GS1 HEALTHCARE US

IMPLEMENTATION GUIDELINE

Using the GS1 System for
U.S. FDA Unique Device Identification (UDI) Requirements

FOR SUPPLIERS & RECEIVERS

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GS1® is a neutral, not-for-profit, global organization that develops and maintains the most widely-used supply chain standards system in the world. GS1 Standards improve the efficiency, safety, and visibility of supply chains across multiple sectors. With local Member Organizations in over 110 countries, GS1 engages with communities of trading partners, industry organizations, governments, and technology providers to understand and respond to their business needs through the adoption and implementation of global standards. GS1 is driven by over a million user companies, which execute more than six billion transactions daily in 150 countries using GS1 Standards.

ABOUT GS1 US

GS1 US, a member of GS1 global, is a not-for-profit information standards organization that facilitates industry collaboration to 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®).

ABOUT GS1 HEALTHCARE

GS1 Healthcare is a global, voluntary healthcare user group developing global standards for the healthcare supply chain and advancing global harmonization. GS1 Healthcare consists of participants from all stakeholders of the healthcare supply chain: manufacturers, wholesalers & distributors, as well as hospitals and pharmacy retailers. GS1 Healthcare also maintains close contacts with regulatory agencies and trade organizations worldwide. GS1 Healthcare drives the development of GS1 Standards and solutions to meet the needs of the global healthcare industry, and promotes the effective utilization and implementation of global standards in the healthcare industry through local support initiatives like GS1 Healthcare US in the United States.

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.

Part 1: Preface

1   Introduction

On September 24, 2013, the United States Food and Drug Administration (FDA) published a rule establishing a unique device identification system for medical devices. Under the rule, the healthcare community and the public will be able to identify a device through a Unique Device Identifier (UDI) that will appear on the label and package of a device. UDIs will be presented on device labels in both plain-text format and a format that can be read by automatic identification data capture (AIDC) technology (e.g., a barcode). In addition, re-usable devices that need to be "reprocessed" before reuse will also be directly marked with a UDI, allowing accurate identification even when the device is no longer accompanied by its label or package. The UDI will provide a standardized way to identify medical devices across all information sources and systems, including electronic health records and devices registries. In addition, device labelers will submit device information to an FDA database called the Global Unique Device Identification Database (GUDID). The GUDID will provide critical information about medical devices, and the UDI will provide the key for obtaining device information from the GUDID.

GS1® has received accreditation by the FDA that permits GS1 to indicate that a segment of the GS1 Standard format qualifies as a UDI. This guideline was prepared by GS1 Healthcare US® to assist U.S. medical device trading partners implementing UDI Rule requirements using GS1 Standards. To that end, this document identifies various requirements of the UDI Rule, specifies the GS1 Standard(s) that can be used to help meet those requirements, and provides detailed guidance on how to apply the standards to the requirements. By so doing, this document serves an implementation guideline that instructs industry members about how to use GS1 Standards within the context of the UDI rule.

2   Document Information

This implementation guideline was prepared by GS1 Healthcare US to assist suppliers and receivers of medical devices in the U.S. to implement the UDI Rule using GS1 Standards. This guideline is based on the *GS1 General Specifications*, and was developed using information obtained from all members of the U.S. healthcare supply chain, from manufacturers to providers.

2.1   Purpose

The purpose of this document is to provide a foundation for the appropriate use of GS1 identification and barcode standards on medical devices within the context of the UDI Rule. This guideline does not provide any guidance or advice regarding regulatory compliance.

2.2   Audience

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

2.3   Scope

This guideline identifies the GS1 identification and barcode standards that correlate to UDI Rule requirements, and explains how to implement these standards within the context of the UDI Rule. Specifically, this document covers the following topics:

REQUIREMENTS OF THE UDI RULE WITH CORRESPONDING GS1 STANDARD(S)	
Device Identifier (DI)	GS1 Global Trade Item Number® (GTIN®)
Production Identifiers (PI)	GS1 Application Identifiers (AIs)
Representation of UDI in AIDC Format *	GS1 BarCodes
Direct Marking UDI on Devices	GS1 Rules for Direct Part Marking
GUDID Data Submission (through HL7 SPL)	GS1 Global Data Synchronization Network™ (GDSN®)

Table A: GS1 Standards for UDI Requirements

* The FDA does not mandate any specific AIDC format.

This guideline provides sufficient information and technical detail to implement these standards for the purposes of the UDI Rule. The *GS1 General Specifications* should be consulted for additional information.

2.4   Normative References

This 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 guideline:

- *GS1 General Specifications* – Available in the Solutions Center through the GS1 US website at www.gs1us.org/solutionscenter

- Healthcare GTIN Allocation Rules – Available on the GS1 US - Healthcare *Tools & Resources* page at http://www.gs1us.org/industries/healthcare/tools-and-resources

2.5   Additional Resources

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

- Healthcare Provider Global Trade Item Number (GTIN) Tool Kit

- Healthcare Suppler Global Trade Item Number (GTIN) Toolkit

- Healthcare Provider Global Data Synchronization Network (GDSN) Tool Kit

- Healthcare Suppler Global Data Synchronization Network (GDSN) Toolkit

- Healthcare Suppler UDI Quick Start Guide

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

- EDI Quick Guide for GLN and GTIN

Use of these documents will increase understanding of all healthcare supply chain partners and facilitate a meaningful dialogue concerning implementation and benefits. Links and additional reference materials are listed in the Resources page of this document. All of these documents can be found on the GS1 US website: www.gs1us.org

3   Overview of the GS1 Standards Used

This chapter provides a brief definition of each GS1 Standard used in this guideline.

3.1   Global Trade Item Number (GTIN)

The Global Trade Item Number (GTIN) is the globally unique GS1 Identification Number 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 ultimate end user. 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. (Detailed information about encoding barcodes is provided in Section 4 of this guideline.) As an FDA Accredited Issuing Agency, GS1 has been given permission to designate the GTIN as equivalent to the Device Identifier (DI) portion of the FDA UDI.

3.2   GS1 Data Carriers

Manufacturers mark all of their products with the applicable GTIN so that they can be properly identified as they move through the supply chain. In order to do this, manufacturers encode the GTIN into GS1 data carriers [i.e., barcodes and/or Radio Frequency Identification (RFID) tags], and then affix a data carrier to each product. GS1 Data Carriers provide *machine-readable representations* of GS1 Identification Numbers that facilitate automatic identification and data capture (e.g., the black bars and spaces on the barcode). In addition to the symbolic representation, most GS1 data carriers include a *plain text version of the GTIN* as well to facilitate manual data entry when necessary [e.g., the numbers below the black bars of the barcode, known in the GS1 System as the Human Readable Interpretation (HRI)]. In order to accommodate a variety of environments and applications, the GS1 System supports eight data carriers: six barcode symbologies (i.e., GS1 BarCodes) and two RFID tags [i.e., GS1 Electronic Product Code / Radio Frequency Identification Tags (EPC/RFID Tags)]. While the FDA does not specify a specific data carrier standard, use of a GS1 Data Carrier to specify the UDI will help meet the FDA requirement to provide the UDI in a machine-readable format.

3.3   GS1 Application Identifiers

In addition to the device identifier (i.e., GTIN), there may be certain *item-specific information* that manufacturers or supply chain partners want marked on products to enable communication of that information *wherever the barcode is scanned* (e.g., expiration date; lot number; batch number; etc.). The GS1 System provides "Application Identifiers" to support this need. GS1 Application Identifiers (AIs) are a finite set of specialized identifiers encoded within barcodes to indicate the type of data represented in the various barcode segments. There are approximately 100 AIs, including an AI for each GS1 Identification Number as well as AIs for various types of secondary information (e.g., expiration date; lot number; batch number). Each data element in a barcode is preceded by its AI. For example, the AI for lot/batch number is 10. Thus, when "10" appears in the numerical string of a barcode, it means a lot/batch number follows in the next segment.

Each AI is a two, three, or four digit numeric code. (When rendered in human-readable form, the AI is usually shown in parentheses. However, the parentheses are not part of the barcode's encoded data.) GS1 AIs are standard throughout the world and are familiar to IT system developers. GS1-128, GS1 DataBar (RSS), GS1 DataMatrix, and Composite Component can all carry AIs, and more than one AI can be carried in one barcode.

GS1 Application Identifiers are used to encode FDA UDI Production Identifiers (PI) as assigned by the brand owner. UDI Production Identifiers are 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 [AI (10)], the serial number of a specific device [AI (21)]; the expiration date of a specific device [AI (17)]; the date a specific device was manufactured [AI (11)]; and, for a human cell or tissue product (HCT/P) regulated as a device, the distinct identification code (encoded using ICCBBA standards).

3.4 Direct (Part) Marking

Direct marking [or Direct Part Marking (DPM) as it is referred to in the GS1 System] refers to the process of marking a GS1 symbol directly onto an item (as opposed to using a label or another indirect marking process). There are a variety of methods for applying DPM, including both intrusive methods (e.g., dot peen; etching; direct laser marking; etc.) and non-intrusive methods (e.g., cast/forge/mold; laser bonding; stencil; etc.). GS1 Standards define key aspects of DPM including substrate requirements, symbol dimensions, symbol quality, and symbol placement. At present, GS1 DataMatrix is the only data carrier endorsed in the *GS1 General Specifications* for DPM in healthcare.

3.5 Global Data Synchronization Network (GDSN)

The Global Data Synchronization Network (GDSN) provides an efficient and effective approach to (1) storing GS1 Identifiers with their associated attributes, (2) checking to make sure that the identifiers and attributes are properly defined and formatted, and (3) sharing that information with supply chain partners. The GDSN is a network of interoperable data pools connected by the GS1 Global Registry®. The GDSN-certified Data Pools store and manage supply chain information for their users, and the GS1 Global Registry connects those data pools together. The GDSN offers a continuous, automated approach to data management that ensures that supply chain information is identical among trading partners, increasing data accuracy and driving costs out of the supply chain.

