**LEARNING THE TERMS**

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**Labeler**
- One who applies or modifies the label with intent to put device into commercial distribution

**DI**
- FDA Device Identifier (DI)
- GTIN (Global Trade Item Number®) GS1 Global Trade Item Number®

**Dynamic Data (PI)**
- FDA Production Identifier (PI) (if applicable)
- Dynamic Data (AI)
  - GTIN 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

**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**

**U.S. FDA UNIQUE DEVICE IDENTIFICATION (UDI)**

**Quick Reference Guide to GS1 Identifiers & Barcodes**

**GUDID**
- Static Data
  - DI = Primary Access Key
  - PI (Dynamic Data)

**UDI**
- GTIN (Static Data)
- PI (Dynamic Data)

**GUIDD**
- Global Unique Device Identification Database

**AIDC**
- Automatic Identification and Data Capture
- Machine Readable Data Carrier
  - Linear Barcode
  - GS1 DataMatrix
  - RFID

**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

**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 |

**NOTES & TOOLS**

- 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.
- 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.

**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.**

**NOTES & TOOLS**

- Symbols are not to scale and are for illustration purposes only.
- UPN, EAN-13, and ITF-14 cannot encode Application Identifiers

**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/hsudi
- 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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GS1 is an FDA UDI Issuing Agency.

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