GS1 US

The Global Language of Business

Standards Guidance for Assigning DIs Using Global Trade Item Numbers (GTINs)

Based on the GS1 US Using the GS1 System for U.S. FDA UDI Requirements Implementation Guideline

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About GS1

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GS1 US®, a member of GS1 global, is a not-for-profit information standards organization that facilitates industry collaboration to help improve supply chain visibility and efficiency through the use of GS1 Standards, the most widely-used supply chain standards system in the world. Nearly 300,000 businesses in 25 industries rely on GS1 US for trading partner collaboration that optimizes their supply chains, drives cost performance and revenue growth while also enabling regulatory compliance. They achieve these benefits through solutions based on GS1 global unique numbering and identification systems, barcodes, Electronic Product Code-based RFID, data synchronization, and electronic information exchange. GS1 US also manages the United Nations Standard Products and Services Code® (UNSPSC®).

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About GS1 Healthcare US

GS1 Healthcare US® is an industry group that focuses on driving the adoption and implementation of GS1 Standards in the healthcare industry in the United States to improve patient safety and supply chain efficiency. GS1 Healthcare US brings together members from all segments of the healthcare industry to address the supply chain issues that most impact healthcare in the United States. Facilitated by GS1 US, GS1 Healthcare US is one of over 30 local GS1 Healthcare user groups around the world that supports the adoption and implementation of global standards developed by GS1.

1   Document Information

This supplement to the GS1 US *Using the GS1 System for U.S. FDA UDI Requirements UDI Implementation Guideline* was prepared by GS1 Healthcare US to assist suppliers and receivers of medical devices in the United States, with the implementation of the U.S. FDA UDI Rule[1] using the GS1 System of Standards. This supplement and the Guideline are based on the *GS1 General Specifications* and were developed using information obtained from all members of the U.S. healthcare supply chain, from manufacturers to providers.

1.1   Purpose

The purpose of this supplement is to provide instruction on 1.) how to create a Device Identifier (DI) and 2.) how to share DI information with trading partners (for database storage) or U.S. FDA Global Unique Device Identification Database (GUDID).

This supplement also provides a foundation for the appropriate structure of GS1 identification and barcode standards on medical devices within the context of the U.S. FDA UDI Rule. This supplement, or the Guideline which it supports, does not provide any guidance or advice regarding regulatory compliance.

1.2   Audience

This supplement was written primarily for medical device manufacturers/suppliers, but it is relevant to the entire healthcare supply chain from the label printer to the healthcare provider.

1.3   Scope

This supplement identifies the GS1 identification and barcode standards that correlate to the Device Identifier (DI) portion of U.S. FDA UDI Rule requirements. It seeks to explain how to determine which Global Trade Item Number® (GTIN®) structure is appropriate based on relevant variables of the device, the scanning environment and the data segment requirements. Specifically, this document covers the following four topics:

1. GLOBAL TRADE ITEM NUMBER® (GTIN®)
2. HOW TO DETERMINE WHICH GTIN STRUCTURE TO USE FOR YOUR DEVICE
3. ASSIGNING DIs USING GS1 GTINs
4. SHARING AND STORING GTINs

This supplement provides sufficient information and technical detail to assign GTINs for the purposes of the U.S. FDA UDI Rule. The *GS1 General Specifications* should be consulted for additional information.

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1 For information about the rule, see the *U.S. FDA Unique Device Identification System*

1.4   Normative References

This supplement to the application guideline is based on the *GS1 General Specifications*. The specific standards referenced in this guideline are listed below, and the relevant provisions of these standards/specifications are to be considered provisions of this supplement:

- GS1 General Specifications – Are available via the GS1 US website at *www.gs1us.org/documents?Command=Core_Download&EntryId=171*

- GS1 Healthcare GTIN Allocation Rules – Are available via the GS1 global website at *www.gs1.org/1/gtinrules/en/healthcare*

1.5   Additional Resources

This document is a companion to the following GS1 Healthcare US documents:

- Using the GS1 System for U.S. FDA UDI Requirements UDI Implementation Guideline