4   Overview of the UDI Rule

The UDI Rule establishes a unique device identification system for medical devices. Under the rule, the healthcare community and the public will be able to identify a device through a Unique Device Identifier (UDI) that will appear on the label and package of a device. UDIs will be presented on device labels in both a human-readable format and a machine-readable format that can be read by automatic identification data capture (AIDC) technology (e.g., a barcode). In addition, re-usable devices that need to be "reprocessed" before reuse will also be directly marked with a UDI. The UDI will provide a standardized way to identify medical devices across all information sources and systems, including electronic health records and devices registries. In addition, device labelers will submit device information to a new FDA database called the Global Unique Device Identification Database (GUDID). The GUDID will provide critical information about medical devices, and the UDI will provide the key for obtaining device information from the GUDID. (Additional information is available in the GUDID Draft Guidance for Industry prepared by the FDA.)

4.1   UDI Segments

A UDI is a unique numeric or alphanumeric identification code assigned to medical devices by the labeler (e.g., manufacturer) of the device using the format specified and agreed upon during the FDA UDI Issuing Agency accreditation process. A UDI includes two segments: a "device identifier" and a "production identifier":

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

- **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: (i) the lot or batch number within which a device was manufactured; (ii) the serial number of a specific device; (iii) the expiration date of a specific device; (iv) the date a specific device was manufactured; and (v) for an HCT/P regulated as a device, the distinct identification code

According to the Rule, a *device identifier* is always present in a UDI. However, a *production identifier* is only required if it appears on the device label. Nonetheless, most devices include at least one piece of production information on the label, and therefore most UDIs would include a *production identifier*. Therefore, UDIs can be comprised of either **DI only**, or **DI and PI**.

Because GS1 is an FDA-accredited Issuing Agency for UDI, the GTIN can be considered a UDI device identifier. Part 2 of this guideline provides detailed information about assigning GTINs as UDI device identifiers. Production identifiers are represented by GS1 Application Identifiers (AIs). Part 3 of this guideline provides detailed information about using GS1 AIs for UDI production identifiers.

UDI SEGMENT WITH CORRESPONDING GS1 STANDARD(S)	
Device Identifier (DI)	GS1 Global Trade Item Number (GTIN)
Production Identifier (PI)	GS1 Application Identifiers (AIs):
Batch/lot number	AI (10)
Production/manufacturing date	AI (11)
Expiration date	AI (17)
Serial number	AI (21)

Table B: UDI Components with Corresponding GS1 Standards

4.2   UDI Labeling

The Rule requires that UDIs be presented on device labels in both human-readable format and AIDC format (e.g., a barcode). GS1 Standards provide for several different barcodes that can be used as the UDI AIDC format. GS1 BarCode standards are presented in Part 4 of this guideline.

Barcodes are utilized for a variety of applications, and the GS1 System supports seven different barcodes in order to enable users to select the barcode that best fits their application. Pursuant to the *GS1 General Specifications*, some barcodes are only approved for retail applications, some barcodes are only approved for non-retail applications, and some are approved for both. In addition, some GS1 BarCodes are able to carry production information (encoded with GS1 AIs) and others are not. Therefore, the GS1 BarCode options for UDI vary depending on (1) whether the barcode will be read in a retail environment, and (2) whether the barcode will need to encode "DI only" or "DI and PI." The table below identifies the GS1 BarCode options for each combination.

BARCODE ENVIRONMENT	UDI SEGMENTS TO BE ENCODED	GS1 BARCODE OPTIONS
RETAIL	DI only	EAN/UPC GS1 DataBar

RETAIL	DI and PI	EAN/UPC *+ one of the following:*
		    GS1 DataMatrix
		    GS1 DataBar
		    GS1-128

NON-RETAIL *	DI only *	GS1-128 GS1 DataMatrix GS1 DataBar ITF-14
NON-RETAIL	DI and PI	GS1 DataMatrix GS1-128 GS1 DataBar

Table C: GS1 BarCode Options Based on Barcode Application Environment & UDI Information to be Encoded

* The barcode options shown for "Non-Retail – encoding DI only" are the most prevalent. However, it should be noted that EAN/UPC could also be used in this group according to the standard.

Each combination is presented separately in Part 4 of this document in order to provide clarity regarding barcode options.

4.3   Direct Marking

The rule requires that the UDI also be directly marked on the medical device itself for re-usable devices that need to be "reprocessed" before reuse. Direct marking supports accurate identification even when a device is no longer accompanied by its label or package. Within the GS1 System, direct marking is referred to as Direct Part Marking (DPM). DPM is the process of marking a GS1 symbol directly onto an item (as opposed to using a label or another indirect marking process). There are a variety of methods for applying DPM, including both intrusive methods (e.g., dot peen; etching; direct laser marking; etc.) and non-intrusive methods (e.g., cast/forge/mold; laser bonding; stencil; etc.) GS1 Standards define key aspects of DPM including substrate requirements, symbol dimensions, symbol quality, and symbol placement. Those rules are presented in Part 5 of this guideline.

4.4   GUDID

Whenever a device must bear a UDI, the rule requires the labeler of that device to submit information concerning the device to the FDA to facilitate the rapid identification of the device and the labeler, and to provide links to other FDA data. The Global Unique Device Identification Database (GUDID) will serve as a reference catalogue for every device with an identifier. No identifying patient information will be stored in this device information center.

The FDA has published a GUDID Draft Guidance for Industry that indicates that there will be two options/methods for Publishing/Reporting UDI and associated data to the FDA's GUDID:

- Structured input via the GUDID Web Interface
- HL7 Structured Product Labeling (SPL) submitted via the FDA Electronic Submissions Gateway (ESG)

In addition, the draft guidance also provides labelers with the option to designate third-party submitters for GUDID submissions. Third-party submitters are companies/individuals authorized to submit GUDID information on behalf of the labeler using one of the two options/methods specified above (e.g., GDSN-certified Data Pools such as 1WorldSync, FSEnet, GHX Health ConneXion, etc.).

Once the GUDID Guidance is finalized, this document will be updated with further information regarding the use of GS1 Standards in the context of GUDID data submission.

5   Background Concepts

5.1   FDA Sunset of Device NHRICs / NDCs

The National Health Related Item Code (NHRIC) and the National Drug Code (NDC) are U.S. regulatory identifiers used to identify medical/surgical and pharmaceutical products (respectively) for regulatory purposes pursuant to FDA regulations. The GTIN is a supply chain identifier used to identify products for supply chain purposes. Pursuant to GS1 Standards, NHRICs and NDCs can be embedded into GTINs so that identification of medical/surgical and pharmaceutical products for supply chain purposes is consistent with identification of medical/surgical and pharmaceutical products for regulatory purposes. In fact, manufacturers of healthcare products have been embedding NHRICs/ NDCs in their GTINs for over forty years. (See the Appendix of this document for more detailed information about how NHRICs/NDCs are embedded into GTINs.)

However, the FDA has announced that it will be phasing out NHRICs and NDCs. To that end, the UDI Rule terminates the use of NHRICs and NDCs *on the date a device must be labeled with a UDI*. Nonetheless, the UDI Rule provides that *Labeler Codes* may endure upon request by the labeler. Any *Labeler Code* not requested to continue will be returned to the issuing agency and therefore may end up being reused at some point. ***Therefore, in order to ensure the uniqueness of your GTINs going forward, it is imperative that any GS1 Member that has a GS1 Company Prefix that embeds its Labeler Code submit a request to the FDA to preserve their Labeler Code.***

5.2   Data Format for GTIN Fields in Databases

GTINs should be represented in software applications as 14 digits by right justifying and zero-filling to the left as appropriate. In order to preserve any leading zeros that may be present, the GTIN field should be represented in a database as a text field, not as a *numeric* field.

5.3   Assigning vs. Storing vs. Encoding GTINs

GTINs can be assigned as 8 digits, 12 digits, 13 digits, or 14 digits in length (known as GTIN-8, GTIN-12, GTIN-13, and GTIN-14 respectively). Within the U.S. medical/surgical supply chain, the 14-digit GTIN ("GTIN-14") and the 12-digit GTIN ("GTIN-12") are predominantly used. GS1 BarCode standards prescribe how GTINs are to be encoded in each GS1 BarCode. However, regardless of how they are assigned and encoded, it is important to understand that GTINs are always stored in databases as 14 digits (i.e. GTIN-14, **or** GTIN-8, GTIN-12 or GTIN-13 *in 14-digit format using leading zeros*).

ASSIGNING GTINs	ENCODING GTINs	STORING GTINs
GTIN-12 *or* **GTIN-14**	**EAN/UPC barcode:** GTIN-12 only **All other GS1 BarCodes:** 14-digit GTIN (i.e. GTIN-14, or GTIN-12 in 14-digit format using leading zeros)	**14-digit format** (i.e. GTIN-14, or GTIN-12 in 14-digit format using leading zeros)

Table D: Key to Assigning, Storing and Encoding GTINs

5.4   Assigning/Allocating Serial Numbers

The *GS1 General Specification*s define a serial number for use with a GTIN as an alphanumeric string whose length is variable between one and 20 characters *(the specific characters allowed are defined in the GS1 General Specifications)*. Therefore, databases and messages that need to contain a GTIN plus serial number should be designed to accommodate any serial number consisting of 1-20 characters. "Zero" characters in serial numbers are treated as any other alphanumeric character such that serial numbers 7, 07, and 007 are all *different* serial numbers according to the standard. Databases should treat the serial number as a <u>text field</u> so that leading zeros are not inadvertently stripped off.

In GS1 BarCodes, serial numbers are represented using AI **(**21**)**. Any serial number consisting of 1-20 characters may be used in a GS1 BarCode per the standard. Although barcodes can accommodate any 1-20 character serial number, the size of the barcode may vary depending on how many characters are used. However, many production systems prefer a consistent barcode size in order to conform to package artwork constraints and to simplify the quality assurance process. For this reason, manufacturers often adopt a consistent serial number length rather than allow their serial numbers to vary between 1 and 20 characters.

