

Know Your GS1 Barcodes and What Is in Them!

Key to Patient Safety and Supply Chain Efficiency

What's in a Barcode?

GTIN® With Expiration Date, Batch/Lot and Serial Number Encoded in a GS1-128 Barcode*



GTIN - Global Trade Item Number

Expiration Date

(01) 0 0614141 00734 9 (17) 141231 (10) A12345B (21) 1234

Batch/Lot Number

Serial Number

Human Readable Interpretation Application Identifier

(01) Global Trade Item Number®

(10) Batch/Lot Number

(17) Expiration Date YYMMDD (21) Serial Number

(11) Production Date YYMMDD

*Same data can be encoded in either GS1-128 or GS1 DataMatrix. Store data in separate fields in database to allow Data Query.

GS1 DataMatrix

Example of GS1 DataMatrix for DSCSA* or U.S. FDA UDI**



GTIN 00314141999995 SN 10000000234 EXP 25 JAN 2015 LOT 987654321GFEDCBA

GS1 recommends GS1 DataMatrix for healthcare use.

*For information about the act, see the 2013 Drug Supply Chain Security Act. **For information about the rule, see the

U.S. FDA Unique Device Identification System

Examples of GS1-128 Barcodes for U.S. FDA UDI*

GTIN With Expiration Date, Batch/Lot and Serial Number Encoded in a GS1-128 Barcode



GTIN With Batch/Lot Number Encoded in a GS1-128 Barcode



GTIN Batch/Lot

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

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

**GTIN can be encoded on the top GS1-128 or the lower GS1-128.

GS1 Barcode Tips

- 1. Parentheses are not encoded
- 2. Spaces are not encoded
- 3. Minimum Grade C except ITF-14 (D)

GS1 US Implementation Resources

GS1 Standards Resources for U.S. FDA Unique Device Identification (UDI) Implementation Support

www.gs1us.org/UDIresources

GS1 Standards Resources for Supporting the Implementation of **Drug Supply Chain Security Act** (DSCSA) www.gs1us.org/DSCSA

GS1 Data Carriers

Electronic Product Code (EPC®)-Enabled in Radio Frequency Identification (RFID) Tag











EAN®/U.P.C.**



North American Retail



ITF - 14



GS1 DataBar®

Stacked

GS1 DataBar Limited With Composite Component



Shipping Containers (Especially Corrugated)

*The appearance of the EPCglobal® Seal is to inform that an EPC-Enabled RFID tag is present on or within the packaging of the product(s).

**In this publication, the letters "U.P.C." are used solely as an abbreviation for the "Universal Product Code," which is a product identification system. They do not refer to the UPC, which is a federally registered certification mark of the International Association of Plumbing and Mechanical Officials (IAPMO) to certify compliance with a Uniform Plumbing Code as authorized by IAPMO.

Notes & Tools

Disclaimer

GTIN With Expiration Date

and Batch/Lot Number

Encoded in a GS1-128**

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

GS1 US® is the local GS1 Member Organization that supports implementation of the GS1 System in the United States. GS1 US employees are not representatives or agents of the U.S. FDA, and the content herein has not been reviewed, approved, or authorized by the U.S. FDA.

GS1 is a U.S. FDA-Accredited Issuing Agency for UDI, and GS1 Standards are authorized for use in implementing the requirements of the U.S. FDA UDI Rule.

Data carriers not to scale.

Contact

GS1 Healthcare US® — www.gs1us.org/Healthcare