- Healthcare Provider GTIN Toolkit

- Healthcare Supplier GTIN Toolkit

- Healthcare Provider Global Data Synchronization Network™ (GDSN®) Toolkit

- Healthcare Supplier GDSN Toolkit

- Healthcare Supplier U.S. FDA UDI Quick Start Guide

- Transitioning to GS1 Standards in the U.S. for UDI

- Guidance for Implementing GLNs and GTINs in Order-to-Cash Transactions

Use of these documents will increase understanding of all healthcare supply chain partners and facilitate a meaningful dialogue concerning implementation and benefits. All of these documents can be found on the GS1 US website: *www.gs1us.org*

2   U.S. FDA Unique Device Identifier (UDI)

A U.S. FDA UDI is a unique numeric or alphanumeric code that consists of two parts[2]:

- **A device identifier (DI),** a mandatory, fixed portion of a UDI that identifies the labeler and the specific version or model of a device, and

- **A production identifier (PI)**, a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of a device:

   - The lot or batch number within which a device was manufactured.
   - The serial number of a specific device.
   - The expiration date of a specific device.
   - The date a specific device was manufactured.
   - The distinct identification code required by §1271.290(c) for a human cell, tissue, or cellular and tissue-based product (HCT/P) regulated as a device.

[2] *www.fda.gov/medicaldevices/deviceregulationandguidance/uniquedeviceidentification/udibasics/default.htm*

3   Global Trade Item Number

3.1   Definition

The Global Trade Item Number® (GTIN®) is the globally unique GS1 Identification Key used to identify "trade items" (i.e., products and services that may be priced, ordered or invoiced at any point in the supply chain). GTINs are assigned by the brand owner of the product and are used to identify products as they move through the global supply chain to the hospital or ultimately the patient.

The GTIN uniquely identifies a product at each packaging level (e.g., a box of 15 Brand X tissues; a carton of six boxes of Brand X tissues; etc.). GTINs can be encoded into barcodes and used in supply chain transactions (e.g., purchase order; invoice; etc.) to promote accurate product identification.

> **Important**: As a U.S. FDA-accredited issuing agency, GS1 has been recognized as an organization that operates a system of standards for assignment of UDIs according to the U.S. FDA UDI Rule. In the GS1 System of Standards, the GTIN serves as the Device Identifier (DI) portion of the U.S. FDA UDI Rule.

3.2   Family of Data Structures

There are four GTIN structures – known as GTIN-8, GTIN-12, GTIN-13 and GTIN-14 (enabling GTINs to be assigned as 8 digits, 12 digits, 13 digits, or 14 digits in length, respectively). These different structures have different or varying segments, and the standards related to each structure needs to be followed to assure the integrity of your application of the standards. Within the U.S. medical/surgical supply chain, the GTIN-12 and GTIN-14 are predominantly used to identify medical devices. *Refer to section 5 of this guide for more on GTIN structures.*

Note: The GTIN-8 is the only GTIN that can be used in EAN-8 barcodes and the use of GTIN-8 is outside of the United States.

GTIN Sunrise 2005 – As of January 1, 2005, all North American retailers and trading partners that scan Universal Product Codes (U.P.C.) should have expanded the data capacity associated with the U.P.C. to a 13-digit field length to process EAN-13 symbols. GS1 US further recommends that this field be 14-digit capable.

3.3 Need to know

Before beginning to assign GTINs to your product hierarchy, it is important to know if you are creating a GTIN-12, GTIN-13 or GTIN-14 for that item. Class I medical devices in the United States often use GTIN-12s so that they can cross a retail point of sale with a UPC-A barcode. When sharing this 12-digit number, it can be shown/used in a 14-digit format by right justifying and placing two fill zeroes at the beginning of the number string (see below image GTIN-12 in 14-digit format).

Important: In accordance with the U.S. FDA UDI Rule, for Class I medical devices exempt from Good Manufacturing Practice (GMP) and marked with a GTIN-12 in a UPC-A barcode, the GTIN-12 and UPC-A barcode meet the DI requirements for these Class I products (reference footnotes 3 and 4 below).

Reference the following:

- **From Search of the Federal Register for Sept. 24, 2013[3]:**

  21 CFR 801.40(d) states that a Class I device that bears a U.P.C. on its label and device packages is deemed to meet all UDI labeling requirements and that the U.P.C. will serve as the UDI required by §801.20.

