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GS1 Healthcare US[®]

Implementation Guideline

Applying the GS1 System of Standards for U.S. FDA Unique Device Identification (UDI)

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About GS1

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 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 (EPC®)-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, and 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 help 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.

Document Summary

Document Item	Current Value
Document Title	Implementation Guideline: Applying the GS1 System of Standards for U.S. FDA UDI
Date Last Modified	January 3, 2022
Document Description	The purpose of this document is to provide sufficient information and guidance to support implementation of GS1 Standards for U.S. FDA UDI.

Log of Changes

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R1.1 – Sept 14 2014	Release/publication
R2.0 – Apr 11, 2019	<ul style="list-style-type: none"> • Updated Template & Section Numbering • Added Document Symbol Legend • Part 1: Updates throughout; Added <ul style="list-style-type: none"> ○ 1.4 GS1 Company Prefix ○ 1.6.5 Barcode Scanners • Part 2: Updates throughout and to GTIN data structure details; Added <ul style="list-style-type: none"> ○ 2.1.2. Family of Data Structures ○ 2.2. Need to Know ○ 2.3 Determining Which GTIN Structure to Use for Your Device ○ 2.3.1 Answer the following questions for each product ○ 2.3.1-1 Table: Barcode Options Based on Barcode Application ○ 2.4.2 GTIN-13 Section ○ 2.5 Sharing and/or Storing your DI Information ○ 2.5.1 Converting the GTIN Structure to a storable/sharable format. • Part 3: Updates throughout; Added <ul style="list-style-type: none"> ○ 3.1 Specification of the order of Application Identifiers ○ 3.1.3. General Guidance for Encoding AIs into GS1 Barcode ○ 3.1.4 Understanding the AI Syntax • Part 4: Updates throughout; Added <ul style="list-style-type: none"> ○ 4.1 Overview of GS1 Barcodes Section ○ 4.2 Title Updated and Important Note ○ 4.4.3-1 Figure: General Guidance for HRI Placement • Part 5: Updates throughout; Added <ul style="list-style-type: none"> ○ 5.2-1 Table: GS1 Symbol Specification Table • Part 6: Updates throughout; Added <ul style="list-style-type: none"> ○ 6.3 Introduction Data Hub • Part 7: Added Glossary of Terms and Definitions
R2.1 – June 28, 2019	GS1 Barcode images updated throughout
R2.2 – October 29, 2019	GS1 Barcode images updated throughout
R2.3 – January 3, 2022	Updated information about NHRIC/NDC codes and GTINs



Note: As with all GS1 Standards and solutions, this *Implementation Guideline* is voluntary, not mandatory. It should be noted that use of the words “must” and “require” throughout this document relate exclusively to technical recommendations for the proper application of the standards to support the integrity of your implementation.



Part 1: Preface

1.1. Introduction

On September 24, 2013, the United States Food and Drug Administration (FDA) published a rule¹ 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 a U.S. FDA database called the Global Unique Device Identification Database (GUDID). The GUDID provides critical information about medical devices, and the UDI is the key for obtaining device information from the GUDID.

GS1 is an FDA-Accredited Issuing Agency for UDI, and GS1 Standards are authorized for use in implementing the requirements of the U.S. FDA UDI Rule. This Guideline was prepared by *GS1 Healthcare US*[®] to assist U.S. medical device trading partners implementing the U.S. FDA UDI Rule using GS1 Standards. To that end, this document provides detailed guidance on how to apply GS1 Standards for U.S. FDA UDI.

 **Important:** 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.

 **Important:** For the U.S. FDA rule, compliance schedule, and various U.S. FDA UDI resources, refer to this webpage:
www.fda.gov/medicaldevices/deviceregulationandguidance/uniquedeviceidentification/

1.2. Document Symbol Legend

Throughout this document, you will find tips on best practices and notes containing additional information. The icons listed below identify the kind of information being presented.

SYMBOL	MEANING
	Indicates a reminder or important note.
	Indicates an informational note.
	Indicates a <i>very</i> important comment or note.

¹ For information about the rule, see the United States Department of Health and Human Services. Food and Drug Administration (September 2013). *Final Rule – Unique Device Identification System*. 78 FR 58785. Retrieved on November 3, 2018 from:

<https://www.federalregister.gov/documents/2013/09/24/2013-23059/unique-device-identification-system>

1.3. Document Information

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.

This version R2.0 has been updated to include new information announced by the U.S. FDA. Additional information from U.S. FDA comes in the form of Draft Guidance, Final Guidance, extensions or modifications to aspects associated with some UDI requirements. Please refer to the U.S. FDA UDI website for more information on these updates.

www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/default.htm

1.3.1. 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 U.S. FDA UDI Rule. This Guideline does not provide any guidance or advice regarding regulatory compliance.

1.3.2. Audience

This Guideline was written primarily for manufacturers/suppliers. Nonetheless, it provides basic information that may be useful to the entire healthcare supply chain from the label printer to the healthcare provider for understanding the application of GS1 Standards for U.S. FDA UDI.

1.3.3. Scope

This Guideline identifies the GS1 identification and barcode standards that correlate to U.S. FDA UDI Rule requirements, and explains how to implement these standards within the context of the U.S. FDA UDI Rule. **It does not provide any guidance or advice regarding regulatory compliance.** Federal requirements for unique medical device identification in the U.S. are specified in the U.S. FDA UDI Rule and subsequent FDA Guidance(s).

! **Important:** 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 (regulatory or quality) for more specific information about current statutory and regulatory requirements applicable to your company and products.

This document covers the following topics:

Table 1.3.3-1: Elements of the U.S. FDA UDI Rule with corresponding GS1 Standard(s)

ELEMENTS OF THE U.S. FDA UDI RULE	APPLICABLE GS1 STANDARD(S)
DEVICE IDENTIFIER (DI)	GS1 Global Trade Item Number® (GTIN®)
PRODUCTION IDENTIFIERS (PI)	GS1 Application Identifiers (AIs)
REPRESENTATION OF UDI IN AIDC AND EASILY READABLE PLAIN TEXT FORMAT	GS1 Barcodes and Human Readable Interpretation (HRI)
DIRECT MARKING UDI ON DEVICES	GS1 Rules for Permanently marked items
GUDID DATA SUBMISSION	GS1 Global Data Synchronization Network™ (GDSN®)

1.3.4. Normative References

This implementation 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 – 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

1.3.5. Additional References

This document is a companion to or further supported by the following GS1 Healthcare US documents:

- o *Healthcare Provider GTIN Toolkit*
- o *Healthcare Supplier GTIN Toolkit*
- o *Healthcare Provider GDSN Toolkit*
- o *Healthcare Supplier GDSN Toolkit*
- o *Healthcare Supplier U.S. FDA UDI Quick Start Guide*
- o *Transitioning to GS1 Standards in the U.S. for UDI*
- o *Standards Guidance for Assigning Device Identifiers Using Global Trade Item Numbers*
- o *UDI Frequently Asked Questions*
- o *GDSN for the FDA Global Unique Device Identifier Database (GUDID) Implementation Guide*
- o *Leveraging GDSN for the FDA Global Unique Device Identifier Database (GUDID) Implementation Guideline*

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 either the GS1 US (www.gs1us.org) or GS1 (www.gs1.org) websites.

1.4. Overview of the GS1 Standards Used

This section provides a brief definition of each GS1 Standard used in this Guideline.

1.4.1. GS1 Company Prefix

GS1 Company Prefixes serve as the foundation for creating any GS1 Identifier. GS1 Company Prefixes are licensed from GS1 member organizations by Brand Owners (aka Labelers). Once licensed, the prefix is used by the Brand Owner to create Global Trade Item Numbers (GTINs) that serve as the DI portion of the UDI. The GS1 Company Prefix is also used to create other GS1 Identifiers (e.g., Global Location Number (GLN), Serial Shipping Container Codes (SSCC) etc.) as needed. In the United States, two types of prefixes are provided under one licensing agreement, the GS1 Company Prefix and the U.P.C. Company Prefix.

1.4.1.1 GS1 Company Prefix: A globally unique number assigned to a company by GS1 US which, when used in its' entirety, serves as the foundation for generating GS1 Identifiers (GTIN-13 or GTIN-14 specifically when referring to product identifiers). GS1 Company Prefixes are assigned in varying lengths depending on the company's needs.

1.4.1.2 U.P.C. Company Prefix: A globally-unique number assigned to a company by GS1 US which, when used as assigned, serves as the foundation for generating only a GTIN-12 for product identification. U.P.C. Company Prefixes vary in length depending on the company/organization's needs.

! **Important:** Brand Owners/Labelers may have more than one GS1 Company Prefix.

1.4.2. Global Trade Item Number (GTIN)

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 (a.k.a. "labeler" in U.S. FDA terminology) 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.

1.4.3. GS1 Data Carriers

Manufacturers mark their products with the applicable GTIN so that they can be properly identified as they move through the supply chain. Manufacturers encode the GTIN into GS1 data carriers [i.e., barcodes and/or GS1 Electronic Product Code (EPC®)-enabled radio frequency identification (RFID) tags], and then affix a data carrier to each product. GS1 Data Carriers provide *machine-readable representations* of that product specific data to 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)]. To accommodate a variety of environments and applications, the GS1 System supports several data carriers and AIDC technologies.

