GS1 US — THE GLOBAL LANGUAGE OF BUSINESS

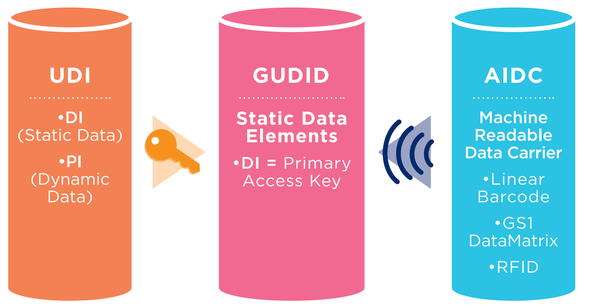
U.S. FDA UNIQUE DEVICE IDENTIFICATION (UDI)

Quick Reference Guide to GS1 Identifiers & Barcodes

LEARNING THE TERMS

FDA UDI	GS1 STANDARDS
FDA UDI Unique Device Identification	**GS1 Standards** Product Identification
Labeler One who applies or modifies the label with intent to put device into commercial distribution	**Brand Owner**
DI FDA Device Identifier (DI)	**GTIN** GS1 Global Trade Item Number® (GTIN®)
Dynamic Data (PI) FDA Production Identifier (PI) *(if applicable)*	**Dynamic Data (AI)** GS1 Application Identifier (AI) • Batch/Lot Number: AI(10) • Production Date: AI(11) • Expiration Date: AI(17) • Serial Number: AI(21)
DI + PI = FDA UDI	**GS1 GTIN** or **GTIN + AI = UDI**

LEARNING THE TERMS



Unique Device Identification

Global Unique Device Identification Database

Automatic Identification and Data Capture

EXAMPLES OF DI WITH PI IN GS1 STANDARD FORMAT*

GTIN with Expiration Date, Lot & Serial encoded in a GS1-128 Barcode

GTIN with Lot Number & Expiration Date encoded in a GS1-128 Barcode

GTIN with Lot Number encoded in a GS1-128 Barcode

GTIN Lot/Batch

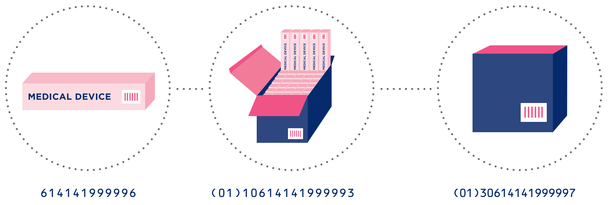
GTIN with Serial, Lot & Expiration Date encoded in a GS1 DataBar® (Stacked) & Composite

GTIN with Expiration Date and Serial Number encoded in a GS1 DataMatrix

*Individual manufacturers select the data encoded based on their control procedures

MEDICAL PACKAGING LEVELS

There should be a Unique Device Identification at every level of packaging except at the logistic unit level.



ITEM ▸ NEW GTIN ▸ INNER PACK ▸ NEW GTIN ▸ CASE

MEDICAL PACKAGING LEVELS

When possible, barcodes are to be displayed on the product packages to allow ready access to scanning equipment when the product is stored or stocked on shelves.

- **Orientation:** The barcode is to be displayed on the package so the human readable portion is oriented to read from the same direction as other labeling information.
- **Display Panel:** Barcodes are to be displayed on the panel or label most likely to be facing out on the shelf when the package is stored.

WHY DO GTINS CHANGE?

The most common reasons for a GTIN to change are:

- Change in the specifications, performance, size, or composition of the device to an extent greater than the specified limits ***(this includes the package itself)***
- Change in quantity of a device package or addition of a new device package
- Change from a non-sterile package to a sterile package, or from a sterile package to a non-sterile package
- Re-labeling of the original labeler's device
- Change in labeling languages for different global markets
- Change in certification mark, e.g., CE Mark
- Change to outside package dimensions

NOTES & TOOLS

Notes

- Symbols are not to scale and are for illustration purposes only
- U.P.C., EAN-13, and ITF-14 cannot encode Application Identifiers
- U.S. FDA published a regulation requiring all medical devices sold in the U.S. to be identified and marked, and product information to be stored in the FDA database

Reference Tools

- Implementation Guideline for FDA UDI
- *GS1 General Specifications*
- FDA UDI FAQs
- GS1 Healthcare GTIN Allocation Rules
- Healthcare Provider & Supplier GTIN Tool Kits
- www.gs1us.org/hcudi
- www.fda.gov

Disclaimer

This document is intended to demonstrate the use of GS1 Standards for UDI. It does not provide any guidance or advice regarding regulatory compliance. Please consult your internal regulatory staff for compliance questions.

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