  This excepts a Class I device with a U.P.C. on its label and packages from UDI labeling requirements regardless of to whom or through what channels it is sold. Such a device will be subject to GUDID reporting requirements. We note that the lowest risk devices available for sale at retail establishments will in any case be excepted from UDI requirements by virtue of §801.30(a)(2).

- **From 21 CFR 801.30(a)(2): General exceptions from the requirement for the label of a device to bear a unique device identifier[4]**

  "A Class I device that FDA has by regulation exempted from the good manufacturing practice requirements of part 820 of this chapter, exclusive of any continuing requirement for record-keeping under §§ 820.180 and 820.198".

Class II and Class III medical devices generally use GTIN-14 so that production information (PI) can be included in the barcode as required by the U.S. FDA UDI Rule.

Packaging hierarchies can be made up of either a GTIN-12 in a 14-digit structure, GTIN-13 in a 14-digit structure, or a GTIN-14 for products that include point of sale packaging.

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3 www.federalregister.gov/documents/2013/09/24/2013-23059/unique-device-identification-system

4 www.gpo.gov/fdsys/pkg/CFR-2014-title21-vol8/pdf/CFR-2014-title21-vol8-sec801-30.pdf

4 Determining Which GTIN Structure to Use for Your Device

A user determines the GTIN structure to use for creating a product DI primarily based on the following:

- UDI segments to be encoded

- Barcode scanning environment

To help you determine the appropriate GTIN structure, we have provided the below table to aid you in your decision-making process.

Important: To accommodate a variety of environments and applications, the GS1 System of Standards supports seven different barcodes. Certain GS1 barcodes can carry production identifiers (encoded with GS1 Application Identifiers; AIs). There are certain GS1 barcodes that are for retail applications, certain barcodes are for non-retail applications, and some are for both. Some barcodes only utilize a certain GTIN structure (e.g., UPC-A only utilizes a GTIN-12). Therefore, choice of barcode may be impacted by the GTIN structure you will use. *Refer to section 6 of this guide for more on GS1 Barcodes.*

4.1 Answer the following questions for each product

Based on the following considerations, choose which GTIN structure and barcode to use when assigning a DI by considering the following:

1. Determine the U.S. FDA Medical Device Product Classification.

2. Determine the scanning environment(s).

3. Determine if Production Information (PI) is required in the barcode.

4. Determine which GS1 barcode you will use.

Important: Consider the above for each product and package level individually to determine which GTIN structure to use.

When following GS1 Standards, the primary DI, which is the lowest level of a trade item grouping to be marked with a UDI, should be a GTIN-12 or GTIN-13 only.

GS1 US is not offering legal services or advice on the Company's regulatory compliance requirements. Each company is individually responsible for meeting all statutory and/or regulatory requirements for their company and their products. Consult with your company's legal counsel or compliance team for more specific information about statutory and regulatory requirements.

Table 4-1: GS1 Barcode Options Based on Barcode Application Environment and UDI Information to be Encoded

QUESTION 1: *Which U.S. FDA Product Classification is your device?*	QUESTION 2: *Which scanning environment applies?*	QUESTION 3: *Is production information (PI) required in the barcode?*	QUESTION 4: *Which GS1 barcode will you use?*	**Use this GTIN Structure**
Class I (and exempt from GMP)	**Retail -- U.S.**	No	UPC-A	GTIN-12*
	Retail -- Non-U.S.	No	EAN-13	GTIN-13*
	Non-Retail	No	GS1-128 GS1 DataMatrix GS1 DataBar	GTIN-12 (in 14-digit format) GTIN-13 (in 14-digit format) GTIN-14
	Non-Retail	Yes/voluntary	GS1-128 GS1 DataMatrix GS1 DataBar	GTIN-12 (in 14-digit format) GTIN-13 (in 14-digit format) GTIN-14
Class II or Class III	**Retail -- U.S.**	Yes	UPC-A (for retail scanning) + *one of the following:* GS1 DataMatrix GS1 DataBar GS1-128	GTIN-12 + GTIN-12 (in 14-digit format)
	Retail -- Non-U.S.	Yes	EAN-13 (for retail scanning) + *one of the following:* GS1 DataMatrix GS1 DataBar GS1-128	GTIN-13 + GTIN-13 (in 14-digit format)
	Non-Retail	Yes	GS1-128 GS1 DataMatrix GS1 DataBar	GTIN-12 (in 14-digit format) GTIN-13 (in 14-digit format) GTIN-14

⚠️ **Important**: When following GS1 Standards, the primary DI, which is the lowest level of a trade item grouping to be marked with a UDI, should be a GTIN-12 or GTIN-13 only (refer to page 15 of this guide for more information on GTIN-12 or GTIN-13 in a 14-digit format). A GTIN-14 is used for like grouping of the same product (refer to page 14 of this guide for more information on GTIN-14 structure).