5.5   Data Format for Serial Number Fields in Databases

Serial numbers should be <u>stored</u> in a text field (not numeric) that is capable of handling from one to 20 characters. Pursuant to the *GS1 General Specifications*, leading zeros should *never* be added to or removed from serial numbers.

5.6   DataMatrix Scanners

GS1 DataMatrix requires camera-based scanners in order to be read. Traditional linear barcode scanners cannot read the GS1 DataMatrix. As a result, it is important for supply chain partners to communicate prior to implementing GS1 DataMatrix to ensure that the appropriate scanners are in place.

5.7   Barcode Scanning Equipment

Prior to purchasing barcode scanning equipment, it is recommended that you consult the *Simplified Guide for U.S. Healthcare Barcode Scanner Acquisition Criteria* (see the Resources page in the Appendix for the link). This document was prepared by GS1 US to assist members of the U.S. healthcare supply chain in evaluating the various barcode scanning equipment options on the market, and selecting the equipment that best fits their needs.

5.8   Barcode Scanning Issues

There are many reasons why a barcode may not scan. Many times it is not the barcode, but the scanner itself. For example, the lens could be dirty or the batteries discharged. GS1 US has prepared another document entitled *Procedure for Responding to Troublesome Barcodes* (see the Resources page in the Appendix for the link) to help resolve barcode scanning issues. This document offers a simplified process to rectify barcode scanning issues based on the experiences of healthcare users. It is recommended that you download this document as a reference to help you respond if a barcode does not scan.

5.9   Tips to Suppliers re: GS1 Standards

- Determine/select the appropriate symbol(s) based on your supply chain.
- The best practice is to encode all data in <u>one</u> barcode symbol.
- Store information in your internal database(s) to reflect the hierarchy.
- When the package is going to both retail and providers, it must have an EAN/UPC barcode for point-of-sale application.
    - Because EAN/UPC cannot contain secondary information, you must use a second barcode to carry the secondary information.
    - The barcode with the secondary information must also have the GTIN.
    - The GTIN in the secondary barcode must be same GTIN as in the EAN/UPC.
    - If EPC/RFID is used, it must have the same GTIN and secondary information as in the barcode, and the package must be labeled that it contains EPC/RFID.*
    - The second barcode must be in the same field of plane as the primary EAN/UPC.
    - Obscure package control symbols if they are similar or may be confusing to the customer. Inform customers of new packaging.

* At present, RFID is only to be used "in addition to" barcodes in healthcare.

5.10 Tips to Receivers re: GS1 Standards

- Store GTIN as 14 digits in databases.
- Upgrade your system/database to read and store information.
- Instruct point-of-service users (e.g., nurses, doctors, pharmacists, etc.) about the new symbology, what it contains, and whether it is captured in the database.

Part 2: UDI Device Identifier (DI) -- GS1 GTIN

The UDI Rule requires that UDIs contain a *device identifier* that identifies the specific version or model of a device and the labeler of that device. Using the GS1 System, the UDI *device identifier* is represented by the Global Trade Item Number (GTIN). This section provides detailed instructions for how to generate GTINs.

The Global Trade Item Number (GTIN) is the globally unique GS1 Identification Number 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 ultimate end user. 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.

GTINs can be assigned as 8 digits, 12 digits, 13 digits, or 14 digits in length (known as GTIN-8, GTIN-12, GTIN-13 and GTIN-14, respectively). However, within the U.S. medical/surgical supply chain, the GTIN-12 and GTIN-14 are predominantly used. The choice of format for medical/surgical manufacturers is often related to point of sale. The most prevalent practices are to:

- Assign a GTIN-12 to medical/surgical products to be sold at retail and marked with an EAN/UPC barcode

- Assign a GTIN-14 to medical/surgical that will not be sold at retail

(Although these practices are the *most prevalent*, they are *not required*. For example, GTIN-12 is also acceptable in non-retail environments as well via long-established business usage, and GTIN-14 is the most predominant format in global healthcare. Consult the GS1 General Specifications for all of your options.)

This chapter provides detailed information about assigning each of those GTIN formats. This information is applicable regardless of whether or not the GTIN will embed an NHRIC/NDC. Additional details about GTINs that embed NHRICs/NDCs are provided in the Appendix.

> *Medical/surgical companies may have more than one GS1 Company Prefix (e.g., one GS1 Company Prefix that integrates their NHRIC Labeler Code, and other GS1 Company Prefixes that do not). Those companies will need to use the GS1 Company Prefix that integrates their Labeler Code when assigning GTINs that embed NHRICs and/or NDCs. Otherwise, they may use whichever GS1 Company Prefix they prefer when assigning GS1 Identification Numbers.*

GS1 US provides an online tool, known as Data Driver®, to support users in creating and managing GTINs and defining the associated attributes (as well as many other tasks like printing barcodes and sharing product information with trading partners). Data Driver guides users with a user-friendly interface and step-by-step instructions -- *no standards knowledge is necessary*. Data Driver is available exclusively to GS1 US Partner Connections members.

For a list of Data Driver features and capabilities, see the Appendix of this document or visit http://www.gs1us.org/resources/tools/data-driver for more information.

6   Products Sold at Retail & Marked with EAN/UPC Barcode: Assign a GTIN-12

Each GTIN-12 is a numerical string comprising three distinct segments. The three segments within a GTIN-12 are:

- **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 a specific representation of a GS1 Company Prefix that serves as the foundation for generating GTIN-12 identifiers. U.P.C. Company Prefixes vary in length depending on the company/organization's needs. (In a GTIN-12 that embeds an NDC, the U.P.C. Company Prefix segment is populated with the NDC Labeler Code with a "3" appended in front.)

- **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 *Healthcare GTIN Allocation Rules* for additional information.) (In a GTIN-12 that embeds an NDC, the Item Reference segment is populated with the NDC Product/Package Code.)

- **Check Digit:** A one-digit number calculated from the first 11 digits of the GTIN-12 used to ensure data integrity. GS1 US provides a check digit calculator to automatically calculate check digits for you. The check digit calculator can be found at http://www.gs1us.org/resources/tools-and-services/check-digit-calculator .

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.
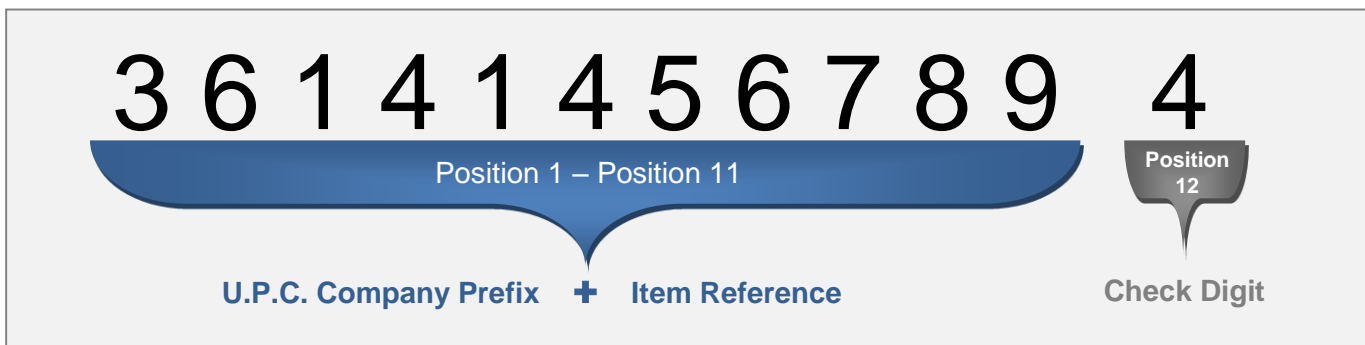

Figure 1. Segments of a GTIN-12 (based on the hypothetical GTIN "361414567894")

7 Products Not Sold at Retail: Assign a GTIN-14

Each GTIN-14 is a numerical string comprising four distinct segments. The four segments in a GTIN-14 are:

- **Indicator Digit:** The indicator digit identifies packaging level. The field consists of a numeric value from 1 to 8. (The number "0" is used in this position as a fill character when a GTIN-12 or GTIN-13 is represented in 14-digit format.)

  Packaging specialists must review the Indicators used on all other packaging levels prior to incorporating a new packaging level. This ensures that there is a unique GTIN on every packaging level.

- **GS1 Company Prefix:** A globally unique number assigned to a company by GS1 US 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.   (In a GTIN-14 that embeds an NDC, the GS1 Company Prefix segment is populated with the NDC Labeler Code with a "03" appended in front.)

- **Item Reference:** A 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 *Healthcare GTIN Allocation Rules* for additional information.) (In a GTIN-14 that embeds an NDC, the Item Reference segment is populated with the NDC Product/Package Code.)

- **Check Digit:** One-digit number calculated from the first 13 digits of the GTIN to ensure data integrity. GS1 US provides a check digit calculator to automatically calculate check digits.   The check digit calculator can be found at http://www.gs1us.org/resources/tools-and-services/check-digit-calculator .