1.4.4. GS1 Application Identifiers

In addition to a GTIN, there may be certain item-specific or attribute 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. Each AI is a two, three, or four-digit numeric code. There are ~150 AIs, including an AI for each GS1 identification key as well as AIs for various types of identifier-specific (attribute) information (e.g., expiration date; lot number; batch number). Each data element in a barcode is preceded by its AI. Some GS1 Barcodes are capable of carrying AI information beyond the GTIN and others are not.

1.4.5. GS1 Standards for Permanently Marked Items (Direct Part Marking)

Direct Part Marking (DPM) [or Permanently Marked Items as it is called 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). Three methods exist for the permanent marking of items.

1. **Direct Part Marking (DPM):** The process of marking a symbol directly onto an item using an intrusive or non-intrusive method instead of applying a label or using another indirect marking process.
2. **Durable Labelling:** The process of marking a symbol onto a label that is intended to permanently stay on the trade item.
3. **Durable RFID-Tagging:** The process of applying an RFID-tag that is intended to permanently stay on the trade item.

1.4.6. 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®. 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.

! **Important:** With respect to the U.S. FDA UDI Rule, the GDSN is a voluntary standard that can serve as an option for meeting the requirements for uploading GTINs and other required data elements about a device to the U.S. FDA’s GUDID. See section 4.4 for more details.

GDSN Data Pools can register data on behalf of the manufacturers using the HL7 Structured Product Labeling (SPL) standard. The GDSN to GUDID process has been tested and proven in a pilot with the U.S. FDA GUDID and has already been selected by a number of suppliers.

For more information on the GDSN and its use for uploading data to GUDID refer to:
https://www.gs1.org/docs/gdsn/GS1_GDSN_GUDID_Implementation_Guide.pdf

! **Important:** The U.S. FDA GUDID is an external database to the GDSN and U.S. FDA does not subscribe to a certified GDSN data pool. The act of registering the manufacturer’s data in the GUDID is a value added service any certified GDSN data pool may choose to offer their customers. Neither GS1, nor GS1 MOs, have any responsibility or liability for such data since it does not travel through any GS1 services or networks. The correct transmission of the data is a service of the data pools for which they are responsible.

1.5. Overview of the U.S. FDA UDI Rule

The U.S. FDA 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 U.S. FDA database called the GUDID. The GUDID will provide critical information about medical devices, and the UDI will provide the key for obtaining device information from the GUDID.

According to the U.S. FDA, "A "labeler" is any person who causes a label to be applied to a device, or who causes the label of a device to be modified, with the intent that the device will be commercially distributed without any subsequent replacement or modification of the label. The addition of the name of, and contact information for, a person who distributes the device, without making any other changes to the label is not a modification for the purposes of determining whether a person is a labeler. In most instances, the labeler would be the device manufacturer, but the labeler may be a specification developer, a single-use device reprocessor, a convenience kit assembler, a repackager, or a relabeler."²

1.5.1. 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 U.S. 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) 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

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**.

For additional information on the form and content of the UDI please reference [Unique Device Identification System: Form and Content of the Unique Device Identifier \(UDI\) Draft Guidance](#) prepared by the U.S. FDA.

² Retrieved on November 18, 2018 from U.S. Food and Drug Administration UDI Basics Page Last Updated: 09/27/2018
<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/UDIBasics/default.htm#labelers>

Because GS1 is a U.S. 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.

Table 1.5.1-1: UDI Components with Corresponding GS1 Standards

UDI SEGMENT WITH CORRESPONDING GS1 STANDARD(S)	
DEVICE IDENTIFIER (DI)	AI (01) Global Trade Item Number (GTIN)
PRODUCTION IDENTIFIER (PI)	GS1 Application Identifiers (AIs):
PRODUCTION/MANUFACTURING DATE	AI (11)
EXPIRATION DATE	AI (17)
BATCH/LOT NUMBER	AI (10)
SERIAL NUMBER	AI (21)



NOTE: This guideline covers those PI relevant to the U.S FDA UDI Rule. Refer to Part 3 “UDI Production Identifiers (PI) – GS1 Application Identifiers” for more detail. For information on all GS1 Application Identifiers, reference the [GS1 General Specifications](#).

1.5.2. UDI Labeling

The U.S. FDA UDI Rule requires that UDIs be presented on device labels in both easily readable plain text 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 a variety of different barcodes symbologies 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.” Refer to table 2.3.1-1 for more details on GS1 Barcode options for various applications.

1.5.3. 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 permanently marked item (reference section 1.4.5). All three methods of permanently marking items can be applied to medical devices. GS1 Standards for permanently marked items are presented in more detail in Part 5 of this Guideline.

For more detail on the U.S. FDA requirements for Direct marking please refer to the following U.S. FDA document: [Unique Device Identification: Direct Marking of Devices - Guidance for Industry and Food and Drug Administration Staff](#)

1.5.4. Global Unique Device Identification Database (GUDID)

Whenever a device must bear a UDI, the U.S. FDA UDI Rule requires the labeler of that device to submit information concerning the device to the U.S. FDA to facilitate the rapid identification of the device and the labeler, and to provide links to other FDA data. The 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.

For more information on GUDID, the U.S. FDA has published a [Global Unique Device Identification Database \(GUDID\): Guidance for Industry](#).

1.6. Background Concepts

This section provides background concepts.

1.6.1. U.S. 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 U.S. FDA regulations. The GTIN is a global identifier used to uniquely identify products for a variety of purposes both regulatory and supply chain. Pursuant to GS1 Standards, manufacturers of healthcare products can request a GS1 Company Prefix that aligns with their U.S. FDA Labeler Code so they can assign GTINs. This enables the identification of medical/surgical and pharmaceutical products for supply chain purposes to be consistent with identification of medical/surgical and pharmaceutical products for regulatory purposes. In fact, manufacturers of healthcare products have been aligning their NHRICs/ NDCs in their GTINs for over forty years. (Refer to the [Appendix](#) of this document for more detailed information about how NHRICs/NDCs are embedded into GTINs.)

However, the U.S. FDA has announced that it will be phasing out NHRICs and NDCs on device labels and device packaging. 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 labelers who have been assigned a U.S. FDA labeler code to facilitate the use of NHRIC/NDC may continue to use their assigned U.S. FDA labeler code to assign UDIs to devices under the GS1 System, so long as they have been granted an extension by the U.S. FDA for continued use of the labeler code. Please see the "[Enforcement Policy on NHRIC and NDC Numbers assigned to Devices: FDA Guidance for Industry](#)" for additional guidance on requesting "continued use" and enforcement dates. Any Labeler Code aligned with a GS1 Company Prefix that has not been granted continued use by the U.S. FDA will be returned to the regulatory issuing agency and therefore may be reassigned.



Very Important: 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 aligns its Labeler Code submit a request to the U.S. FDA for continued use of their Labeler Code. For details on how to embed an NHRIC/NDC into GS1 GTIN's, refer to part 6 Section, 6.2.

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).

1.6.2. GTIN Overview for Assigning vs. Encoding vs. Storing

- **Assigning** – 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.
- **Encoding** – GS1 Barcode standards prescribe how GTINs are to be encoded in each GS1 Barcode.
- **Storing** - When sharing or storing GTINs, the GTIN should be kept in its entirety. Always ensure any applicable leading zeros, indicator digit, and check digit are included. 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.

For additional information on assigning, encoding, and storing GTINs, please refer to Part 2 of this document.

1.6.3. Assigning/Allocating Serial Numbers

The GS1 Application Identifier (21) indicates that the GS1 AI data field contains a serial number. The GS1 General Specifications 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 one to 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 text field so that leading zeros are not inadvertently stripped off.

Although barcodes can accommodate any one to 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 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 one and 20 characters.

1.6.4. Data Format for Serial Number Fields in Databases

Serial numbers should be stored 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.

1.6.5. Barcode Scanners

GS1 DataMatrix requires imaging-based scanners to be read, whereas, GS1-128 linear barcodes are read with imaging-based scanners or traditional linear barcode scanners. While industry has seen a significant shift toward versatile scanners capable of reading both linear/1 dimensional and 2 dimensional barcodes, healthcare trading partners who are still using linear based scanner technology may not be able to successfully scan the GS1 DataMatrix. As a result, it may be important for supply chain partners to communicate prior to implementing GS1 DataMatrix to ensure that the appropriate scanners are in place.

1.6.6. 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](#). 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.

1.6.7. 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 [Responding to Troublesome Barcodes](#) 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.

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

The U.S. FDA 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.

2.1 Global Trade Item Number

2.1.1 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:** When using GS1 Standards to implement the U.S. FDA UDI Rule, the GTIN is used to represent the Device Identifier (DI) portion of the UDI.

