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GS1 Healthcare US

Healthcare Supplier U.S. FDA UDI Quick Start Guide

U.S. FDA Unique Device Identification (UDI) Using GS1 Standards

In September 2013, the United States Food and Drug Administration (U.S. FDA) published a rule establishing a unique device identification system for medical devices. Under the rule, the healthcare community and the public will be able to identify a device through a Unique Device Identifier (UDI).

UDIs will be presented on device labels in both plain-text format and a format that can be read by Automatic Identification and Data Capture (AIDC) technology (e.g., a barcode). In addition, device labelers will submit device information to a U.S. FDA database called the Global Unique Device Identification Database (GUDID). GS1 is a U.S. FDA-accredited issuing agency for UDI, and GS1 Standards are authorized for use by manufacturers for UDI implementation. This guide was prepared by GS1 Healthcare US® to assist U.S. medical device trading partners implementing UDI Rule requirements through the use of GS1 Standards.

Components of the UDI Identifier

Pursuant to the UDI Rule, a UDI may consist of two parts:

1. **A Device Identifier (DI)** identifying the specific version or model of a device and the labeler of that device; and
2. **A Production Identifier (PI)** identifying one or more of the following when present on the label of the device: batch/lot, serial number, expiration date, or date of manufacture.

According to the rule, a Device Identifier is always present in a UDI. However, production information 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.

Snapshot of the UDI Rule

The UDI Rule establishes a unique device identification system for medical devices. The system is designed to enable the healthcare community and the public to identify a device using a UDI that will appear on the label and package of the device.

UDIs will appear in both plain-text format and a format that can be read by AIDC technology (e.g., a barcode). The UDI will provide a key to obtain critical device information from a new database, the GUDID. The GUDID will provide the information needed for the identification of medical devices. For more information, visit www.fda.gov.

Basic Terminology

Labeling

The label of medical devices and device packages must include a UDI that is presented on the product label in an easily readable plain-text version and a form that uses AIDC technology.

Data Submission

Device labelers must submit information concerning the device to the U.S. FDA to facilitate rapid identification of the device and the labeler and to provide links to other U.S. FDA data.

Standardized Date Format

Dates on device labels and packages must be presented in a standard format defined by the rule.

Risk-Based Approach to Implementation

The UDI proposed ruling-implementation timeline is based on the product classification, with the emphasis on risks. The U.S. FDA UDI Compliance dates are listed below.

Support Resources

- **GS1 US UDI Implementation Guideline—FORM**
  www.gs1us.org/UDIguide
- **GS1 US U.S. FDA UDI Online Resource Site**
  www.gs1us.org/hcudi
- **UDI Quick Reference Poster**
  www.gs1us.org/udiposter
- **Know Your Barcodes Poster**
  www.gs1us.org/hcbarcode
- **Education & Training**
  www.gs1us.org/hcedu
- **GS1 US Solution Provider Finder**
  www.gs1us.org/SolutionProviderFinder

Please refer to the U.S. FDA Guidance Document for GUDID

The U.S. FDA-proposed rule also includes the need for product-data attributes to be collected, maintained, and submitted to the GUDID. The GUDID is available at www.fda.gov.

U.S. FDA UDI Compliance Dates Summary

Sept. 23, 2013	• U.S. FDA UDI Final Rule issued
Sept. 24, 2014	• Class III labels and packages must bear UDI (includes stand-alone software) • Dates on these labels must be formatted as YYYY-MM-DD • Data for these devices must be submitted to U.S. FDA GUDID
Sept. 24, 2015	• Labels and packages of implantable, life-supporting, and life-sustaining devices must bear UDI • Dates on these labels must be formatted as YYYY-MM-DD • These devices, if intended to be used more than once and intended to be reprocessed before each use, must bear UDI as a permanent marking on the device itself • Data for these devices must be submitted to U.S. FDA GUDID
Sept. 24, 2016	• Class III devices, if intended to be used more than once and intended to be reprocessed before each use, must bear UDI as a permanent marking on the device itself • Class II labels and packages must bear UDI (includes stand-alone software) • Dates on Class II labels must be formatted as YYYY-MM-DD • Data for Class II devices must be submitted to U.S. FDA GUDID
Sept. 24, 2018	• Class II devices, if intended to be used more than once and intended to be reprocessed before each use, must bear UDI as a permanent marking on the device itself
Sept. 24, 2020	• Class I and unclassified medical device labels and packages must bear UDI (includes Class I stand-alone software) • Dates on these labels must be formatted as YYYY-MM-DD • Data for Class I and unclassified devices must be submitted to U.S. FDA GUDID
Sept. 24, 2022	• Class I and unclassified devices, if intended to be used more than once and intended to be reprocessed before each use, must bear UDI as a permanent marking on the device itself

Some of these compliance dates have been granted enforcement extensions by the U.S. FDA. Please refer to the U.S. FDA website for more detail.