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 and the Check Digit comprise the remaining 2 digits of the GTIN-14.
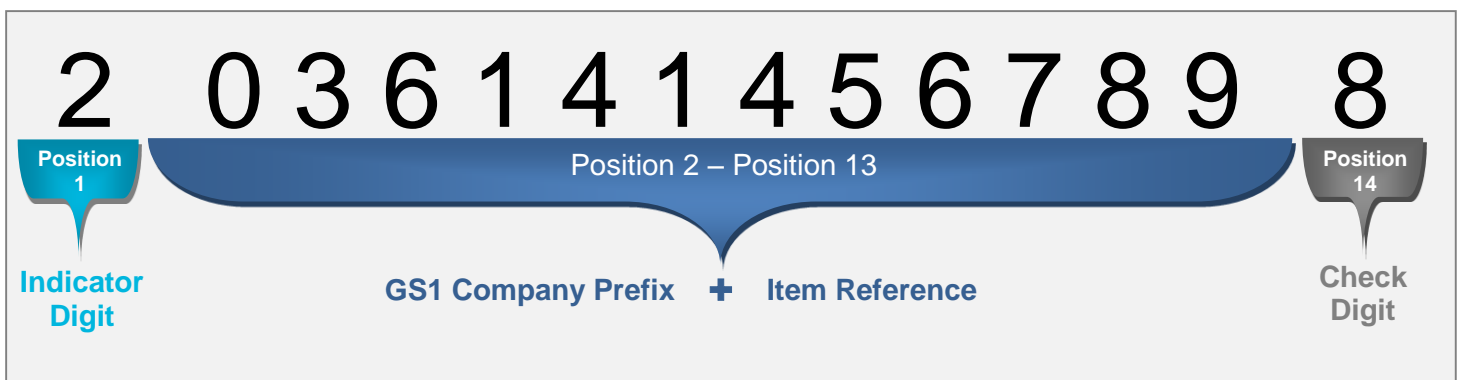
Figure 2. Segments of a GTIN-14 (based on the hypothetical GTIN "20361414567898")

Part 3: UDI Production Identifiers (PI) -- GS1 Application Identifiers

Pursuant to the U.S. FDA UDI Rule, a UDI must include a *production identifier* if production information (e.g., manufacturing date; expiration date; batch/lot number; serial number) appears on the device label. Because most devices include at least one of piece of production information on the label, most UDIs would include a *production identifier*. Using the GS1 System, UDI *production identifiers* are represented by GS1 Application Identifiers (AIs). This part of the guideline offers detailed information about GS1 AIs.

GS1 Application Identifiers (AIs) are a finite set of specialized identifiers encoded within barcodes to indicate the type of data represented in the various barcode segments (e.g., GTIN, serial number, expiration date, etc.). Each AI is a two, three, or four digit numeric code. There are approximately 100 AIs in total, including one AI for each GS1 Identification Number (e.g., GTIN, GLN, SSCC, etc.) as well as numerous AIs for item-specific information (e.g., expiration date; batch/lot number; serial number; etc.). The complete definitions for all of the Application Identifiers reside in the GS1 General Specifications.

GS1 AIs are assigned during the barcode encoding process. This section introduces the AIs associated with UDI production identifiers. Information about encoding AIs in barcodes is provided in Part 4 of this guideline.

The four AI's associated with the production identifiers in the UDI Rule are:

AI (10)   Batch/Lot Number

AI (11)   Manufacturing/Production Date

AI (17)   Expiration Date

AI (21)   Serial Number

When encoding a barcode, each data element in the barcode is preceded by its AI. The AI defines data type and field size. For example, the AI for GTIN it is (01). Thus, when "(01)" appears in the numerical string, it means a GTIN follows in the next segment. The AI for expiration date is it is (17). When "(17)" appears in the numerical string of a barcode, it means an expiration date follows in the next segment.

(01) 2 0887511 00734 6 (17) 15 03 31

Figure 3. GS1 DataMatrix with AI (01) for GTIN and AI (17) for Expiration Date

When rendered in human-readable form, AIs are usually shown in parentheses. However, neither the parentheses (nor the spaces) are part of the encoded data.

8   Batch/Lot Number: AI (10)

A *Batch/Lot Number* is typically assigned at the point of manufacturer using a production lot number, a shift number, a machine number, a time or an internal production code. *Batch/Lot Number* is represented by Application Identifier (10). The data is alphanumeric and the length is variable with a maximum of 20 alphanumeric characters.

Figure 4. GS1-128 with AI (01) for GTIN and AI (10) for Batch/Lot Number

Encoding principles:

- The two-digit AI **(10)** is used to indicate *Batch/Lot Number*.
- A variable-length field of up to 20 alphanumeric characters of *Batch/Lot Number* data follows the AI.
- The data syntax for *Batch/Lot Number* is n2 + a20 (where n2 is the **AI** and a20 is the ***Batch/Lot Number***).
- <u>EXAMPLE:</u> **10A1B2C3D4E5**

9   Manufacturing/Production Date: AI (11)

Manufacturing Date can also be referred to as production date. It indicates the production or assembly date determined by the manufacturer. *Manufacturing/Production Date* is represented by Application Identifier (11). The data is numeric and the length is fixed at six numeric characters with the structure YYMMDD.

Figure 5. GS1 DataMatrix with AI (01) for GTIN and AI (11) for Production Date

Encoding principles:

- The two-digit AI **(11)** is used to indicate *Manufacturing/Production Date*.
- A fixed-length field of six numeric characters representing the *Manufacturing/Production Date* as **YYMMDD** follows the AI.

  YY = the tens and units of the year (e.g., 2014 = 14).

  MM = the number of the month (e.g., March = 03).

  DD = the number of the day of the relevant month (e.g., second day = 02).
- The data syntax for *Manufacturing/Production Date* is n2 + n6 (where n2 is the **AI** and n6 is the ***Manufacturing/Production Date***).
- <u>EXAMPLE:</u> **11140331**

> *Per the UDI Rule, the standardized date format of YYYY-MM-DD does <u>not</u> apply to how dates are encoded. The standardized date format only applies to the human-readable format of dates on labels/packages. Thus, the YYMMDD format used to encode the AI is permissible.*
>
> *The UDI Rule requires that the day be specified. Therefore, a "00" value in the DD segment is not permitted by the UDI Rule.*

10 Expiration Date: AI (17)

Expiration Date is often referred to as expiry date or maximum durability date. It indicates the limit of consumption or use of a product. *Expiration Date* is represented by Application Identifier (17). The data is numeric and the length is fixed at six numeric characters with the structure YYMMDD.

Figure 6. GS1 DataMatrix with AI (01) for GTIN and AI (17) for Expiration Date

Encoding principles:

- The two-digit AI **(17)** is used to indicate *Expiration Date*.
- A fixed-length field of six numeric characters representing the *Expiration Date* as **YYMMDD** follows the AI.

    YY = the tens and units of the year (e.g., 2015 = 15).

    MM = the number of the month (e.g., March = 03).

    DD = the number of the day of the relevant month (e.g., second day = 02).

- The data syntax for *Expiration Date* is n2 + n6 (where n2 is the AI and n6 is the *Expiration Date*).
- EXAMPLE: **17150331**

Per the UDI Rule, the standardized date format of YYYY-MM-DD does not apply to how dates are encoded. The standardized date format only applies to the human-readable format of dates on labels/packages. Thus, the YYMMDD format used to encode the AI is permissible.

The UDI Rule requires that the day be specified. Therefore, a "00" value in the DD segment is not permitted by the UDI Rule.

11 Serial Number: AI (21)

Serial Number is represented by Application Identifier (21). The data is alphanumeric and the length is variable with a maximum of 20 alphanumeric characters.*

Figure 7. GS1 DataMatrix with AI (01) for GTIN and AI (21) for Serial Number

Encoding principles:

- The two-digit AI **(21)** is used to indicate the *Serial Number*.
- A variable-length field of up to 20 alphanumeric characters of *Serial Number* data follows the AI.
- The data syntax for *Serial Number* is n2 + a20 (where n2 is the AI and a20 is the *Serial Number*).
- EXAMPLE: **21ABCDEFG123456789**

*The overall creation and structure of the Serial Number (e.g., random versus sequential, numeric versus alphanumeric; etc.) is determined by the manufacturer.

Part 4: UDI Labeling -- GS1 BarCodes

The U.S. FDA UDI Rule requires that UDIs be presented on device labels in both human readable format and AIDC format (e.g., a barcode). GS1 Standards provide for several different barcodes that can be used for the UDI AIDC format. In addition, GS1 Standards include rules for a "plain text format" that appears below a barcode [known as the Human Readable Interpretation (HRI)]. This part of the guideline offers detailed information about applying GS1 BarCode and HRI standards that may be used for UDI.

GS1 BarCodes provide machine-readable representations of GS1 Identification Numbers (and secondary information) that facilitate automatic identification and data capture (e.g., the black bars and spaces on the barcode). In addition, most barcodes also include a human readable interpretation (HRI) of the encoded information in order to facilitate manual data entry when necessary (e.g., the numbers below the black bars of the barcode).

In order to accommodate a variety of environments and applications, the GS1 System supports seven different barcodes. Some barcodes are only approved for retail applications. Some barcodes are only approved for non-retail applications. And some are approved for both. In addition, some GS1 BarCodes are able to carry production information (encoded with GS1 AIs) and others are not.

According to the UDI Rule, a *device identifier* (DI) is always present in a UDI. However, a *production identifier* (PI) is only required if the production information appears on the device label. (Because most devices include at least one of piece of production information on the label, most UDIs will include a PI.) Thus, UDIs can be comprised of either **DI only**, or **DI and PI**.

Based on these considerations, the GS1 BarCode options for UDI vary depending on (1) whether the barcode will be read in a retail environment, and (2) whether the barcode will need to encode "DI only" or "DI and PI." The table below identifies the GS1 BarCode options for each combination. Each combination is presented separately in this chapter in order to provide clarity.

BARCODE ENVIRONMENT	UDI SEGMENTS TO BE ENCODED	GS1 BARCODE OPTIONS
RETAIL	DI only	EAN/UPC GS1 DataBar

RETAIL	DI and PI	EAN/UPC + one of the following:
		    GS1 DataMatrix
		    GS1 DataBar
		    GS1-128

NON-RETAIL *	DI only *	GS1-128 GS1 DataMatrix GS1 DataBar ITF-14
NON-RETAIL	DI and PI	GS1 DataMatrix GS1-128 GS1 DataBar

Table E: GS1 BarCode Options Based on Barcode Application Environment & UDI Information to be Encoded

* The barcode options shown for "Non-Retail – encoding DI only" are the most prevalent. However, it should be noted that EAN/UPC could also be used in this group according to the standard.