2.1.2 Key Components

- **Indicator Digit:** The Indicator Digit identifies packaging level in order to define packaging hierarchy of a product with the same Item Reference. The field consists of a numeric value from 1 to 9 and is only used in GTIN-14.
- **GS1 Company Prefix:** A globally unique number issued to a company by a 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. For GTIN-12, a U.P.C. Company Prefix is used.
- **Item Reference:** A number assigned by the user to identify a trade item. The Item Reference varies in length as a function of the GS1 Company Prefix length. Although GS1 US discourages the practice of assigning intelligence to the Item Reference, it remains the responsibility of the Brand Owner to ensure the uniqueness of the Item Reference.
- **Check Digit:** A one-digit number calculated from the preceding digits of the GTIN used to assure data integrity.

! **Important:** The application and use of each segment can vary depending in the GTIN structure being used (e.g., GTIN-8, GTIN-12, GTIN-13, or GTIN-14). The specific rules are defined within the [GS1 General Specification](#).

2.1.3 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.

Note: The GTIN-8 is the only GTIN that can be used in EAN-8 barcodes and the use of GTIN-8 is usually 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.s) 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.

2.2 Need to know

Before beginning to assign GTINs to your product, it is important to know if you are creating a GTIN-12, GTIN-13 or GTIN-14 for that item. Medical devices in the United States often use a GTIN-12 so they can cross retail point of sale with a UPC-A barcode. All GTIN structures are stored in databases and systems (including GUDID) as a 14-digit number. When sharing or storing a 12-digit GTIN, add leading zeros to total 14 digits. For example, a GTIN-12 would be stored as a 14-digit number by right justifying and adding two zeroes at the beginning of the number string.

Class II and Class III medical devices generally use GTIN-12 in 14-digit format, GTIN-13 in 14-digit format or GTIN-14 so that production information (PI) can be included in the barcode as required by the U.S. FDA UDI Rule.

 **Important:** Per the U.S. FDA and specific to Class I medical devices, reference:

- **From Search of the Federal Register for Sept. 24, 2013³:**

“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 identifier⁴**

“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”.

³ Retrieved on November 3, 2018 from www.federalregister.gov/documents/2013/09/24/2013-23059/unique-device-identification-system

⁴ Retrieved on November 3, 2018 from www.gpo.gov/fdsys/pkg/CFR-2014-title21-vol8/pdf/CFR-2014-title21-vol8-sec801-30.pdf

2.3 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 a variety of 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 Part 4 of this guide for more on GS1 Barcodes.

2.3.1 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, as defined by the U.S. FDA⁵, is the lowest level of a trade item grouping to be marked with a UDI, should be a GTIN-12 or GTIN-13 only.

⁵ Global Unique Device Identification Database (GUDID): Guidance for Industry and Food and Drug Administration Staff, Document issued on June 27, 2014 Retrieved on November 3, 2018 from <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM369248.pdf>

Table 2.3.1-1: GS1 Barcode and GTIN structure options based on Barcode Application Environment and UDI Information to be Encoded

Question 1: <i>Which U.S. FDA Product Classification is your device?</i>	Question 2: <i>Which scanning environment applies?</i>	Question 3: <i>Is production information (PI) required in the barcode?</i>	Question 4: <i>Which GS1 barcode will you use?</i>	GTIN Structure Options
CLASS I	Retail	No	UPC-A EAN-13	GTIN-12* GTIN-13*
	Non-Retail	No	EAN/UPC GS1-128 GS1 DataMatrix GS1 DataBar® ITF-14	GTIN-12 or GTIN-13 GTIN-12 (in 14-digit format) GTIN-13 (in 14-digit format) GTIN-14
	Non-Retail	No/however, if being provided voluntarily	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	Yes	UPC-A or EAN-13 (for retail scanning) + <i>one of the following:</i> GS1 DataMatrix GS1 DataBar GS1-128	GTIN-12 + GTIN-12 (in 14-digit format) Or GTIN-13 + GTIN-13 (in 14-digit format)
	Non-Retail	Yes	GS1-128 GS1 DataMatrix GS1 DataBar ITF-14	GTIN-12 (in 14-digit format) GTIN-13 (in 14-digit format) GTIN-14

! **Important:** When following GS1 Standards, the Primary DI, which, as defined by the U.S. FDA, 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 Figure 2.5.1-1 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 GTIN-14 section for more information on that 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

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

For a list of Data Hub features and capabilities, see the [Appendix](#) of this document or visit <https://www.gs1us.org/tools/gs1-us-data-hub> for more information.

2.4 Family of GTIN Data Structure

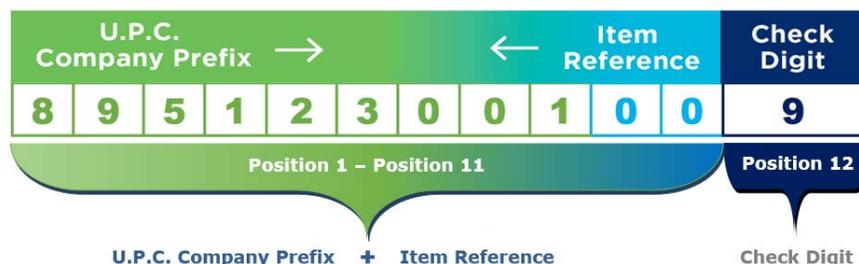
2.4.1 GTIN-12 Structure

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 or 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:** Pursuant to GS1 Standards, manufacturers of healthcare products can request a GS1 Company Prefix that aligns with their U.S. FDA Labeler Code so they can assign GTINs. For a GTIN-12 that uniquely identifies an NDC/NHRIC, the assigned U.P.C. Company Prefix may be 5 or 6-digits. Upon assignment (if available), the requested U.P.C. Company Prefix will begin with "3" and the remaining digits of the U.P.C. Company Prefix will align with the U.S. FDA assigned NDC/NHRIC Labeler Code. Refer to Part 6 Section 6.2 on NHRIC/NDC for additional information.
2. **Item Reference:** A number assigned by the licensee 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 aligns with an NDC/NHRIC, the Item Reference segment is usually 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, transferred, or keyed manually. 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 2.4.2 for GTIN-13 structure.

Figure 2.4.1-1: Segments of a GTIN-12 (based on the U.P.C. Company Prefix "895123001" and hypothetical GTIN "895123001009")



2.4.2 GTIN-13 Structure

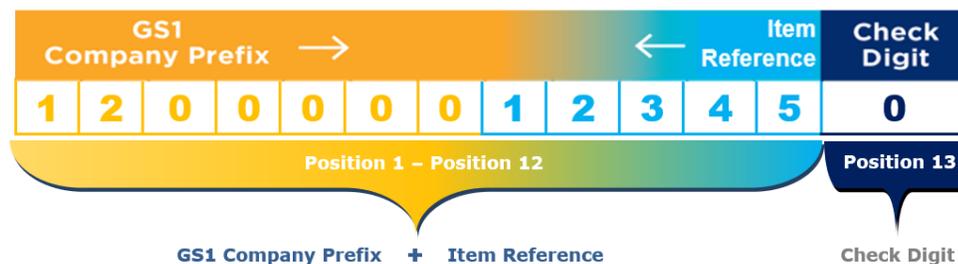
The GTIN-13 is the only GTIN that can be used in EAN-13 barcodes. Each GTIN-13 is a numerical string comprising three distinct segments. The three segments within a GTIN-13 are:

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. **NOTE:** 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 licensee 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, transferred, or keyed manually. 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 1-9, 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 2.4.1 for GTIN-12 structure.

Figure 2.4.2-1: Segments of a GTIN-13 (based on the GS1 Company Prefix "120000" and hypothetical GTIN "1200000123450")



2.4.3 GTIN-14 Structure

The entity known as a “trade item grouping” is a stable homogeneous packaging of identical trade items. For example, a single trade item packaged in a box of 5 and 10 of those 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. The GTIN-14 maintains uniqueness through the assignment of a different indication digit at each packaging level and incorporates the same Company Prefix and Item Reference (digits 2-13) of the contained trade item 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 signifies a different packaging level. The indicator is a digit with a value of 1 through 8. It is the first element in the construction of a GTIN-14 and 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:** for information on NDC/NHRIC that align with the GS1 Company Prefix, refer to Section 6.2.)
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:** For a GTIN-14 that aligns with an NDC/NHRIC, the Item Reference segment is usually 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, transferred, or keyed manually. 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 2.4.3-1: Segments of a GTIN-14 (based on the GS1 Company Prefix “0895123001”, item reference of contained items “00”, resulting in hypothetical GTIN-14 “20895123001003”)



2.5 Sharing and/or Storing GTINs

GTINs should be stored and shared in 14-digit format. When sharing or storing GTINs, the GTIN should be kept in its entirety including any applicable leading zeros, indicator digit, and check digit.

Figure 2.5-1: 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.

2.5.1 Converting the GTIN structure to a storable/sharable format

GTINs should 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.

Figure 2.5.1-1: 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

Figure 2.5.1-2: 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



Very Important: A GTIN-12 or a GTIN-13 remains a GTIN-12 or GTIN-13 whether it is in its original 12/13-digit format or represented in a 14-digit format using leading zero(s). Technically speaking, when you left fill a GTIN-12/GTIN-13, it is called a “GTIN-12/GTIN-13 in a 14-digit format.” It is not a GTIN-14. Therefore, when a product needs to be marked with a UPC-A, it should be assigned a GTIN-12 (not a GTIN-14) in



Very Important, cont.: 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. Furthermore, when a product needs to be marked with an EAN-13, it should be assigned a GTIN-13 (not a GTIN-14) for the same reason.