* *GTIN Sunrise 2005* – As of January 1, 2005, all North American retailers and trading partners that scan Universal Product Codes (U.P.C.) should have expanded the data capacity associated with the U.P.C. to a 13-digit field length to process EAN-13 symbols.
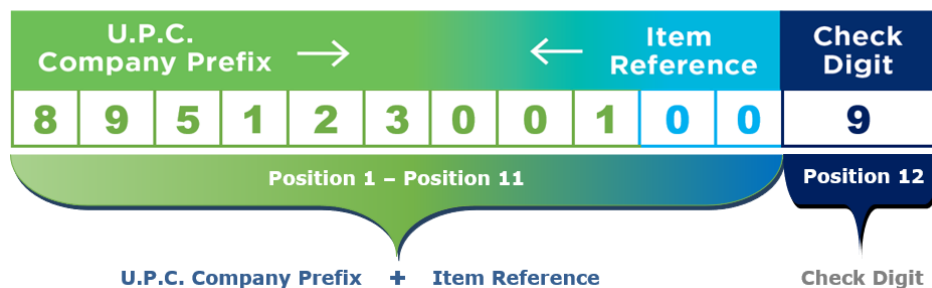
5   Family of GTIN Data Structures

5.1   GTIN-12 Structure

The GTIN-12 is the only GTIN that can be used in UPC-A barcodes. Each GTIN-12 is a numerical string comprising three distinct segments. The three segments within a GTIN-12 are:

1. **U.P.C. Company Prefix:** A globally-unique number assigned to a company/organization by GS1 US to serve as the foundation for generating GS1 identifiers (e.g., GTIN). The U.P.C. Company Prefix is derived from the GS1 Company Prefix and serves as the foundation for generating GTIN-12 identifiers. U.P.C. Company Prefixes vary in length depending on the company/organization's needs.

❗ **Important**: For a GTIN-12 that embeds an NDC/NHRIC, the U.P.C. Company Prefix may be 5 or 6-digits. After having the Labeler Code registered by GS1 US, and having been issued the U.P.C. Company Prefix, the U.P.C. Company Prefixes will be comprised of the NDC/NHRIC Labeler Code with a "3" appended in front.

2. **Item Reference:** A number assigned by the holder of the U.P.C. Company Prefix to uniquely identify a trade item. The Item Reference varies in length as a function of the U.P.C. Company Prefix length. (Refer to the _GS1 General Specifications_ and the _GS1 Healthcare GTIN Allocation Rules_ for additional information.) **Note**: For a GTIN-12 that embeds an NDC/NHRIC, the Item Reference segment is populated with the NDC/NHRIC Product/Package Code.

3. **Check Digit:** A one-digit number calculated from the first 11 digits of the GTIN-12. This digit is used to check that the data has been correctly composed. GS1 US provides a check digit calculator to automatically calculate check digits for you.   The check digit calculator can be found at _www.gs1us.org/resources/tools-and-services/check-digit-calculator_.

❗ **Important**: Although the length of the U.P.C. Company Prefix and the length of the Item Reference vary, **they will always be a combined total of 11 digits** in a GTIN-12. The addition of the Check Digit completes the 12 digits of the GTIN-12.

Another Important Note: Adding zero to the beginning of a GTIN-12 does not make the GTIN-12 a GTIN-13. _Refer to section 5.2 for GTIN-13 structure._

Figure 5.1: Segments of a GTIN-12 (based on the hypothetical GTIN "895123001009")

5.2   GTIN-13 Structure

The GTIN-13 is the only GTIN that can be used in EAN-13 barcodes. Each GTIN-13 is a numerical string comprising three distinct segments. The three segments within a GTIN-13 are:

1. **GS1 Company Prefix:** A globally unique 7-11 digit number assigned to a company by GS1 US or other GS1 Member Organization to serve as the foundation for generating GS1 identifiers (e.g., GTINs). GS1 Company Prefixes are assigned in varying lengths depending on the company's needs. To build a GTIN-13, your GS1 Company Prefix must start with digit '1' through digit '9'.