12 UDI AIDC Format: GS1 BarCodes

The data elements within a barcode are separated (or delimited) through the use of GS1 Application Identifiers (AIs). GS1 AIs are a finite set of specialized identifiers encoded within barcodes to indicate the type of data represented in the various barcode segments. Each AI is a two, three, or four digit numeric code. The AI's that are relevant to this guideline are:

AI (01)	**GTIN**	**AI (17)**	**Expiration Date**
AI (10)	**Batch/Lot Number**	**AI (21)**	**Serial Number**
AI (11)	**Production/Manufacturing Date**		

Each data element in a barcode is preceded by its AI. For example, the AI for GTIN it is (01). Thus, when "(01)" appears in the numerical string, it means a GTIN follows in the next segment. (When rendered in human-readable form, the AI is usually shown in parentheses. However, the parentheses are not part of the barcode's encoded data.)

12.1 General Encoding Principles

The following table presents some high-level concepts and principles for encoding barcodes.

PRINCIPLE	EXAMPLE / ILLUSTRATION	
Each barcode data element has a two- to four-digit AI that defines data type and field size.	GTIN	**AI (01)**
	Batch/Lot Number	**AI (10)**
	Manufacturing Date	**AI (11)**
	Expiration Date	**AI (17)**
	Serial Number	**AI (21)**
When encoding, each data element is preceded by its corresponding AI. NOTE: *For clarity, the numbers representing the AI and numbers representing the date element are shown in different colors in the examples to the right.*	GTIN	**01**20361414567898
	Batch/Lot Number	**10**987654321gfedcba
	Manufacturing Date	**11**140731
	Expiration Date	**17**151231
	Serial Number	**21**ABCDEFG123456789

PRINCIPLE	EXAMPLE / ILLUSTRATION
Encode the GTIN first. Encode any production data (e.g., batch/lot number, expiration date, etc.) following the identifier. NOTE: *The parentheses and spaces appearing in the HRI are not encoded in the barcode itself.*	 (01) 00314141999995 (10) 987654321GFEDCBA
For the most efficient encoding, ensure that fixed-length AI's precede variable-length AI's.	 (01) 20887511007346 (17) 150331 (10) A1B2C3D4E5 (21) 123456789 GTIN *fixed* Expiration Date *fixed* Batch/Lot Number *variable* Serial Number *variable*

Table F: Encoding Principles

12.2 Barcodes for Products Sold at Retail -- Encoding DI only

There are two GS1 BarCode options that may be used for devices falling within this group:

- EAN/UPC, and
- GS1 DataBar.

Encoding principles and examples of each barcode are provided below.

12.2.1 EAN/UPC

UDI ELEMENT(S)	GS1 STANDARD(S)	ENCODING PRINCIPLES
DI	GTIN	- ONLY A GTIN-12 MAY BE ENCODED. - The data syntax for the GTIN is n12. - Enter the 12 numeric characters of the GTIN-12 into the fixed-length field. - EXAMPLE: **314141999995**

Table G: EAN/UPC Encoding Principles

Figure 8. GTIN Encoded in an EAN/UPC

12.2.2 GS1 DataBar

UDI ELEMENT(S)	GS1 STANDARD(S)	ENCODING PRINCIPLES
DI	GTIN	- GTIN MUST BE IN A 14-DIGIT FORMAT (*For GTIN-12 or GTIN-13: encode in 14-digit format using leading* zeros <u>as described above</u>) - The data syntax for the GTIN component is n2 + n14 (where n2 is the AI and n14 is the GTIN). - Begin with the **two-digit AI "01"** to indicate GTIN. - Enter the 14 numeric characters representing the **"GTIN in 14-digit format"** into the fixed-length field following the AI. - EXAMPLE: **01**00314141999995

Table H: GS1 DataBar Encoding Principles for DI Only

Figure 9. GTIN Encoded in a GS1 DataBar (Limited)

Figure 10. GTIN Encoded in a GS1 DataBar (Stacked)

12.3 Barcodes for Products Sold at Retail -- Encoding DI and PI

Retail items in the United States require an EAN/UPC barcode to be scanned for product identification (GTIN). However, UPCs cannot carry secondary information. To resolve this, the GS1 Healthcare US workgroup has made the following recommendations for devices sold at retail that include DI and PI:

- These devices should utilize two barcodes: an EAN/UPC and a second barcode.*
- The second barcode should be either a GS1 DataBar, a GS1-128, or a GS1 DataMatrix.
- The second barcode should contain both the GTIN that is carried in the EAN/UPC and the secondary information (such as lot, expiration date or serial number). While this practice may be redundant, this very redundancy assures users that the information is correct.
- The GTIN in the secondary barcode must be the same as in the EAN/UPC.
- The second barcode used for retail must be in the same field of plane as the primary EAN/UPC.

Based on these recommendations, there are three options that may be used for devices falling within this group (presented in the order of preference recommended by the GS1 Healthcare US workgroup):

- EAN/UPC and GS1 DataBar
- EAN/UPC and GS1-128, or
- EAN/UPC and GS1 DataMatrix

* *Refer to section 4.14 in the General Specifications for more information on managing multiple barcodes*.

IMPORTANT NOTE:

As described above, devices sold at retail that are marked with both DI and PI will carry two barcodes: an EAN/UPC and either a GS1 DataBar, GS1-128 or GS1 DataMatrix. The EAN/UPC holds a maximum of 12 digits, but the other barcodes require the GTIN to be in a format that is 14 digits long. In order to ensure that the GTIN encoded in both barcodes is the same, follow the recommendations below:

- *assign a GTIN-12 to identify the product at the lowest saleable level (i.e., the bottle or pack)*
- *create the EAN/UPC linear barcode using the GTIN-12*
- *pad the GTIN-12 with two leading zeros to create a "GTIN-12 in 14-digit format"* **

GTIN-12	31414 199999 5
GTIN-12 in 14-digit format	0 031414 199999 5

- *create the GS1 DataBar, GS1-128 or GS1 DataMatrix using the "GTIN-12 in 14-digit format"*
- *when storing GTIN-12s in databases, store them in the 14-digit format*

A GTIN-12 remains a GTIN-12 whether it is in its original 12-digit format or represented in a 14-digit format using leading zeros. Technically speaking, the padded GTIN-12 is called a "GTIN-12 in a 14-digit format." It is not a GTIN-14. Therefore, when a product needs to be marked with a UPC, it should be assigned a GTIN-12 (not a GTIN-14) in order to preserve the manufacturer's ability to represent the GTIN in a 12-digit U.P.C. as well as any barcode that requires a 14-digit format.

THIS SHOULD NOT BE DONE IN THE OPPOSITE DIRECTION (i.e., assign a GTIN-14 and remove the first two digits in an attempt to create a GTIN-14 in a 12-digit format). A true GTIN-14 (one with digits other than "00" in the 1st and 2nd positions) cannot be converted to a 12-digit format because, among other reasons, the check digit (which is calculated using the value and position of each digit) would not match.

12.3.1 EAN/UPC and GS1 DataBar

The EAN/UPC encodes the GTIN. Encoding principles for the EAN/UPC are the same as described above. The GS1 DataBar should contain both the GTIN that is carried in the EAN/UPC and whatever production information is required. Encoding principles for the GS1 DataBar are provided below. The data elements are presented in the order in which they should be encoded.

Although we have included all PI from the UDI Rule here in order to be complete, you will only encode those applicable to your product. Regardless of which or how many PI you encode, encode the data elements in the relative order in which they are presented in the table below.

UDI ELEMENT	GS1 STANDARD	ENCODING PRINCIPLES FOR THE GS1 DATABAR
DI	GTIN	• GTIN MUST BE IN A 14-DIGIT FORMAT (*For GTIN-12 or GTIN-13: encode in 14-digit format using leading zeros as described above*) • The data syntax for the GTIN component is n2 + n14 (where n2 is the AI and n14 is the GTIN). • Begin with the **two-digit AI "01"** to indicate GTIN. • Enter the 14 numeric characters representing the **"GTIN in 14-digit format"** into the fixed-length field following the AI. • EXAMPLE: **01**00314141999995
MANUFACTURING / PRODUCTION DATE	AI (11)	• Begin with the **two-digit AI "11"** to indicate *Production Date*. • Enter the six numeric characters representing the ***Production Date* as YYMMDD** into the fixed-length field following the AI. • **YY** = tens and units of the year (e.g., 2014 = 14). • **MM** = number of the month (e.g., January = 01). • **DD** = number of the day of the relevant month (e.g., first day = 01). (note: a "00" value in the DD segment is not permitted by the UDI Rule) • EXAMPLE: **11**140726
EXPIRATION DATE	AI (17)	• Begin with the **two-digit AI "17"** to indicate *Expiration Date*. • Enter the six numeric characters representing the ***Expiration Date* as YYMMDD** into the fixed-length field following the AI. • **YY** = tens and units of the year (e.g., 2015 = 15). • **MM** = number of the month (e.g., January = 01). • **DD** = number of the day of the relevant month (e.g., first day = 01). (note: a "00" value in the DD segment is not permitted by the UDI Rule) • EXAMPLE: **17**151231
BATCH/LOT NUMBER	AI (10)	• Begin with the **two-digit AI "10"** to indicate *Batch/Lot Number*. • Enter up to 20 alphanumeric characters representing the ***Batch/Lot Number*** into the variable-length field following the AI. • EXAMPLE: **10**987654321gfedcba
SERIAL NUMBER	AI (21)	• Begin with the **two-digit AI "21"** to indicate *Serial Number*. • Enter up to 20 alphanumeric characters representing the ***Serial Number*** into the variable-length field following the AI. • EXAMPLE: **21**ABCDEFG123456789

Table I: GS1 DataBar Encoding Principles for DI and PI

Figure 11. GTIN Encoded in an EAN/UPC, and GS1 DataBar encoding both GTIN and Expiration Date

NOTE: The GTIN-12 from the EAN/UPC is encoded as a "GTIN-12 in 14-digit format" on the GS1 DataBar (RSS) Limited (i.e., padded with leading zeros), and the Expiration Date is encoded on the Composite.

12.3.2   EAN/UPC and GS1-128

The EAN/UPC encodes the GTIN. Encoding principles for the EAN/UPC are the same as described above. The GS1-128 should contain both the GTIN that is carried in the EAN/UPC and whatever production information is required. (Note that the GS1-128 symbol size will increase with the number of PIs.) Encoding principles for the GS1-128 are provided below. The data elements are presented in the order in which should be encoded:

Although we have included all PI from the UDI Rule here in order to be complete, you will only encode those applicable to your product. Regardless of which or how many PI you encode, encode the data elements in the relative order in which they are presented in the table below.