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.

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 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.

3.1 Introduction to GS1 Application Identifier (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 150 AIs in total, including one AI for each GS1 Identification Number, also referred to as GS1 Keys (e.g., GTIN, GLN, SSCC, etc.), as well as numerous AIs for identifier-specific (attribute) information (e.g., expiration date; batch/lot number; serial number; etc. for a product). The complete definitions for all of the Application Identifiers reside in the [GS1 General Specifications](#).



Hint: 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.

3.1.1 GS1 Specification of the order of Application Identifiers

When encoding GS1 Application Identifiers to a GS1 Barcode, it is important to know that there is a recommended order to how they are presented. GS1 Key (e.g., GTIN) is always presented first, followed by any fixed length AI element(s) (e.g., manufacturing/production date, expiration date) and then followed by any variable length element(s) (e.g., batch/lot, serial number, etc.). Within the predefined element strings or the following non-predefined element strings, where there is more than one, the sequence of element strings should be at the discretion of the creator.

Example: GS1 Key + Fixed Length AI(s) + Variable Length AI(s)

3.1.2 AI's associated with the Production Identifiers for U.S. FDA UDI

GS1 Standards and the U.S. FDA UDI Rule allow for additional production information to be included in the barcode however, it is strongly recommended that any of these UDI relevant AIs come first in the data string before non-UDI relevant AIs. Refer to [Unique Device Identification System: Form and Content of the Unique Device Identifier \(UDI\) draft guidance](#).

The AI's associated with the production identifiers in the U.S. FDA UDI Rule are:

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



Important: The DI portion of a U.S. FDA UDI is represented by GTIN with its associated AI (01). As explained in the Overview of the U.S. FDA Section on page 12, one or more of the above AIs may be encoded in the GS1 barcode as required by the rule.

3.1.3 General Guidance for Encoding AIs into GS1 Barcode

When encoding a barcode, each data element in the barcode is preceded by its AI to create an element string. The AI defines data type and field size that follows it. For example, the AI for GTIN it is (01). Thus, when "(01)" appears first 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 0860000 92399 0 (17) 250101

Figure 3.1.3-1: GS1 DataMatrix with AI (01) for GTIN and AI (17) for Expiration Date



VERY IMPORTANT: 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.

3.1.4 Understanding the AI Syntax

For purposes of understanding the following details about the structure of UDI relevant AIs refer to the following:

- N = numeric digit
- X = any allowable character as defined in the *GS1 General Specification*
- N3 = 3 numeric digits, fixed length
- N..3 = up to 3 numeric digits
- X..3 = up to 3 allowable characters as defined in the *GS1 General Specification*

NOTE: For more information on Application Identifiers, allowable characters, invalid pairs of element strings, etc. please refer to the [GS1 General Specifications](#).

3.1.5 Manufacturing/Production Date: AI (11)

The GS1 Application Identifier (11) indicates that the data field contains a production date. Production Date can also be referred to as the manufacturing date. The production date is the production or assembly date determined by the manufacturer. The date may refer to the trade item or to items contained. The data is numeric, and the length is fixed at six numeric characters with the structure YYMMDD.



(01) 2 0860000 92399 0 (11) 190601

Figure 3.1.5-1: 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., 2024 = 24).
 - **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*).

GS1 Application Identifier	Production date		
	Year	Month	Day
1 1	N ₁ N ₂	N ₃ N ₄	N ₅ N ₆

- **N** = numeric digit
- EXAMPLE: **11140331**



Important: Per the UDI Rule, the standardized date format of YYYY-MM-DD does not apply to how dates are encoded in a GS1 Barcode. The standardized date format only applies to the text (non-barcode) format of dates on labels/packages. Thus, the YYMMDD format used to encode the AI is permissible. See section 4.4 and Figure 4.4-1 for further explanation.

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

3.1.6 Expiration Date: AI (17)

The GS1 Application Identifier (17) indicates that the data field contain an expiration date. The expiration date is the date that determines the limit of consumption or use of a product/coupon. Its meaning is determined based on the trade item context (e.g., for pharmaceutical products, it will indicate the possibility of an indirect health risk resulting from the ineffectiveness of the product after the date). Expiration Date is often referred to as expiry date or maximum durability date. The data is numeric, and the length is fixed at six numeric characters with the structure YYMMDD.



(01) 2 0860000 92399 0 (17) 250101

Figure 3.1.6-1: 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., 2025 = 25).
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**).

GS1 Application Identifier	Expiration date		
	Year	Month	Day
1 7	N ₁ N ₂	N ₃ N ₄	N ₅ N ₆

- N = numeric digit
- **EXAMPLE:** **17150331**



Important: Per the UDI Rule, the standardized date format of YYYY-MM-DD does not apply to how dates are encoded in a GS1 Barcode. The standardized date format only applies to the text (non-barcode) format of dates on labels/packages. Thus, the YYMMDD format used to encode the AI is permissible. See Section 4.4 and Figure 4.4-1 for further explanation.

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

3.1.7 Batch/Lot Number: AI (10)

The GS1 Application Identifier (10) indicates that the data field contains a batch or lot number. The batch or lot number associates an item with information the manufacturer considers relevant for traceability of the trade item to which the element string is applied. The data may refer to the trade item itself or to items contained. Batch/Lot Number is typically assigned at the point of manufacturer using, for example, a production lot number, a shift number, a machine number, a time or an internal production code. The data is alphanumeric, and the length is variable with a maximum of 20 alphanumeric characters.



Figure 3.1.7-1: 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 + X..20 (where N2 is the **AI** and X..20 is the **Batch/Lot Number up to 20 characters**).

GS1 Application Identifier	Batch or lot number
1 0	X ₁ —————> variable length —————> X ₂₀

- X = any character from 7.11-1 of the [GS1 General Specifications](#)
- EXAMPLE: **10A1B2C3D4E5**

3.1.8 Serial Number: AI (21)

The GS1 Application Identifier (21) indicates that the data field contains a serial number. A serial number is assigned to an entity for its lifetime. When combined with a GTIN, a serial number uniquely identifies a specific individual item. The data is alphanumeric, and the length is variable with a maximum of 20 alphanumeric characters.*



(01) 2 0860000 92399 0 (21) 12345

Figure 3.1.8-1: 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 + X..20 (where N2 is the **AI** and X..20 is the **Serial Number up to 20 characters**).

GS1 Application Identifier	Serial number
2 1	X ₁ ————— variable length —————> X ₂₀

- X = any character from 7.11-1 of the [GS1 General Specifications](#)
- EXAMPLE: **21ABCDEFGF123456789**

* *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 with 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.

4.1 Overview of GS1 Barcodes

To accommodate many environments and applications, the GS1 System of Standards supports a variety of 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.

GS1 Barcodes provide machine-readable representations of GS1 Identification Numbers (and production 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 to facilitate manual data entry when necessary (e.g., the numbers below the black bars of the barcode).

Below are examples of the most commonly used barcodes supporting UDI. [Refer to the GS1 US Barcode Chart](#) for specifics on numeric digits, data structure, usage, etc.

Important: A GS1 DataMatrix is often mistaken for a GS1 QR Code. While they may visually look similar, they are two separate and distinct barcodes with separate and distinct uses that are not interchangeable at this time in healthcare. The GS1 QR Code is not used in regulated healthcare for UDI. The GS1 QR Code can be used for marketing information retrieved by a consumer from a point of sale product. Please refer to the [GS1 General Specifications](#) for more information.

Figure 4.1-1: GTIN-12 in a UPC-A Barcode (DI only)



Figure 4.1-2: GTIN-13 in an EAN-13 Barcode (DI only)



Figure 4.1-3: GTIN-12 in a GS1 DataMatrix Barcode (DI + PI)

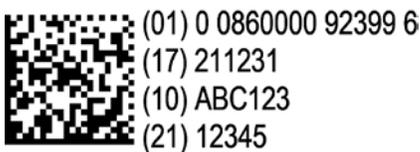


Figure 4.1-4: GTIN-14 in a GS1 DataMatrix Barcode (DI only or PI can be added as shown in 4.1-3)



Figure 4.1-5: GTIN-12 in a GS1-128 Barcode (DI + PI)



Figure 4.1-6: GTIN-14 in a GS1-128 Barcode (DI + PI)



According to the U.S. FDA 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. Most devices include at least one piece of production information on the label therefore, most UDIs will include one or more PIs. An exception, in accordance with the U.S. FDA UDI Rule and as footnoted previously in Section 2.2, for Class I medical devices 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. Such qualifying products would not have PI encoded in the barcode. 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 2.3.1-1 in Section 2.3 of this guide provides direction on barcode choices for various use case scenarios.