Source: U.S. Food & Drug Administration (FDA), Device Advice: Comprehensive Regulatory Assistance, *www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance*

There has been tremendous momentum across the healthcare industry to use GS1 Standards for regulatory compliance, resulting in enhanced patient safety and improved supply chain efficiency.

Join the movement today!

Follow the simple steps in this guide to start preparing for and implementing UDI requirements.

GS1 Standards Can Support Components of the Proposed U.S. FDA UDI System

U.S. FDA UDI	GS1 Standards
DI (Device Identifier)	**GS1 Global Trade Item Number®** (GTIN®)
PI (Production Identifier)	**GS1 Application Identifier** (AI)
AIDC Labeling	**GS1 Barcodes/Radio Frequency Identification** (RFID)
Data Submission	**GS1 Global Data Synchronization Network™** (GDSN®)

Quick Steps for Implementing GS1 Standards for UDI

1. Assess how your company currently identifies and marks its products in terms of the UDI requirements (e.g., identification numbers, labeling, barcodes). Have you identified the internal source of product data required to meet the UDI requirements?

2. Determine the responsible party within your organization for assignment of:

- UDI/GTINs (usually those responsible for packaging)
- GUDID: data aggregation, submission, and maintaining the data to the U.S. FDA's database
- UDI and GUDID updates (regulatory person)

3. Join GS1 US® for a GS1 Company Prefix, which is the foundation for creating GS1 Identification Numbers (e.g., GTINs) and using GS1 Standards for UDI requirements. You may also need to identify your locations by using GS1 Global Location Numbers (GLNs) to meet customer requirements:

- Determine the number of GTINs required based on current products and future expansion
- Join GS1 US to obtain a GS1 Company Prefix
- Go to the Get Started Guide at www.gs1us.org/get-started or call GS1 US at +1 937.610.4226 for more information (initial fee and annual maintenance fee required)

4. Assign GTINs and design your approach to production information for your products.

5. If you choose, assign your GTINs at dh.gs1us.org by using GS1 US Data Hub | Product, an online tool that's included with your GS1 US membership. For training on how to assign a GTIN, go to resources.gs1us.org/gs1-us-data-hub-help-center and enter "UDI" in the search box.

6. Prepare notification of adoption of GS1 Standards for product and location identification:

- Inform internal stakeholders (e.g., call center, sales, marketing, customer-facing groups)
- Update product catalogs and collateral for external stakeholders

7. Begin marking products with barcodes containing GTIN plus the secondary information, if applicable:

- Refer to the Healthcare Supplier GTIN Tool Kit: www.gs1us.org/hcsuptoolkit
- Additional guidelines, such as UDI Guidelines, are also available on the GS1 US website: www.gs1us.org/hctools

8. Upload your product device identifiers to the GUDID:

- Maintain and share product data: Beyond regulatory compliance, you can use GDSN to share accurate product information electronically with your supply chain partners

9. Transact: Notify customers as to the new packaging, labeling, and usage in procurement and contracting efforts.

10. Assign GLNs and share location information with trading partners through GS1 US Data Hub | Location: www.gs1us.org/datahublocation

From Search of the Federal Register for Sept. 24, 2013:

- "21 CFR 801.40(d) states that a Class I device that bears a U.P.C.* on its label and device packages is deemed to meet all UDI labeling requirements and that the U.P.C. will serve as the UDI required by §801.20. This excepts a Class I device with a U.P.C. on its label and packages from UDI labeling requirements regardless of to whom or through what channels it is sold. Such a device will be subject to GUDID reporting requirements. We note that the lowest-risk devices available for sale at retail establishments will in any case be excepted from UDI requirements by virtue of §801.30(a)(2)."
- From 21 CFR 801.30(a)(2): General exceptions from the requirement for the label of a device to bear a unique device identifier "A Class I device that [U.S.] 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."

To learn more, visit
www.gs1us.org/healthcare
or contact us at **gs1healthcareus@gs1us.org**

*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.

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