2. **Item Reference:** A 1-5 digit number assigned by the holder of the GS1 Company Prefix to uniquely identify a trade item. The Item Reference varies in length as a function of the GS1 Company Prefix length. (Refer to the *GS1 General Specifications* and the *GS1 Healthcare GTIN Allocation Rules* for additional information.)

3. **Check Digit:** A one-digit number calculated from the first 12 digits of the GTIN-13. This digit is used to check that the data has been correctly composed.   GS1 US provides a check digit calculator to automatically calculate check digits for you.   The check digit calculator can be found at *www.gs1us.org/resources/tools-and-services/check-digit-calculator*.

🛑 **Important**: Although the length of the GS1 Company Prefix and the length of the Item Reference vary, they will always be a combined total of 12 digits in a GTIN-13. The addition of the Check Digit completes the 13 digits of the GTIN-13.

Another Important Note: Since GTIN-13 must start 1-8, adding zero to the beginning of a GTIN-12 does not make the GTIN-12 a GTIN-13 and, removing digits from a GTIN-13 does not make it a GTIN-12. *Refer to section 5.1 for GTIN-12 structure.*

**Figure 5-2:** Segments of a GTIN-13 (based on the hypothetical GTIN "1200000123450")

5.3   GTIN-14 Structure

A uniform grouping of trade items is a standard and stable grouping of identical trade items. For example, a single trade item packaged in a box of 5 and 10 boxes to a case would require a unique GTIN/DI for the each, the box, and the case. The manufacturer or supplier has the option of either assigning a unique GTIN-12 or GTIN-13 to each grouping or assigning a unique GTIN-14 with an indicator digit to the box or case in this example. These 14-digit GTINs incorporate the GTIN of the contained trade item (less its check digit) in each grouping. The check digit for each GTIN-14 is then recalculated. The four segments in a GTIN-14 are:

1. **Indicator Digit:** The indicator digit identifies packaging level. The indicator is a digit with a value of 1 to 8. It is assigned as required by the company that constructs the identification number. It can provide up to eight separate GTIN-14 identification numbers to identify groupings of trade items. The value 9 is reserved for variable measure items. These are rare in healthcare, but an example could be gases used in operations. The amount of gas used for any given operation is variable but can be priced or ordered or invoiced in predefined quantities (e.g., cubic meters) when delivered to a hospital.

2. **GS1 Company Prefix:** A globally unique 7-11 digit number assigned to a company by GS1 US or other GS1 Member Organization to serve as the foundation for generating GS1 identifiers (e.g., GTINs). GS1 Company Prefixes are assigned in varying lengths depending on the company's needs.   (**Note**: a GTIN-14 that embeds an NDC/NHRIC, the GS1 Company Prefix is the NDC/NHRIC Labeler Code with a "03" appended in front.)

3. **Item Reference (of items contained):** The number assigned by the holder of the GS1 Company Prefix to uniquely identify the contained trade item. The Item Reference varies in length as a function of the GS1 Company Prefix length. (Refer to the *GS1 General Specifications* and the *GS1 Healthcare GTIN Allocation Rules* for additional information.) **Note**: In a GTIN-14 that embeds an NDC/NHRIC, the Item Reference segment is populated with the NDC/NHRIC Product/Package Code*.*)

4. **Check Digit:** One-digit number calculated from the first 13 digits of the GTIN-14. This digit is used to check that the data has been correctly composed.   GS1 US provides a check digit calculator to automatically calculate check digits.   The check digit calculator can be found at *www.gs1us.org/resources/tools-and-services/check-digit-calculator*.

⚠ **Important**: Although the length of the GS1 Company Prefix and the length of the Item Reference vary, they will always be a combined total of 12 digits in a GTIN-14. The Indicator Digit (1-8 or 9) plus the Check Digit comprise the remaining 2 digits of the GTIN-14.