4.2 UDI AIDC Format and Encoding Principles: GS1 Barcodes

GS1 AIs are a finite set of specialized identifiers encoded within barcodes to indicate the type of data represented in the element strings. Each AI is a two, three, or four digit numeric code. Each data element within a barcode is preceded by the GS1 AI that identifies it and separates it from any previous data element, and can be thought of also as a delimiter. The AI's that are relevant to this guideline are:

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

Each data element in a barcode is preceded by its AI. For example, the AI for GTIN is (01). Thus, when "01" appears first in the scanned numerical string, it means a GTIN follows in the next segment.

! **Important:** 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.

4.2.1 General Encoding Principles

Table 4.2.1-1: High-level concepts and principles for encoding barcodes

PRINCIPLE	EXAMPLE / ILLUSTRATION										
Each barcode data element has a two, three or four-digit AI that defines data type and field size	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 60%;">GTIN</td><td style="text-align: right;">AI (01)</td></tr> <tr><td>Manufacturing Date</td><td style="text-align: right;">AI (11)</td></tr> <tr><td>Expiration Date</td><td style="text-align: right;">AI (17)</td></tr> <tr><td>Batch/Lot Number</td><td style="text-align: right;">AI (10)</td></tr> <tr><td>Serial Number</td><td style="text-align: right;">AI (21)</td></tr> </table>	GTIN	AI (01)	Manufacturing Date	AI (11)	Expiration Date	AI (17)	Batch/Lot Number	AI (10)	Serial Number	AI (21)
GTIN	AI (01)										
Manufacturing Date	AI (11)										
Expiration Date	AI (17)										
Batch/Lot Number	AI (10)										
Serial Number	AI (21)										
When encoding, each data element is preceded by its corresponding AI. Parentheses used in the human readable interpretation are NOT encoded or counted as part of the total character capacity. NOTE: For clarity, the numbers representing the AI and numbers representing the data element are shown in different colors in the examples to the right.	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 60%;">GTIN</td><td style="text-align: right;">0100850006000012</td></tr> <tr><td>Manufacturing Date</td><td style="text-align: right;">11140731</td></tr> <tr><td>Expiration Date</td><td style="text-align: right;">17151231</td></tr> <tr><td>Batch/Lot Number</td><td style="text-align: right;">10987654321gfedcba</td></tr> <tr><td>Serial Number</td><td style="text-align: right;">21ABCDEFGF123456789</td></tr> </table>	GTIN	0100850006000012	Manufacturing Date	11140731	Expiration Date	17151231	Batch/Lot Number	10987654321gfedcba	Serial Number	21ABCDEFGF123456789
GTIN	0100850006000012										
Manufacturing Date	11140731										
Expiration Date	17151231										
Batch/Lot Number	10987654321gfedcba										
Serial Number	21ABCDEFGF123456789										
Encode the GTIN first and ensure that fixed-length AIs precede variable-length AI's. NOTE: It is highly recommended that any UDI relevant AI(s) precede non-UDI relevant AI(s) <u>See: U.S. FDA Unique Device Identification System: Form and Content of the Unique Device Identifier (UDI) Draft Guidance</u>	<div style="display: flex; align-items: flex-start;"> <div style="flex: 1;">  <p>(01) 0 0860000 92399 6 (17) 211231 (10) ABC123 (21) 12345</p> </div> <div style="flex: 1; padding-left: 20px;"> <p>GTIN <i>fixed</i> Expiration Date <i>fixed</i> Batch/Lot Number <i>variable</i> Serial Number <i>variable</i></p> </div> </div>										

4.2.2 GS1 Barcode Encoding Principles Further Defined

Some medical devices, depending on their U.S. FDA Classification, must carry a UDI to include both DI and PI. Retail items in the United States require an EAN/UPC barcode to be scanned at point of sale. EAN/UPC cannot carry production information. Thus, for retail items that must carry both DI and PI, two barcodes will be required (an EAN/UPC plus a second barcode).

- ✓ The second barcode should be either a GS1-128, GS1 DataMatrix, GS1 DataBar.
- ✓ The second barcode shall contain both the same GTIN that is carried in the EAN/UPC and the production 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.
- ✓ For devices sold in retail, the second barcode must be on the same side of the packaging as the primary EAN/UPC barcode.

! **Important:** As a best practice, apply only one barcode at each packaging level of a trade item. The above requirement for two barcodes is being driven by the need for both a point of sale barcode and a barcode that can carry PI as part of the U.S. FDA UDI Rule. Applying multiple barcodes to the same package should be avoided whenever possible.

Figure 4.2.2-1: GS1 Barcode Reference table

U.S. FDA Classification	Selling Environment	Production Information	GS1 Barcode Type	Reference Section
CLASS I	Retail	No (DI Only)	UPC-A EAN-13	4.2.3
	Non-Retail	No (DI Only)	EAN/UPC GS1-128 GS1 DataMatrix GS1 DataBar® ITF-14	4.2.3
CLASS II or CLASS III	Retail	Yes (DI + PI)	UPC-A or EAN-13 (for retail scanning) + <i>one of the following:</i> GS1-128 GS1 DataMatrix GS1 DataBar	4.3.3
	Non-Retail	Yes (DI + PI)	GS1-128 GS1 DataMatrix GS1 DataBar	4.3.1

! **Important:** For those non-retail Class I devices where production information is being provided voluntarily (DI + PI), use either a GS1-128, GS1 DataMatrix, or GS1 DataBar. Refer to Section 4.3 for encoding principles.

4.2.3 Encoding DI Only

There are several GS1 Barcode options that may be used for devices falling within this group such as:

- EAN/UPC
- GS1-128
- GS1 DataMatrix
- GS1 DataBar
- ITF-14

Table 4.2.3-1: Encoding Principles for DI only

UDI ELEMENT(S)	GS1 STANDARD(S)	ENCODING PRINCIPLES
DI	GTIN	<p>For EAN/UPC:</p> <ul style="list-style-type: none"> • ONLY A GTIN-12 or GTIN-13 MAY BE ENCODED • The data syntax for the GTIN-12 is N12. • Enter the 12 or 13 numeric characters of the GTIN-12 or GTIN-13 into the fixed-length field. • <u>EXAMPLE:</u> 850006000012
DI	GTIN	<p>For GS1-128, GS1 DataMatrix, GS1 DataBar, or ITF-14:</p> <ul style="list-style-type: none"> • GTIN-14 or GTIN-12/GTIN-13 IN A 14-DIGIT FORMAT (For GTIN-12 or GTIN-13: encode in 14-digit format using adding leading zeros. Refer to section 2.4 on Family of GTIN's for more information) • 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-14 or GTIN-12/GTIN-13 in 14-digit format into the fixed-length field following the AI. • <u>EXAMPLES:</u> 0120887511007346 or 0100850006000012

4.2.4 Examples of Barcodes Encoding DI Only

Figure 4.2.4-1: GTIN-12 Encoded in a UPC-A



Figure 4.2.4-2: GTIN-14 Encoded in a GS1-128



Figure 4.2.4-3: GTIN-14 Encoded in a GS1 DataMatrix



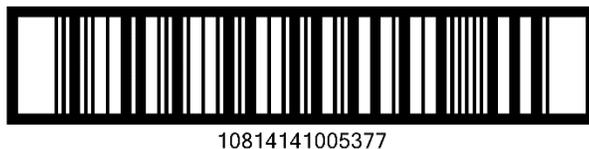
Figure 4.2.4-4: GTIN-12 (in 14-digit format) Encoded in a GS1 DataBar (Limited)



Figure 4.2.4-5: GTIN-12 (in 14-digit format) Encoded in a GS1 DataBar (Stacked)



Figure 4.2.4-6: GTIN-14 Encoded in an ITF-14



4.3 Encoding DI and PI

4.3.1 Using a Single Barcode

The GS1-128, GS1 DataMatrix or GS1 DataBar are the three GS1 Barcode options that may be used for devices that require both DI and PI. The encoding principles are the same for each barcode, and are presented in the table below. Examples of each barcode follow the table.



Hint: Although we have included all GS1-relevant PI from the U.S. FDA 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.