UDI ELEMENT	GS1 STANDARD	ENCODING PRINCIPLES FOR THE GS1-128
DI	GTIN	• GTIN MUST BE IN A 14-DIGIT FORMAT (*For GTIN-12 or GTIN-13: encode in 14-digit format using leading* zeros as described above) • The data syntax for the GTIN component is n2 + n14 (where n2 is the AI and n14 is the GTIN). • Begin with the **two-digit AI "01"** to indicate GTIN. • Enter the 14 numeric characters representing the **"GTIN in 14-digit format"** into the fixed-length field following the AI. • EXAMPLE: **01**00314141999995

MANUFACTURING / PRODUCTION DATE	AI (11)	• Begin with the **two-digit AI "11"** to indicate *Production Date*.
		• Enter the six numeric characters representing the ***Production Date* as YYMMDD** into the fixed-length field following the AI.
		    • **YY** = tens and units of the year (e.g., 2014 = 14).
		    • **MM** = number of the month (e.g., January = 01).
		    • **DD** = number of the day of the relevant month (e.g., first day = 01). (note: *a "00" value in the DD segment is not permitted by the UDI Rule*)
		• EXAMPLE: **11**140726

EXPIRATION DATE	AI (17)	• Begin with the **two-digit AI "17"** to indicate *Expiration Date*.
		• Enter the six numeric characters representing the ***Expiration Date* as YYMMDD** into the fixed-length field following the AI.
		    • **YY** = tens and units of the year (e.g., 2015 = 15).
		    • **MM** = number of the month (e.g., January = 01).
		    • **DD** = number of the day of the relevant month (e.g., first day = 01). (note: *a "00" value in the DD segment is not permitted by the UDI Rule*)
		• EXAMPLE: **17**151231

BATCH/LOT NUMBER	AI (10)	• Begin with the **two-digit AI "10"** to indicate *Batch/Lot Number*. • Enter up to 20 alphanumeric characters representing the ***Batch/Lot Number*** into the variable-length field following the AI. • EXAMPLE: **10**987654321gfedcba
SERIAL NUMBER	AI (21)	• Begin with the **two-digit AI "21"** to indicate *Serial Number*. • Enter up to 20 alphanumeric characters representing the ***Serial Number*** into the variable-length field following the AI. • EXAMPLE: **21**ABCDEFG123456789

Table J: GS1-128 Encoding Principles for DI and PI

Figure 12. EAN/UPC encoding GTIN, and GS1-128 encoding both GTIN and Batch/Lot

3 14141 99999 5

(01) 0 0314141 999995 (10) 987654321GFEDCBA

12.3.3 EAN/UPC and GS1 DataMatrix

The EAN/UPC encodes the GTIN. Encoding principles for the EAN/UPC are the same as described above. The GS1 DataMatrix should contain both the GTIN that is carried in the EAN/UPC and whatever production information is required. Encoding principles for the GS1 DataMatrix are provided below. The data elements are presented in the order in which should be encoded.

Although we have included all PI from the UDI Rule here in order to be complete, you will only encode those applicable to your product. Regardless of which or how many PI you encode, encode the data elements in the relative order in which they are presented in the table below.

UDI ELEMENT	GS1 STANDARD	ENCODING PRINCIPLES FOR THE GS1 DATAMATRIX
DI	GTIN	• GTIN MUST BE IN A 14-DIGIT FORMAT (*For GTIN-12 or GTIN-13: encode in 14-digit format using leading* zeros as described above) • The data syntax for the GTIN component is n2 + n14 (where n2 is the AI and n14 is the GTIN). • Begin with the **two-digit AI "01"** to indicate GTIN. • Enter the 14 numeric characters representing the **"GTIN in 14-digit format"** into the fixed-length field following the AI. • EXAMPLE: **01**00314141999995

MANUFACTURING / PRODUCTION DATE	AI (11)	• Begin with the **two-digit AI "11"** to indicate *Production Date*.
		• Enter the six numeric characters representing the ***Production Date* as YYMMDD** into the fixed-length field following the AI.
		  • **YY** = tens and units of the year (e.g., 2014 = 14).
		  • **MM** = number of the month (e.g., January = 01).
		  • **DD** = number of the day of the relevant month (e.g., first day = 01). (note: *a "00" value in the DD segment is not permitted by the UDI Rule*)
		• EXAMPLE: **11**140726

EXPIRATION DATE	AI (17)	• Begin with the **two-digit AI "17"** to indicate *Expiration Date*.
		• Enter the six numeric characters representing the ***Expiration Date* as YYMMDD** into the fixed-length field following the AI.
		  • **YY** = tens and units of the year (e.g., 2015 = 15).
		  • **MM** = number of the month (e.g., January = 01).
		  • **DD** = number of the day of the relevant month (e.g., first day = 01). (note: *a "00" value in the DD segment is not permitted by the UDI Rule*)
		• EXAMPLE: **17**151231

BATCH/LOT NUMBER	AI (10)	• Begin with the **two-digit AI "10"** to indicate *Batch/Lot Number*. • Enter up to 20 alphanumeric characters representing the ***Batch/Lot Number*** into the variable-length field following the AI. • EXAMPLE: **10**987654321gfedcba
SERIAL NUMBER	AI (21)	• Begin with the **two-digit AI "21"** to indicate *Serial Number*. • Enter up to 20 alphanumeric characters representing the ***Serial Number*** into the variable-length field following the AI. • EXAMPLE: **21**ABCDEFG123456789

Table K: GS1 DataMatrix Encoding Principles for DI and PI

Figure 13. EAN/UPC encoding GTIN, and GS1 DataMatrix encoding both GTIN and secondary information (i.e., Production Date, Batch/Lot, Number, Serial Number)

(01) 0 0887511 00734 2
(11) 140331
(10) A1B2C3D4E5
(21) 123456789

12.4 Barcodes for Products Not Sold at Retail -- Encoding DI only

There are four GS1 BarCode options that may be used for devices falling within this group:

- GS1-128

- GS1 DataMatrix

- ITF-14

- GS1 DataBar

The encoding principles are the same for each barcode option, and are presented in the table below. Examples of each barcode follow the table.

UDI ELEMENT(S)	GS1 STANDARD(S)	ENCODING PRINCIPLES
DI	GTIN	• GTIN MUST BE IN A 14-DIGIT FORMAT (*For GTIN-12 or GTIN-13: encode in 14-digit format using leading* zeros <u>as described above</u>) • The data syntax for the GTIN component is n2 + n14 (where n2 is the AI and n14 is the GTIN). • Begin with the **two-digit AI "01"** to indicate GTIN. • Enter the 14 numeric characters representing the **"GTIN in 14-digit format"** into the fixed-length field following the AI. • <u>EXAMPLE:</u> **01**00314141999995

Table L: Encoding Principles for Non-Retail, DI only

12.4.1   GS1-128

(01) 2 0887511 007346

Figure 14. GTIN Encoded in a GS1-128

12.4.2   GS1 DataMatrix

Figure 15. GTIN Encoded in GS1 DataMatrix

(01) 2 08875110 07 34 6

12.4.3   GS1 DataBar

(01) 0 0314141 999995

Figure 16. GTIN Encoded in GS1 DataBar (Limited)

(01) 0 0314141 999995

Figure 17. GTIN Encoded in a GS1 DataBar (Stacked)

12.4.4   ITF-14

2 08 87511 00734 6

Figure 18. GTIN Encoded in an ITF-14

12.5 Barcodes for Products Not Sold at Retail -- Encoding DI and PI

There are three GS1 BarCode options that may be used for devices falling within this group: GS1-128, GS1 DataMatrix and GS1 DataBar. The encoding principles are the same for each barcode option, and are presented in the table below. Examples of each barcode follow the table.

Although we have included all PI from the UDI Rule here in order to be complete, you will only encode those applicable to your product. Regardless of which or how many PI you encode, encode the data elements in the relative order in which they are presented in the table below.

UDI ELEMENT	GS1 STANDARD	ENCODING PRINCIPLES
DI	GTIN	• GTIN MUST BE IN A 14-DIGIT FORMAT (*For GTIN-12 or GTIN-13: encode in 14-digit format using leading* zeros as described above) • The data syntax for the GTIN component is n2 + n14 (where n2 is the AI and n14 is the GTIN). • Begin with the **two-digit AI "01"** to indicate GTIN. • Enter the 14 numeric characters representing the **"GTIN in 14-digit format"** into the fixed-length field following the AI. • <u>EXAMPLE:</u> **01**00314141999995

MANUFACTURING / PRODUCTION DATE	AI (11)	• Begin with the **two-digit AI "11"** to indicate *Production Date*.
		• Enter the six numeric characters representing the ***Production Date* as YYMMDD** into the fixed-length field following the AI.
		   • **YY** = tens and units of the year (e.g., 2014 = 14).
		   • **MM** = number of the month (e.g., January = 01).
		   • **DD** = number of the day of the relevant month (e.g., first day = 01). (note: *a "00" value in the DD segment is not permitted by the UDI Rule*)
		• <u>EXAMPLE:</u> **11**140726

EXPIRATION DATE	AI (17)	• Begin with the **two-digit AI "17"** to indicate *Expiration Date*.
		• Enter the six numeric characters representing the ***Expiration Date* as YYMMDD** into the fixed-length field following the AI.
		   • **YY** = tens and units of the year (e.g., 2015 = 15).
		   • **MM** = number of the month (e.g., January = 01).
		   • **DD** = number of the day of the relevant month (e.g., first day = 01). (note: *a "00" value in the DD segment is not permitted by the UDI Rule*)
		• <u>EXAMPLE:</u> **17**151231

