulations.

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 allowing for more accurate reports of adverse events, more effective management of medical device recalls and reduction of medical errors by providing precise information for healthcare professionals, thereby providing a secure global supply chain.

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 Healthcare members include over 60 leading Healthcare organisations worldwide.

Contact information:

Interested in learning more about UDI?
www.gs1.org/healthcare/udi

Or contact your local GS1 Member Organisation:
www.gs1.org/contact

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