Table 4.3.1-1: Encoding Principles for a Single Barcode with DI and PI

UDI ELEMENT	GS1 STANDARD(S)	ENCODING PRINCIPLES
DI	GTIN	<p>For GS1-128, GS1 DataMatrix, or GS1 DataBar:</p> <ul style="list-style-type: none"> • GTIN-14 or GTIN-12/GTIN-13 IN A 14-DIGIT FORMAT (<i>For GTIN-12 or GTIN-13: encode in 14-digit format using adding leading zeros. Refer to section 2.4 on Family of GTIN's for more information</i>) • 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-14 or GTIN-12/GTIN-14 in 14-digit format into the fixed-length field following the AI. • EXAMPLE: 0120887511007346 or 0100850006000012
PI: MANUFACTURING / PRODUCTION DATE	AI (11)	<ul style="list-style-type: none"> • Begin with the two-digit AI "11" to indicate <i>Production Date</i>. • Enter the six numeric characters representing the Production Date as YYMMDD into the fixed-length field following the AI. <ul style="list-style-type: none"> • 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: 11140726
PI: EXPIRATION DATE	AI (17)	<ul style="list-style-type: none"> • Begin with the two-digit AI "17" to indicate <i>Expiration Date</i>. • Enter the six numeric characters representing the Expiration Date as YYMMDD into the fixed-length field following the AI. <ul style="list-style-type: none"> • 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: 17151231

PI: BATCH/LOT NUMBER	AI (10)	<ul style="list-style-type: none"> • Begin with the two-digit AI "10" to indicate <i>Batch/Lot Number</i>. • Enter up to 20 alphanumeric characters representing the <i>Batch/Lot Number</i> into the variable-length field following the AI. • EXAMPLE: 10987654321gfedcba
PI: SERIAL NUMBER	AI (21)	<ul style="list-style-type: none"> • Begin with the two-digit AI "21" to indicate <i>Serial Number</i>. • Enter up to 20 alphanumeric characters representing the <i>Serial Number</i> into the variable-length field following the AI. • EXAMPLE: 21ABCDEFGH123456789

4.3.2 Examples Encoding DI and PI Using a Single Barcode

Figure 4.3.2-1: GTIN-14 with Batch/Lot Number Encoded



Figure 4.3.2-2: GTIN-14 with Expiration Date, Batch/Lot and Serial Number Encoded



Figure 4.3.2-3: GTIN-12 (in 14-digit format) with Expiration Date, Batch/Lot and Serial Number Encoded

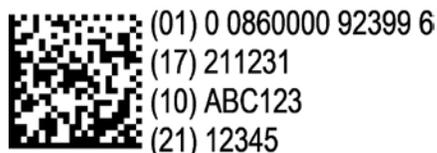


Figure 4.3.2-4: GTIN-14 Encoded in GS1 DataBar (Limited), with Expiration Date, Batch/Lot & Serial Number Encoded on Composite Component



4.3.3 Using Two Barcodes to Accommodate Point of Sale

For retail items that must carry both DI and PI, two barcodes will be required (an EAN/UPC plus a second barcode). There are several GS1 Barcode options that may be used for devices falling within this group: EAN/UPC plus GS1-128, GS1 DataMatrix or GS1 DataBar

Table 4.3.3-1: Encoding Principles for DI and PI (two barcodes)

UDI ELEMENT	GS1 STANDARD(S)	ENCODING PRINCIPLES
DI: BARCODE 1 – DI ONLY	GTIN	<p>EAN/UPC:</p> <ul style="list-style-type: none"> ONLY A GTIN-12 or GTIN-13 MAY BE ENCODED The data syntax for the GTIN-12 is N12. Enter the 12 numeric characters of the GTIN-12 into the fixed-length field. EXAMPLE: 850006000012
DI: BARCODE 2 – DI + PI	GTIN	<p>PLUS either: GS1-128, GS1 DataMatrix, or GS1 DataBar:</p> <ul style="list-style-type: none"> GTIN MUST BE IN A 14-DIGIT FORMAT (<i>Add leading zero(s) to the GTIN-12 or GTIN-13 being used above</i>) 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: 0100850006000012
PI: MANUFACTURING / PRODUCTION DATE	AI (11)	<ul style="list-style-type: none"> Begin with the two-digit AI "11" to indicate <i>Production Date</i>. Enter the six numeric characters representing the Production Date as YYMMDD into the fixed-length field following the AI. <ul style="list-style-type: none"> 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: 11140726
PI: EXPIRATION DATE	AI (17)	<ul style="list-style-type: none"> Begin with the two-digit AI "17" to indicate <i>Expiration Date</i>. Enter the six numeric characters representing the Expiration Date as YYMMDD into the fixed-length field following the AI. <ul style="list-style-type: none"> 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: 17151231

PI: BATCH/LOT NUMBER	AI (10)	<ul style="list-style-type: none"> • Begin with the two-digit AI "10" to indicate <i>Batch/Lot Number</i>. • Enter up to 20 alphanumeric characters representing the Batch/Lot Number into the variable-length field following the AI. • <u>EXAMPLE:</u> 10987654321gfedcba
PI: SERIAL NUMBER	AI (21)	<ul style="list-style-type: none"> • Begin with the two-digit AI "21" to indicate <i>Serial Number</i>. • Enter up to 20 alphanumeric characters representing the Serial Number into the variable-length field following the AI. • <u>EXAMPLE:</u> 21ABCDEFGH123456789

4.3.4 Examples Encoding DI and PI Using Two Barcodes to Accommodate Point of Sale

Figure 4.3.4-1: EAN/UPC encoding GTIN-12 (left side image) plus GS1-128 encoding same GTIN-12 (in 14-digit format) with Batch/Lot (right side image)



Figure 4.3.4-2: EAN/UPC encoding GTIN-12 (left side image) plus GS1 DataMatrix encoding same GTIN-12 (in 14-digit format) with Production Date, Batch/Lot Number, and Serial Number (right side image)



Figure 4.3.4-3: GTIN-12 Encoded in an EAN/UPC (left side image) and GS1 DataBar encoding same GTIN-12 (in 14-digit format) with Expiration Date, Batch/Lot and Serial Number (right side image).



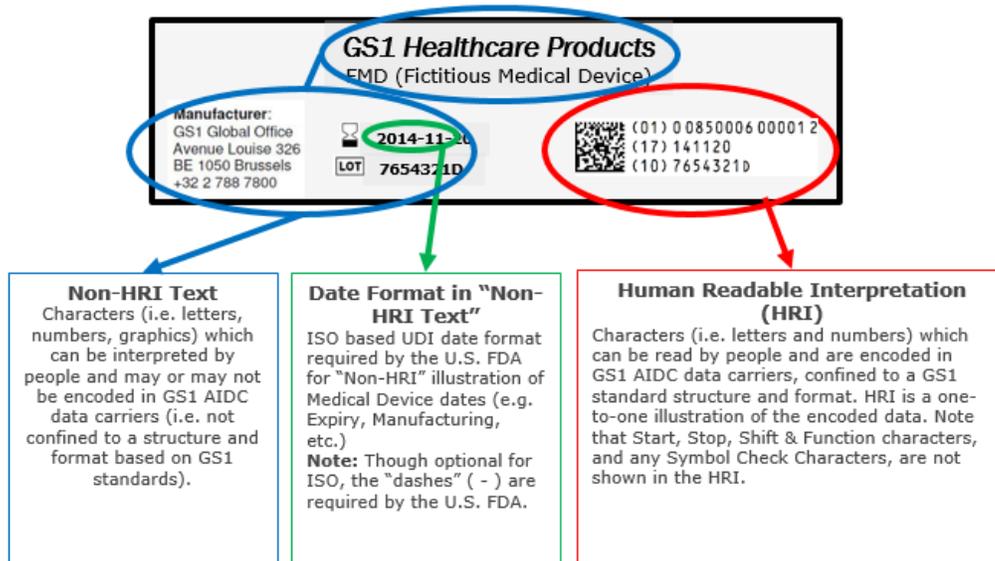
4.4 GS1 HRI Rules

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. This GS1 System requirement supports the U.S FDA UDI Rule requiring that the UDI be presented in both AIDC (barcode) and easily readable plain text (referred to in the GS1 System as HRI).

Figure 4.4-1: Human Readable and Non-Human Readable Example



! Important (DATE FORMAT): The U.S. FDA UDI Rule adopted YYYY-MM-DD, which is an ISO standard. However, the ISO standard also includes abbreviated date formats (like YYYY-MM), which the U.S. FDA UDI Rule does not allow. Only the full ISO format is acceptable pursuant to the U.S. FDA UDI Rule. In addition, the rule requires the dashes between the date segments, whereas the dashes are optional under the ISO rule. This is depicted in the "green" Non-HRI text in the above graphic.

For the HRI, governed by the GS1 System and depicted in "red" above, the date format is YYMMDD.

When entering DD information, 00 is not an acceptable date within the context of the U.S. FDA UDI Rule. While the [GS1 General Specifications](#) permit a day of 00, it is NOT RECOMMENDED that this be used for this application.

There are two categories of HRI Rules:

- General Rules that apply independent of sector, product category, or region. The human readable interpretation (HRI) rules can be found in Section 4.15 of the [GS1 General Specifications](#).
- Sector-Specific Rules which must be aligned with the General Rules. The Healthcare human readable interpretation rules can be found in Section 4.15.1 of the [GS1 General Specifications](#).

This section provides the general principles articulated in the HRI Rules. For more information, consult the [GS1 General Specifications](#) sections noted above.

 **Important:** 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).

4.4.1 Location

- The HRI SHOULD be placed below the barcode and grouped together whenever physically possible while maintaining the HRI legibility and minimum barcode height. For more information, refer to section 4.15 of the [GS1 General Specifications](#).
- If there is not sufficient space to print the HRI of the optional attribute data below the barcode, print it above the symbol in proper sequence of the Application Identifiers (AIs).

4.4.2 Font

- Use a clearly legible font for the HRI, 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.

 **Important:** The U.S. FDA UDI Rule does not include specific font requirements but, instead ask that you follow the guidance of your Issuing Agency.

4.4.3 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, in this instance, GTIN.

- Print the data with the preceding AIs 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 formatted number.

Figure 4.4.3-1: General Guidance for HRI placement. For additional information on HRI placement, please refer to the [GS1 General Specifications](#).