BATCH/LOT NUMBER	AI (10)	• Begin with the **two-digit AI "10"** to indicate *Batch/Lot Number*. • Enter up to 20 alphanumeric characters representing the ***Batch/Lot Number*** into the variable-length field following the AI. • <u>EXAMPLE:</u> **10**987654321gfedcba
SERIAL NUMBER	AI (21)	• Begin with the **two-digit AI "21"** to indicate *Serial Number*. • Enter up to 20 alphanumeric characters representing the ***Serial Number*** into the variable-length field following the AI. • <u>EXAMPLE:</u> **21**ABCDEFG123456789

Table M: Encoding Principles for Non-Retail, DI and PI

12.5.1   GS1-128
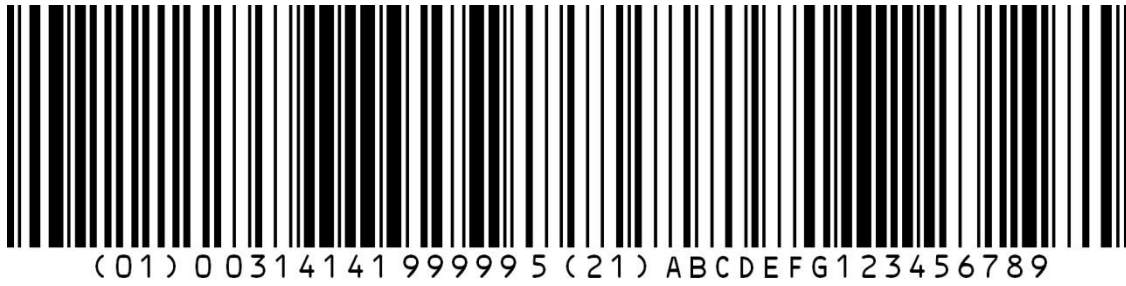
Figure 19. GTIN with Serial Number Encoded in a GS1-128

Figure 20. GTIN with Batch/Lot Number Encoded in a GS1-128

Figure 21. GTIN with Expiration Date, Batch/Lot & Serial Number Encoded in a GS1-128

12.5.2   GS1 DataMatrix

(01) 2 0887511 007346
(21) 123456789

Figure 22. GTIN with Serial Number Encoded in a GS1 DataMatrix

(01) 00314141999995
(10) 987654321GFEDCBA

Figure 23. GTIN with Batch/Lot Number Encoded in a GS1 DataMatrix

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

Figure 24. GTIN with Expiration Date, Batch/Lot & Serial Number Encoded in a GS1 DataMatrix

12.5.3   GS1 DataBar

Figure 25. GTIN Encoded in a GS1 DataBar (Limited) & Serial Number Encoded in the Composite Component

Figure 26. GTIN Encoded in a GS1 DataBar (Stacked) & Serial Number Encoded in the Composite Component

Figure 27. GTIN Encoded in GS1 DataBar (Limited), and Batch/Lot Number encoded on the Composite Component

Figure 28. GTIN Encoded in GS1 DataBar (Stacked), and Batch/Lot Number encoded on Composite Component

Figure 29. GTIN Encoded in GS1 DataBar (Stacked), and Production Date, Batch/Lot & Serial Number Encoded on Composite Component

Figure 30. GTIN Encoded in GS1 DataBar (Limited), and Expiration Date, Batch/Lot & Serial Number Encoded on Composite Component

13 GS1 HRI Rules

For the purposes of the GS1 Standards, there are two types of text that appear on a label, package, or item; Human-Readable Interpretation (HRI) and Non-HRI Text.

- *Human Readable Interpretation (HRI) is the information below or beside a barcode which is encoded in the barcode and represents the same characters as carried in the barcode.*

- *Non-HRI Text is all other text on package, label or item.*

The GS1 System requires the printing of both the GS1 BarCode and the HRI that represents all the information encoded within that barcode.

There are two categories of HRI Rules:

- General Rules that apply independent of sector, product category, or region. The General HRI Rules can be found in Section 4.13 of the *GS1 General Specifications*.

- Sector-Specific Rules which must be aligned with the General Rules. The Healthcare-specific HRI Rules can be found in Section 4.13.1 of the *GS1 General Specifications*.

This section provides the general principles articulated in the HRI Rules. For more information, consult the General Specification sections noted above.

There may be local variants for non-HRI text on the label (e.g., dates, prices) which are formatted based on local practice rather than the way the data is encoded in GS1 AIDC data carriers. In this case, the HRI associated with AIDC shall still be expressed as it is encoded in the GS1 AIDC data carrier (per Application Identifier definition).

13.1 Location

- Print the GTIN in human readable form underneath the symbol.

- If there is sufficient space to print the human readable form of the optional attribute data, print it above the symbol in proper sequence of the Application Identifiers (AI's).

13.2 Font

- Use a clearly legible font for the human-readable digits, such as OCR-B, as defined in *ISO 1073-2.*

- Reasonable alternative fonts and character sizes are acceptable provided the HRI is clearly legible.

- Use a font that is considered suitable and compatible with other printed materials.

- When necessary, ensure the font used is in accordance with applicable government laws & regulations.

13.3 Printing and Expressing the Data

- Print the data from top to bottom and left to right.

- The order of the data should be the same as encoded according to the rules in the *GS1 General Specifications.*

- Printing of both the barcode and the associated HRI may not be always be possible due to many factors such as the type of item being labeled or marked, intended use of the item, available space for marking, etc. When it is not possible to print all of the HRI, preference for printing shall be given to the GS1 Key.

- Print the data with the preceding AI's enclosed in parenthesis. (The parentheses are not part of the data and are not encoded in the barcode symbol.)

- A single AI with accompanying data is displayed on one line and is not broken into two lines.

- It is preferred that the HRI echo the data structure encoded in the barcode (whether 1D/linear or 2D/matrix). To meet specific customer needs and with customer agreement, the expiration date and lot number may be printed in another appropriate and understandable format. For example, an expiration date and lot may be written as EXP May 07 Lot 123abc."
- Print the GTIN as a single 14-digit number.

Part 5: UDI Direct Marking -- GS1 Standards for Direct Part Marking

The U.S. FDA UDI Rule requires that certain categories of medical devices for which the labeling requirement may not be sufficient must be directly marked with their UDI (e.g., devices that remain in use for an extended period of time and devices that are likely to become separated from their labeling). GS1 Standards include rules for marking a GS1 symbol directly onto an item. This part of the guideline offers key concepts from those rules, as well as references to applicable sections of the *GS1 General Specifications*, to support direct marking for UDI.

Direct marking [or Direct Part Marking (DPM) as it is called in the GS1 System] refers to the process of marking a symbol directly onto an item (as opposed to using a label or another indirect marking process). GS1 Standards include rules for marking a GS1 symbol directly onto an item. These rules define key aspects of DPM including substrate requirements, symbol dimensions, symbol quality, and symbol placement.

14 Marking Methods

There are a variety of methods for applying DPM to devices, including both intrusive methods and non-intrusive methods. The table below presents a non-exhaustive list of some currently used methods.

DPM MARKING METHODS	
INTRUSIVE MARKING *methods that remove or alter the material of the host (i.e., Subtractive Methods)*	Abrasive blast Dot peen Electro-chemical marking, coloring, or etching Engraving/milling Fabric embroidery/weaving Direct laser marking Laser shot peening Laser Inducted Surface Improvement (LISI) Gas Assisted Laser Etch (GALE) Laser Induced Vapor Deposition (LIVD)
NON-INTRUSIVE MARKING *methods that do not affect the host material, and usually involve the addition of material (i.e., Additive Methods)*	Cast, forge, mold Inkjet Laser bonding Liquid metal jet Silk screen Stencil

Table N: DPM Marking Methods

When selecting a method of marking, it is important to analyze the following considerations:

- How the marking method may affect the viability or lifetime of the device
- Finishes that cause an excess of shadowing or glare
- Surfaces that do not provide sufficient contrast - less than 20 percent difference in surface reflectance
- Safety critical parts that cannot be marked with intrusive methods
- Marking method must comply with the users requirements
- Location of the symbol should <u>not</u> be In direct air/water (streams, etc.), on sealing surfaces, or on surfaces subject to wear or exposure to heavy contact

Laser etching is recommended for small instrument marking.

15 Recommended GS1 BarCode Symbol for Direct Marking

The use of GS1 DataMatrix in direct part marking applications is endorsed by GS1 for those applications that require permanent marking for cradle-to-grave history of the part's lifecycle. Therefore, GS1 DataMatrix is the recommended symbol for UDI direct marking. Use GS1 DataMatrix if:

- The marking method will not produce an acceptable linear symbol but will produce an acceptable GS1 DataMatrix (e.g., dot peen marking and high-speed ink jet).
- A GS1 Identification Key plus attribute Element String are to be encoded.
- GS1 DataMatrix is the only symbology that will fit on the item at the application specified X-dimension.
- Low contrast signal is expected from the application.
- The use of 2D (two-dimensional) array scanners and/or vision systems are specified exclusively for the application and can read GS1 DataMatrix.

There are two basic types of non-ink based DPM:

1: those with "connected modules" in the "L-shaped" finder pattern (i.e., GS1 DataMatrix Direct Part Marking – A) created by DPM marking technologies such as laser or chemical etching, and

2: those with "non-connected modules" in the "L" shaped finder pattern (GS1 DataMatrix Direct Part Marking – B) created by DPM marking technologies such as dot peen

Due to the marking technologies and characteristics of reading, they each have varied ranges of X-Dimensions and different recommended quality criteria, and may require different reading equipment.

GS1 DataMatrix – A is suggested for the marking of small medical / surgical instruments.

16 Important Caveats

- In small instrument marking, mixed marking technologies used within the same scanning environment should be avoided to ensure highest reading performance.
- At no time should two different identification numbers be marked on a single instrument.
- Section 2.1.1.8 of the *GS1 General Specifications* provides rules and recommendations for DPM of small medical / surgical instruments for the management of instruments within the micro-logistics cycle of use, cleaning and sterilization.

Part 6: Appendices

17 Resources

Except where otherwise noted, all Resources listed below are available on the GS1 US - Healthcare *Tools & Resources* page (http://www.gs1us.org/industries/healthcare/tools-and-resources).