Figure 5-3: Segments of a GTIN-14 (based on the hypothetical GTIN "20895123001003")
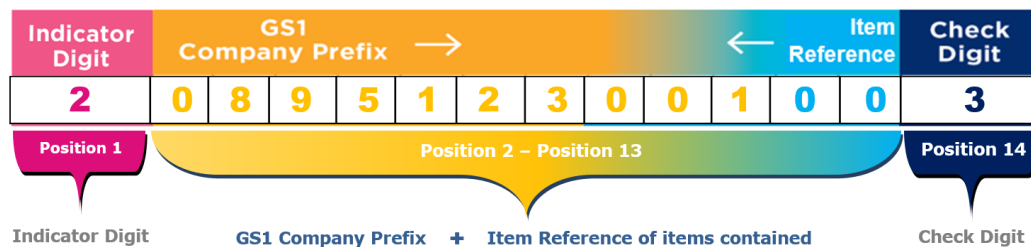
6   Family of Barcodes

To accommodate a variety of environments and applications, the GS1 System of Standards supports seven different barcodes. Certain GS1 barcodes can carry production identifiers (encoded with GS1 Application Identifiers; AIs). There are certain GS1 barcodes that are for retail applications, certain barcodes are for non-retail applications, and some are for both. Some barcodes only utilize a certain GTIN structure (e.g., UPC-A only utilizes a GTIN-12). Therefore, choice of barcode may be impacted by the GTIN structure you will use.

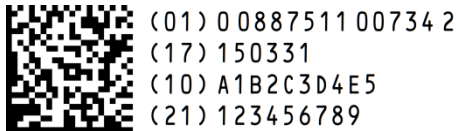Below are examples of the most commonly used barcodes supporting UDI.

Figure 6a: GTIN-12 in a UPC-A Barcode
(DI only)

8 50006 00001 2

Figure 6b: GTIN-13 in an EAN-13 Barcode
(DI only)

1 200000 123450

Figure 6c: GTIN-12 in a GS1 DataMatrix Barcode
(DI + PI)

(01) 0 0887511 00734 2
(17) 150331
(10) A1B2C3D4E5
(21) 123456789

Figure 6d: GTIN-14 in a GS1 DataMatrix Barcode
(DI only **or** PI can be added
as shown in 6c)

(01) 2 0887511 00734 6

Figure 6e: GTIN-12 in a GS1-128 Barcode
(DI + PI)

(01) 0 0887511 007342 (17) 150331 (10) A1B2C3D4E5 (21) 123456789

Figure 6f: GTIN-14 in a GS1-128 Barcode
(DI + PI)

(01) 2 0887511 007346 (17) 150331 (10) A1B2C3D4E5 (21) 123456789

7 Sharing and/or Storing your DI information

When sharing or storing information about your DI, it is recommended that the GTIN be kept in its entirety. Always ensure the check digit, indicator digit, and any leading zeros are included.

Figure 6.0: GTINs in Databases/Applications

GTIN® Storage	Global Trade Item Number® (GTIN®) Field													
-	N_1	N_2	N_3	N_4	N_5	N_6	N_7	N_8	N_9	N_{10}	N_{11}	N_{12}	N_{13}	N_{14}
GTIN-8	0	0	0	0	0	0	D_1	D_2	D_3	D_4	D_5	D_6	D_7	D_8
GTIN-12	0	0	D_1	D_2	D_3	D_4	D_5	D_6	D_7	D_8	D_9	D_{10}	D_{11}	D_{12}
GTIN-13	0	D_1	D_2	D_3	D_4	D_5	D_6	D_7	D_8	D_9	D_{10}	D_{11}	D_{12}	D_{13}
GTIN-14	D_1	D_2	D_3	D_4	D_5	D_6	D_7	D_8	D_9	D_{10}	D_{11}	D_{12}	D_{13}	D_{14}

- 'N' represents the numeric space within the database/application.

- 'D' represents the digit allocated for each position of the GTIN.

- The GTIN-8, GTIN-12, and GTIN-13 structures are right-justified and back-filled with zeroes '0' in order to complete the 14-digit format. The GTIN-14 is stored in its entirety.

7.1 Converting the GTIN structure to a storable/sharable format

It is recommended that GTINs be stored in databases and applications as 14-digits. If necessary, when sharing or storing a GTIN-8, GTIN-12, or GTIN-13, you can accomplish this by right justify and then zero-fill left to create a 14-digit format.