Part 5: UDI Direct Marking -- GS1 Standards for Permanently Marked Items (Direct Part Marking)

According to the U.S. FDA UDI Rule, a device that must bear a unique device identifier (UDI) on its label must also bear a permanent marking providing the UDI on the device itself (in either plain text format, AIDC format, or both) if the device is intended to be used more than once and intended to be reprocessed before each use. GS1 Standards include rules for marking a [GS1 symbol](#) directly onto an item (i.e., UDI direct marking in AIDC format). 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 of AIDC symbols for UDI.

5.1. GS1 Standards for Permanently Marked Items (Direct Part Marking)

Direct Part Marking (DPM) [or Permanently marked items as it is called 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). Three methods exist for the permanent marking of items.

1. **Direct Part Marking (DPM):** The process of marking a symbol directly onto an item using an intrusive or non-intrusive method instead of applying a label or using another indirect marking process.
2. **Durable Labelling:** The process of marking a symbol onto a label that is intended to permanently stay on the trade item.
3. **Durable RFID-Tagging:** The process of applying an RFID-tag that is intended to permanently stay on the trade item.

For the purpose of this application, Direct Part Marking (DPM) is covered in this Guideline. For additional information on Durable Labelling or Durable RFID-Tagging, refer to the [GS1 General Specifications](#) for DPM in healthcare.

5.2. Direct Part Marking (DPM) Methods

Specific to Direct Part Marking, there are a variety of methods which can be applied 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.

The table below presents a non-exhaustive list of some currently used methods.

Table 5.2-1: DPM Methods

DPM METHODS	
<p>INTRUSIVE MARKING</p> <p><i>Methods that remove or alter the material of the host (i.e., Subtractive Methods)</i></p>	<ul style="list-style-type: none"> 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)
<p>NON-INTRUSIVE MARKING</p> <p><i>Methods that do not affect the host material, and usually involve the addition of material (i.e., Additive Methods)</i></p>	<ul style="list-style-type: none"> Cast, forge, mold Inkjet Laser bonding Liquid metal jet Silk screen Stencil

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 user's requirements

5.3. UDI Direct Marking in AIDC Format: GS1 Data Matrix

When using GS1 Standards, the GS1 DataMatrix is the only barcode used for directly marking a device with a UDI in AIDC format. See section 2.1.8 Medical devices (non-retail trade items) of the [GS1 General Specifications](#) for more details.



Very Important: *Data Carriers*, Section 5 of the [GS1 General Specifications](#), provides comprehensive information on all GS1 barcodes. Specific to permanently marking medical devices, please refer to *Symbol specification table 7 - Direct part marking Figure 5. 9.3.7-1* in [GS1 General Specifications](#)

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

1. those with "connected modules" in the "L-shaped" finder pattern created by DPM marking technologies such as laser or chemical etching, and
2. those with "non-connected modules" in the "L" shaped finder pattern created by DPM marking technologies such as dot pen

Due to the marking technologies and characteristics of reading "connected" and "non-connected modules", they each have varied ranges of X-Dimensions and different recommended quality criteria, and may require different reading equipment. Consideration should be taken on which type of non-ink based DPM would be suited for a particular product marking application.

5.4. 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.



Part 6: Appendices

6.1 Additional Resources

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

GS1 US Resources:

- GS1 Healthcare US UDI Online Resource Site
www.gs1us.org/industries/healthcare/standards-in-use/udi
- [Healthcare Provider GTIN Toolkit](#)
- [Healthcare Supplier GTIN Toolkit](#)
- [Healthcare Provider 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](#)
- [Standards Guidance for Assigning Device Identifiers Using Global Trade Item Numbers](#)
- [Guidance for Implementing GLNs and GTINs in Order-to-Cash Transactions](#)
- [UDI Frequently Asked Questions](#)
- The GS1 US Check Digit Calculator is available at
<https://www.gs1us.org/resources/tools-and-services/check-digit-calculator>.
- GS1 US Data Hub Product Overview web page is located at
<https://www.gs1us.org/tools/gs1-us-data-hub>.

GS1 Global Resources:

- [GS1 General Specifications](#)
- [GS1 Healthcare GTIN Allocation Rules](#)
- [Leveraging GDSN for the FDA Global Unique Device Identifier Database \(GUDID\) Implementation Guideline](#)
- [GDSN for the FDA Global Unique Device Identifier Database \(GUDID\) Implementation Guide](#)
- [AIDC Healthcare Implementation Guideline](#)

U.S. FDA Resources:

- [U.S. FDA UDI Website](#)
 - All UDI relevant draft and final guidance can be found on the U.S. FDA UDI website. For example, [draft guidance for Convenience Kits](#)
 - Have questions like “Does software need to be labeled with a UDI?” or “What changes would require a new device identifier?”, refer to the U.S. FDA Frequently Asked Questions located at: <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM410439.pdf>
- U.S. FDA [Global Unique Device Identification Database \(GUDID\): Guidance for Industry](#)

6.2 GTINs that Align with NHRIC/NDC

Pursuant to GS1 Standards, NHRICs and NDCs can be aligned so that identification of medical/surgical and pharmaceutical products with a GTIN, is consistent with identification of the same 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 aligning NHRICs/ NDCs in their GTINs for more than forty years. This chapter provides additional information about how NHRICs/NDCs are aligned and is provided to support industry’s understanding of this practice.



Important: The UDI Rule terminates the use of NHRICs and NDCs on the date a device must be labeled with a UDI. Consult the [U. S. FDA Enforcement Policy Regarding Use of National Health Related Item Code or National Drug Code Numbers on Device Labels or Packages](#).

This guidance describes the Agency’s policy regarding the prohibition against providing National Health Related Item Code (NHRIC) or National Drug Code (NDC) numbers on device labels and device packages.

6.2.1 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 U.S. 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.



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

6.2.2 GS1 Company Prefixes with NHRIC/NDC Labeler Codes

In order to facilitate the alignment of NHRICs/NDCs with GTINs, GS1 US has reserved a placeholder in the GS1 Company Prefix numbering system that allows the Labeler Code to be aligned with 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 its Labeler Code with “03” appended in front. For example:

GS1 Prefix	03
U.S. FDA-assigned <i>Labeler Code</i>	61414
GS1 <i>Company Prefix</i>	0361414



Very Important: In order to align a Labeler Code with a GS1 Company Prefix, manufacturers must first contact GS1 US to request the GS1 Company Prefix that aligns with their Labeler Code. If the GS1 Company Prefix is available, it may be licensed to the manufacturer.

6.2.3 NHRICs/NDCs as GTINs

GTINs include a segment for Company Prefix and a segment for Item Reference. When aligning NHRICs/NDCs into GTINs, the NDC *Labeler Code* is aligned with the Company Prefix (as described above), and the NHRIC/NDC *Product/Package Code* can be used to populate the Item Reference segment. The figure below illustrates how an NHRIC/NDC can be aligned with a GTIN-14.



Hint: Medical/surgical companies may have more than one GS1 Company Prefix (e.g., one GS1 Company Prefix that aligns to the NHRIC/NDC Labeler Code, and other GS1 Company Prefixes that do not). When assigning GTINs to align with NHRIC/NDC codes, utilize only the GS1 Company Prefix that has been aligned with that NHRIC/NDC Labeler Code. Otherwise, use the preferred GS1 Company Prefix when assigning all other GS1 identifiers.

6.2.4 NHRIC/NDC aligned with a GTIN-12

The table below provides a color-coded example of a hypothetical GTIN-12 that aligns with an NHRIC/NDC, and a key explaining how to construct.

Table 6.2.4-1: Populating the 12 digits of a GTIN-12 so as to align with an NHRIC/NDC using hypothetical GTIN “312345678906”

EXAMPLE OF A GTIN-12 FROM AN NHRIC/NDC												
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	NHRIC/NDC <i>Labeler Code</i> as assigned by U.S. FDA <u>plus</u> <i>Product/Package Code</i> created by the manufacturer (Although the length of the <i>Labeler Code</i> and the <i>Product/Package Code</i> vary, they will always be a combined total of 10 digits.)											
POSITION 12	Check Digit											

6.2.5 NHRIC/NDC aligned with a GTIN-14

The table below provides a color-coded example of a hypothetical GTIN-14 that aligns with an NHRIC/NDC, and a key explaining how to construct.

Table 6.2.5-1: Populating the 14 digits of a GTIN-14 so as to align with an NHRIC/NDC using hypothetical GTIN “1031234567891”

EXAMPLE OF A GTIN-14 FROM AN NHRIC/NDC														
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 through 8) Note: 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.													
POSITION 2 AND 3	GS1 Prefix “03”													
POSITION 4 THROUGH 13	NDC <i>Labeler Code</i> as assigned by U.S. FDA <u>plus</u> NDC <i>Product/Package Code</i> created by the manufacturer (Although the length of the <i>Labeler Code</i> and the <i>Product/Package Code</i> vary, they will always be a combined total of 10 digits.)													
POSITION 14	Check Digit													

6.3 Introduction to GS1 US Data Hub | Product

GS1 Data Hub | Product can be a valuable tool for medical device manufacturers implementing GS1 Standards for U.S. FDA Unique Device Identification (UDI), and pharmaceutical traceability initiatives, as well as meet supply chain partner product identification (GTIN) requirements.