- U.S. FDA UDI website

- U.S. FDA GUDID Draft Guidance for Industry

- GS1 Healthcare US UDI Online Resource Site www.gs1us.org/hcudi

- *GS1 General Specifications* – Available in the Solutions Center through the GS1 US website at http://www.gs1us.org/resources/standards

- Healthcare GTIN Allocation Rules

- Healthcare Provider Global Trade Item Number (GTIN) Tool Kit

- Healthcare Supller Global Trade Item Number (GTIN) Toolkit

- Healthcare Provider Global Data Synchronization Network (GDSN) Tool Kit

- Healthcare Supller Global Data Synchronization Network (GDSN) Toolkit

- Healthcare Supller UDI Quick Start Guide

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

- EDI Quick Guide for GLN and GTIN

- A Check Digit Calculator is available at http://www.gs1us.org/resources/tools-and-services/check-digit-calculator

- Data Driver web page www.gs1us.org/resources/tools/data-driver

18 GTINs that Embed NHRIC/NDC

Pursuant to GS1 Standards, NHRICs and NDCs can be embedded into GTINs so that identification of medical/surgical and pharmaceutical products for supply chain purposes is consistent with identification of medical/surgical and pharmaceutical products for regulatory purposes. This enables manufacturers to use one identifier to help meet both regulatory and supply chain needs. In fact, manufacturers of healthcare products have been embedding NHRICs/ NDCs in their GTINs for over forty years. This chapter provides additional information about how NHRICs/NDCs are embedded into GTINs.

> *The UDI Rule terminates the use of NHRICs and NDCs on the date a device must be labeled with a UDI. Consult the chapter of this document entitled* Implications of Sunsetting NHRICs and NDCs *for recommendations about managing the transition to the NHRIC/NDC sunset.*

18.1 NHRIC/NDC Structure

The NHRIC and NDC are 10-digit identifiers comprising two segments: a *Labeler Code* and a *Product/Package Code*.

- The *Labeler Code* is a variable length identifier assigned by the FDA to identify a company that manufactures a medical device (including repackers or relabelers) or distributes a medical device (under its own name). The *Labeler Code* can be either 4- or 5-digits in length.

- The *Product/Package Code* is a variable length identifier assigned by the holder of the *Labeler Code* to identify the product. The *Product/Package Code* can be either 5- or 6-digits in length.

> *Although both segments vary in length, they will always be a combined total of 10 digits.*

18.2 GS1 Company Prefixes with NHRIC/NDC Labeler Codes

In order to facilitate the integration of NHRICs/NDCs into GTINs, GS1 US has reserved a placeholder in the *GS1 Company Prefix* numbering system that enables the *Labeler Code* to be integrated into the *GS1 Company Prefix* for medical/surgical companies. The placeholder (named the "GS1 Prefix") is **03**, and the GS1 *Company Prefix* for a medical/surgical company is simply its *Labeler Code* with an "03" appended in front. For example:

GS1 Prefix	**03**
FDA-assigned *Labeler Code*	**61414**
GS1 *Company Prefix*	**0361414**

> *In order to use a Labeler Code as a GS1 Company Prefix, manufacturers must first contact GS1 US to have a GS1 Company Prefix that embeds their Labeler Code assigned to the company.*

18.3 Embedding NHRICs/NDCs into GTINs

GTINs include a segment for Company Prefix and a segment for Item Reference. When embedding NHRICs/NDCs into GTINs, the NDC *Labeler Code* is integrated into the Company Prefix (as described above), and the NHRIC/NDC *Product/Package Code* is used to populate the Item Reference segment. The figure below illustrates how an NHRIC/NDC is embedded into a GTIN-14.
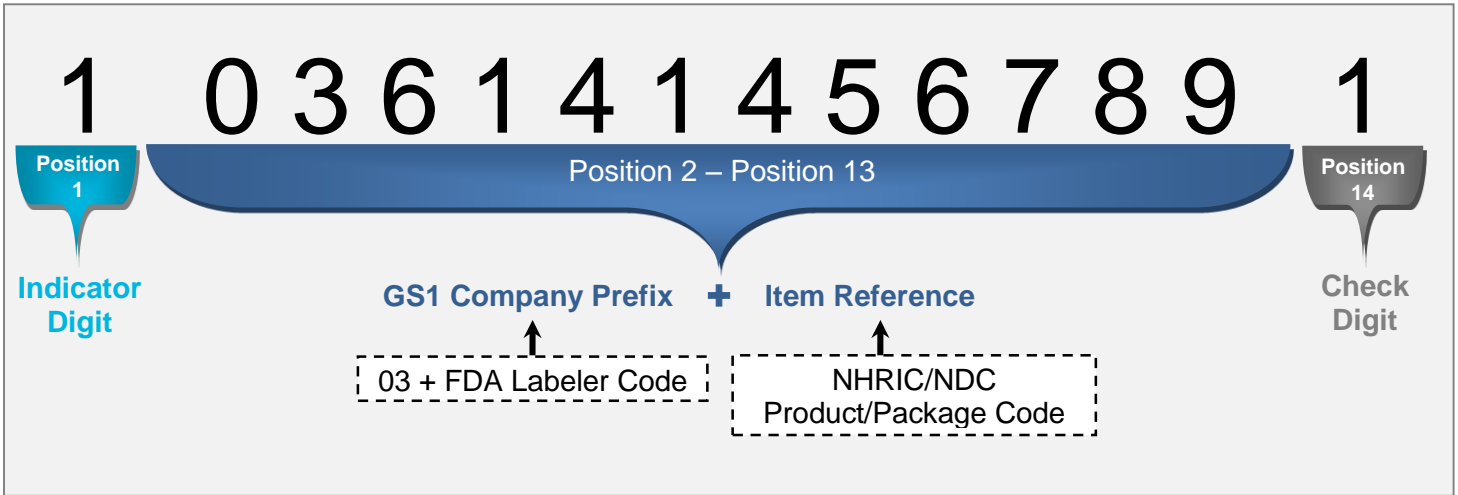
Figure 31. Segments of a GTIN-14 that embeds an NHRIC/NDC (based on the hypothetical GTIN "10361414567891")

Medical/surgical companies may have more than one GS1 Company Prefix (e.g., one GS1 Company Prefix that integrates their NHRIC Labeler Code, and other GS1 Company Prefixes that do not). Those companies will need to use the GS1 Company Prefix that integrates their Labeler Code when assigning GTINs that embed NHRICs and/or NDCs. Otherwise, they may use whichever GS1 Company Prefix they prefer when assigning GS1 Identification Numbers.

18.4 Examples

18.4.1 GTIN-12 Embedding NHRIC/NDC

The table below provides a color-coded example of a hypothetical GTIN-12 that embeds an NDC, and a key explaining how each digit is populated.

EXAMPLE OF A GTIN-12 WITH AN NDC EMBEDDED
showing how to populate each digit (color-coded to coordinate with the GTIN-12 shown)

GTIN-12	3	1	2	3	4	5	6	7	8	9	0	6
Digit/Position	1	2	3	4	5	6	7	8	9	10	11	12

POSITION 1	GS1 Prefix "3"
POSITION 2 THROUGH 11	NDC *Labeler Code* as assigned by FDA <u>plus</u> NDC *Product/Package Code* created by the manufacturer (Although the length of the *Labeler Code* and the *Product/Package Code* vary, they will always be a combined total of 10 digits.)
POSITION 12	Check Digit

Table O: Populating the 12 digits of a GTIN-12 with an NDC embedded (using hypothetical GTIN 312345678906)

18.4.2   GTIN-14 Embedding NHRIC/NDC

The table below provides a color-coded example of a hypothetical GTIN-14 that embeds an NDC, and a key explaining how each digit is populated.

EXAMPLE OF A GTIN-14 WITH AN NDC EMBEDDED showing how to populate each digit (color-coded to coordinate with the GTIN-14 shown)														
GTIN-14	1	0	3	6	1	4	1	4	5	6	7	8	9	1
Digit/Position	1	2	3	4	5	6	7	8	9	10	11	12	13	14

POSITION 1	Indicator Digit (numeric value from 1 to 9)
POSITION 2 AND 3	GS1 Prefix "03"
POSITION 4 THROUGH 13	NDC _Labeler Code_ as assigned by FDA <u>plus</u> NDC _Product/Package Code_ created by the manufacturer (Although the length of the _Labeler Code_ and the _Product/Package Code_ vary, they will always be a combined total of 10 digits.)
POSITION 14	Check Digit

Table P: Populating the 14 digits of a GTIN-14 with an NDC embedded (using hypothetical GTIN 10361414567891)

19 Introduction to Data Driver

Data Driver® can help medical device manufacturers prepare for pending FDA Unique Device Identification (UDI) regulatory requirements, support federal and state pharmaceutical traceability initiatives, and also meet supply chain partner product identification (GTIN) requirements.

- **Easily create GS1-128 and GS1 DataMatrix* barcodes:** Define GTINs for your products with multiple data carriers

- **Data Driver is your company's private GTIN and GLN database:** No one else can view or modify your data

- **No technical knowledge is required:** Data Driver guides you with simple step-by-step instructions and helpful resources

- **Add extended data to your GTINs:** Lot/batch number, serial number, production data, and expiry date

- **Make a mistake? No problem:** You can easily edit your product information

- **Manage your GTINs:** Manage the lifecycle of your GTINs with new and revised GTIN statuses — Reserved, In Use, and Available

- **Create Product Sales Sheets and Product Summary Sheets for your customers**

Only print specifications for GS1 DataMatrix barcode. The image created is for illustration purposes and the user should not use the image for printing.

Data Driver is an exclusive benefit of a Partner Connections membership, yours when you license a GS1 Company Prefix from GS1 US. Get your barcodes right the first time and start using Data Driver today!

For more information contact:
   Member Support
   T +1 937.435.3870
   E **info@gs1us.org**

To learn more, visit:
   www.gs1us.org/datadriver

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IAPMO

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