- GTIN-12 in a 14-digit format – for certain GS1 barcodes, sharing with trading partners (for database storage), and U.S. FDA GUDID

Fill Digits		U.P.C. Company Prefix →							← Item Reference				Check Digit
0	0	N_3	N_4	N_5	N_6	N_7	N_8	N_9	N_{10}	N_{11}	N_{12}	N_{13}	N_{14}

- GTIN-13 in a 14-digit format – for certain GS1 barcodes, sharing with trading partners (for database storage), and U.S. FDA GUDID

| Fill Digit	GS1 Company Prefix →							← Item Reference					Check Digit
0	N_2	N_3	N_4	N_5	N_6	N_7	N_8	N_9	N_{10}	N_{11}	N_{12}	N_{13}	N_{14}

8   Identification within a hierarchy

The different levels within a hierarchy (e.g., Single Unit or Single Unit Package, Shipper or Case, Pallet, etc.) are assigned different GTINs. It is for the Brand Owner or Responsible Entity to determine the hierarchy level(s) to which a GTIN should be assigned. Typically, any hierarchy level that is priced or ordered or invoiced at any point in the Supply Chain should receive its own GTIN. In some healthcare applications this may also be recorded and included in patient records.

There are several different options for assignment of GTINs in a hierarchy, below are just two of several examples.

Figure 6.2a: Indicator Digit for Higher Levels of Packaging (GTIN-12 as primary DI)
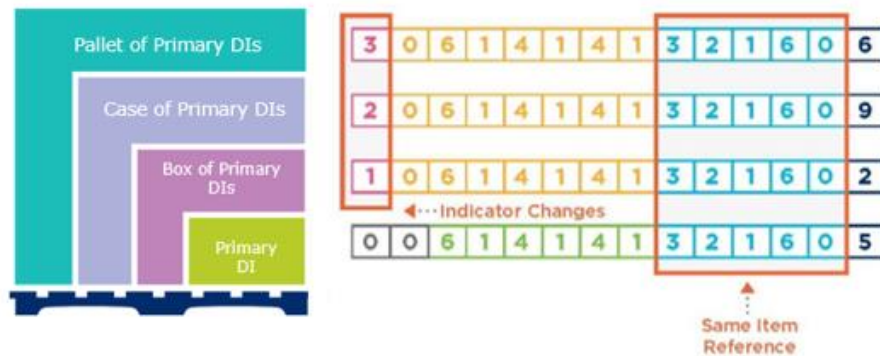
Figure 6.2b: Indicator Digit for Higher Levels of Packaging (GTIN-13 as primary DI)
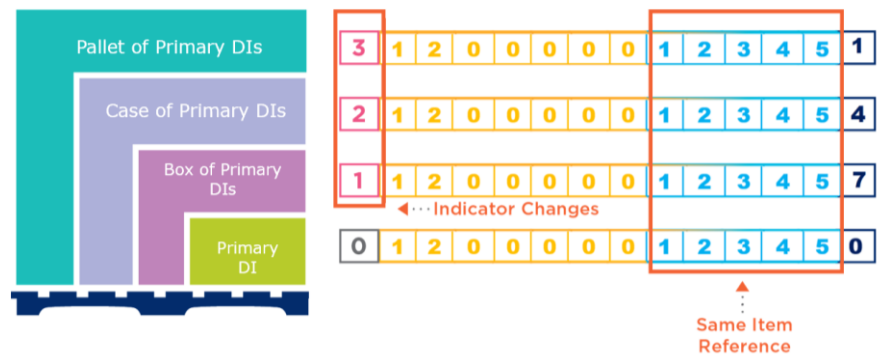
In the above examples, the various package levels all have the same Item Reference number and different indicator digits to represent the hierarchal structure. Note how the GTIN-12 (figure 6.2a) and GTIN-13 (figure 6.2b) is placed into a 14-digit format by adding two zeros to the beginning of the number string.

Color Legend:

Magenta = Indicator Digit

Gray = Fill Digit (s)

Green = U.P.C. Company Prefix

Gold = GS1 Company Prefix

Blue = Item Reference

Dark Blue = Check Digit

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