- **Easily create UPC-A, GS1-128, and GS1 DataMatrix (image only*) barcodes:** Assign GTINs for your products and encode them in various data carriers.
- **GS1 US Data Hub | Product is your company's private GTIN and GLN (Global Location Number) database:** No one else can modify your data and only third-party subscribers you choose to share your information with can view your information – called Circles of Trust.
- **No technical knowledge is required:** GS1 US Data Hub employs an interactive online tool to guide you with simple step-by-step instructions on assigning GTINs, creating barcodes, navigating the home page, and more.
- **Helpful instructions:** Download the [GS1 US Data Hub | Product UDI Mini Creation Guide](#) to learn how to create a new GTIN to serve as your UDI Device Identifier for a Primary Device, Unit of Use and Higher Packaging Level. Learn how to auto assign a GTIN, change the status to In Use, and create the barcode with production identifiers.
- **Add UDI Production Identifiers or Other Secondary Identifiers:** Batch/lot number, serial number, production data, and expiry date.
- **Make a mistake? No problem:** You can easily edit your product information before assigning a GTIN to the record.
- **Manage your GTINs:** Manage the lifecycle of your GTINs — Reserve GTINs to manually assign them to devices. Track your prefix capacity on the home page dashboard to determine the number of Reserved, Available, Draft and In Use GTINs at a glance.
- **Create Product Sales Sheets and Product Summary Sheets**

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

Access to GS1 US Data Hub is yours at no added cost when you license your first GS1 Company Prefix from GS1 US. Get your barcodes right the first time and start using GS1 US Data Hub today!

For more information contact:

Member Support

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E udigs1us@gs1us.org

To learn more, visit:

www.gs1us.org/datahub



Part 7: Glossary of Terms and Definitions

7.1. GS1 Glossary of Terms and Definitions

The glossary lists the terms and definitions that are applied in this document. For a full glossary list, please refer to the [GS1 General Specifications](#) or www.gs1.org/glossary for the online version.

TERM	DEFINITION
2-dimensional symbology	Optically readable symbols that must be examined both vertically and horizontally to read the entire message. Two-dimensional symbols may be one of two types: matrix symbols and multi-row symbols. Two-dimensional symbols have error detection and may include error correction features
Automatic Data and Data Capture (AIDC)	A technology used to automatically capture data. AIDC technologies include barcodes, smart cards, biometrics and RFID.
Barcode	A symbol that encodes data into a machine readable pattern of adjacent, varying width, parallel, rectangular dark bars and pale spaces
Check Digit	A final digit calculated from the other digits of some GS1 identification keys. This digit is used to check that the data has been correctly composed. (See GS1 check digit calculation.)
Direct Part Marking (DPM)	Direct part marking refers to the process of marking a symbol on an item using an intrusive or non-intrusive method.
EAN/UPC Symbology	A family of barcodes including EAN-8, EAN-13, UPC-A, and UPC-E barcodes. Although UPC-E barcodes do not have a separate symbology identifier, they act like a separate symbology through the scanning application software. See also EAN-8 barcode, EAN-13 barcode, UPC-A barcode, and UPC-E barcode.
EAN-13 Barcode	A barcode of the EAN/UPC symbology that encodes GTIN-13 or RCN-13.
Element String	The combination of a GS1 Application Identifier and GS1 Application Identifier data field.
Fixed Length	Term used to describe a data field in an element string with an established number of characters.
Global Location Number	The GS1 identification key used to identify physical locations or parties.
Global Trade Item Number® (GTIN®)	The GS1 identification key used to identify trade items. The key comprises a GS1 Company Prefix, an item reference and check digit.
GS1 Application Identifier (AI)	The field of two or more digits at the beginning of an element string that uniquely defines its format and meaning.
GS1 Company Prefix	A unique string of four to twelve digits used to issue GS1 identification keys. The first digits are a valid GS1 Prefix and the length must be at least one longer than the length of the GS1 Prefix. The GS1 Company Prefix is issued by a GS1 Member Organization. As the GS1 Company Prefix varies in length, the issuance of a GS1 Company Prefix excludes all longer strings that start with the same digits from being issued as GS1 Company Prefixes. See also U.P.C Company Prefix.

TERM	DEFINITION
GS1 DataBar®	A family of barcodes, including GS1 DataBar Omnidirectional; GS1 DataBar Stacked Omnidirectional; GS1 DataBar Expanded; GS1 DataBar Expanded Stacked GS1 DataBar Truncated, GS1 DataBar Limited, and GS1 DataBar Stacked symbols.
GS1 DataMatrix	GS1 implementation specification for use of Data Matrix
GS1 Identification Keys	A unique identifier for a class of objects (e.g., a trade item) or an instance of an object (e.g., a logistic unit).
GS1 QR Code	GS1 implementation specification for use of QR Code.
GS1-128	A subset of Code 128 that is utilized exclusively for GS1 system data structures.
GTIN-12	The 12-digit GS1 identification key composed of a U.P.C. Company Prefix, item reference, and check digit used to identify trade items.
GTIN-13	The 13-digit GS1 identification key composed of a GS1 Company Prefix, item reference, and check digit used to identify trade items.
GTIN-14	The 14-digit GS1 identification key composed of an indicator digit (1-9), GS1 Company Prefix, item reference, and check digit used to identify trade items.
Healthcare Primary Packaging	The first level of packaging for the product marked with an AIDC data carrier either on the packaging or on a label affixed to the packaging. For non-sterile packaging, the first level of packaging can be the packaging in direct contact with the product. For sterile packaging, the first level of packaging can be any combination of the sterile packaging system, may consist of a single item or group of items for a single therapy such as a kit. For packaging configurations that include a retail consumer trade item, primary packaging is a packaging level below the retail consumer trade item.
Healthcare Provider	An organization or facility that delivers healthcare to a subject of care. Corresponds to “care delivery organization,” “healthcare organization,” etc.
Healthcare Secondary Packaging	A level of packaging marked with an AIDC carrier that may contain one or more primary packages or a group of primary packages containing a single item.
Human Readable Interpretation (HRI)	Characters, such as letters and numbers, which can be read by persons and are encoded in GS1 AIDC data carriers confined to a GS1 standard structure and format. The human readable interpretation is a one-to-one illustration of the encoded data. However, start, stop, shift and function characters, as well as the symbol check character, are not shown in the human readable interpretation.
Non-HRI text	Characters such as letters and numbers that can be read by persons and may or may not be encoded in GS1 AIDC data carriers and are not confined to a structure and format based on GS1 standards (e.g., a date code expressed in a national format that could be used to encode a date field in a GS1 AIDC data carrier, brand owner name, consumer declarations).

TERM	DEFINITION
Regulated Healthcare Non-Retail Consumer Trade Item	A consumer trade item not intended for scanning at point-of-sale (POS) and identified with a GTIN-14, GTIN13, GTIN-12 or GTIN-8 utilizing linear or 2D matrix barcodes that can be scanned by image based scanners
Regulated Healthcare Retail Consumer Trade Item	A regulated healthcare trade item to be sold to the end consumer at a regulated healthcare retail point-of-sale (pharmacy). They are identified with a GTIN-13, GTIN-12 or GTIN-8 utilizing linear or 2D matrix barcodes that can be scanned by image-based scanners.
Regulated Healthcare Trade Item	Pharmaceuticals or medical devices that are sold or dispensed in a controlled environment (e.g., retail pharmacy, hospital pharmacy).
Unique Device Identifier (UDI)	A series of numeric or alphanumeric characters that is created through a globally accepted device identification and coding standard. It allows the unambiguous identification of a specific medical device on the market. The UDI is comprised of the UDI-DI and the UDI-PI. The word 'Unique' does not imply serialization of individual production units.
Unique Device Identifier – Device Identifier (UDI – DI)	A unique identifier specific to a medical device trade item represented by a Global Trade Item Number (GTIN).
Unique Device Identifier – Production Identifier (UDI – PI)	A numeric or alphanumeric code that identifies the unit of device production. The different types of UDI-PIs include serial number, lot number, software identification and manufacturing or expiry date or both types of date.
Unit of Use UDI-DI (UoU UDI-DI)	The Unit of Use UDI-DI serves to associate the use of a device with a patient in instances in which a UDI is not labelled on the individual device at the level of its actual use on a patient. For example, three clips (which do not carry a physical UDI marking themselves) are contained in a cartridge which is packaged inside a container, which does carry a labelled UDI.
U.P.C. Company Prefix	A GS1 Company Prefix starting with a zero ('0') becomes a U.P.C. Company Prefix by removing the leading zero. A U.P.C. Company Prefix is used to issue GTIN-12.
Unit of Use	Refers to an individual unit package that is used to make up the patient-specific prescription that is prescribed for administering to a patient.
UPC-A Barcode	A barcode of the EAN/UPC symbology that encodes GTIN-12 and RCN-12.
Variable Length	Term used to describe a data field in an element string with variable number of characters up to a defined maximum.



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IAPMO

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*If applicable

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