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.
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.

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<tr>
<th>U.S. FDA UDI Compliance Dates Summary</th>
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<td>Sept. 23, 2013</td>
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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.


Support Resources

- GS1 US UDI Implementation Guideline—FORM
  www.gs1us.org/UDIguide
- GS1 US U.S. FDA UDI Online Resource Site
  www.gs1us.org/ncudi
- UDI Quick Reference Poster
  www.gs1us.org/udiposter
- Know Your Barcodes Poster
  www.gs1us.org/hcbcode
- 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.
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.**

### 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/hcuptoolkit
   - 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

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

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

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.

*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.