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# Guide to Label and Marking Compliance Medical Packaging

**Unique Device Identification (UDI)** 



LABELING & CODING

L&C

# **Unique Device Identification**

# Guide to Label and Marking Compliance

# For Medical Device Manufacturers

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#### Introduction

Patient safety with regards to the identification of medical devices, protection from counterfeit devices, and the ability to recall devices quickly and accurately has led to the development of the Unique Device Identification (UDI) system.

The Food and Drug Administration (FDA) issued a final rule to establishing a system to adequately identify devices through distribution and use.

The content in this ebook focuses on understanding UDI formation, identification labeling, and marking at the required unit through packaging levels.

# What is UDI?

A UDI stands for Unique Device Identification. It is a unique numeric or alphanumeric code that includes a device identifier, which is specific to a device model, and a production identifier. It includes the current production information for that specific device, such as the lot or batch number, the serial number and/ or expiration date.

The UDI must appear on every device using a label or direct marking such as with ink jet or lasers, except where it is not feasible according to the FDA definition.



A UDI label for a fictitious medical device. The label contains information about the product name, its expiration date, reference and lot numbers, manufacturer information, bar code, and details about the item

#### What are the Benefits of UDI?

When fully implemented, the UDI system will:

- Allow more accurate reporting, reviewing and analysis of adverse event reports so that problem devices can be identified and corrected quickly.
- Reduce medical errors by giving health care professionals and others the ability to rapidly and precisely identify a device and obtain important information concerning the device's characteristics.
- Provide a standardized identifier to allow manufacturers, distributors and healthcare facilities to better manage medical device recalls.
- Provide a foundation for a global, secure distribution chain, helping to address counterfeiting and diversion and

prepare for medical emergencies.

- Lead to the development of a medical device identification system that is recognized around the world.
- Enhance analysis of devices on the market by providing a standard and clear way to document device use in electronic health records, clinical information systems, claim data sources and registries. A more robust postmarket surveillance system can also be leveraged to support premarket approval or clearance of new devices and new uses of currently marketed devices.

#### **UDI Acronyms**

When reading the FDA's final ruling on UDI and working to meet compliance regulations for UDI, you will come across acronyms that stand for terms related to the UDI mandate.

If you are already working with identifying, labeling and tracking your products, you will most likely be familiar with many of the acronyms listed here.

New users may want to refer to this guide when learning to become familiar with these terms. Definitions can easily be found online or through your associated vendor.

UDI Acronyms	Meaning
DUNS	D&B number used for the GUDID
UDI	Unique Device Identification
GLN	Global Location Number GS1
GTIN	Global Trade Item Number GS1
GMDN	Global Medical Device Nomenclature
GUDID	Global UDI Datebase
DI	Device Identifier
PI	Production Identifier
AIDC	Automatic Identification and Date Capture
GS1	The GS1 Standards Organization
HIBCC	Health Industry Business Communication
ІССВВА	International Council for Commonality in Blood Banking Automation, Inc.

# **Classification of Medical Devices**

Medical devices are classified into three classes according to the amount of risk involved with the medical device.

A Class I medical device has little to no risk, such as a hand-held surgical instrument, elastic bandages, or examination gloves. This class of devices need to follow general FDA policies, such as registering the device, correctly branding and labeling the device, and proper manufacturing techniques.

Class II medical devices are the largest classification, and include devices such as X-ray machines, powered wheelchairs, infusion pump and surgical and acupuncture needles Class II devices pose a minimal risk. Such devices must follow general policy and special labeling, mandatory performance standards and post market surveillance.

Class III medical devices have the strictest guidelines because they pose the greatest risk to patients Class III Medical Devices must follow Class I and Class II guidelines but must also be pre-market approved by the FDA and a scientific review of the medical device must be made prior to marketing. Class III medical devices

support or sustain human lives and include devices such as implanted pacemakers and heart valves.



The Food and Drug Administration issued a final rule to establishing a system to adequately identify devices through distribution and use.

The new requirements are:

-The unique identifier includes the lot or serial number if specified by FDA.

-The label of a device bears a unique identifier, unless an alternative location is specified by the U.S. Food and Drug Administration (FDA) or unless an exception is made for a particular device or group of devices.

-The unique identifier is able to identify the device through distribution and use by its label, marking, and can be cross referenced with the GUDID.

The Company is called "The Labeler" in the Rule.

# Steps Towards Compliance

Complying with the UDI standard means manufacturers ("Labelers") must assign a UDI-compliant code developed using globally accepted standards to their product, label the products with the UDI appropriately, and then publish the data to the UDI database or GUDID (Global Unique Device Identification Database.)

#### Create the UDI

The UDI code is a unique numeric or alphanumeric code that includes two parts: a device identifier (DI), which is specific to a device model, and a production identifier (PI), which includes the current production information for that specific device, such as the lot or batch number, the serial number and/or expiration date.

Manufacturers are responsible for creating and maintaining the uniqueness of its medical device UDI and shall not be altered.

#### Place UDI on the Label or Directly on Device

The label and device package of each medical device must now include a UDI. This rule requires the label of medical devices to include a unique device identifier (UDI), except where the rule provides for an exception or alternative placement.

The UDI shall be on the label of the device or directly marked on the device itself and requires that each UDI be provided in a plain-text version and in a form that uses automatic identification and data capture (AIDC) technology.

#### Store the UDI in the UDID

The labeler must submit product information concerning devices to FDA's GUDID, unless subject to an exception or alternative. The manufacturer is responsible for maintaining the accessibility of their UDI and the related information in the UDI Database.



Identify which of your devices must come into compliance right now. The final rule is made, and if you do not have a UDI system in place within the time line specified by the FDA, you will not be able to sell your product.

# **Compliance Guidelines**

The FDA defined a phased in approach to compliance depending upon the device's risk classification:

- By 2014, Class III medical devices must comply.
- By 2015, Class II and Class I implants and life-supporting or life-sustaining devices must comply
- By 2016, Class II items my comply
- By 2018, Class I and items that have not been assigned a class must be in compliance.

Devices that are manufactured and labeled before their compliance date have an exception from the rule, which expires three years from the compliance date. For medical devices that are direct marked, compliance is extended by two years.

# Implementation Timeline



UDI compliance may require changes in your current procedures and impact several areas in your organization.

It's a good idea to get started now to develop an implementation plan that will bring you in to UDI compliance by the mandated deadline. Not only will you have necessary time to ensure compliance is 100%, but you'll most likely realize opportunities for additional longer-term benefits from your UDI investment.



# AIDC - The Linear Barcode and the 2D DataMatrix

The FDA requires the use of at least one Automatic Identification/Data Capture (AIDC) technology to carry the UDI identifier on all non-exempt devices and/or packaging.

The two common forms of AIDC are linear barcodes and 2D barcodes, which include the QR code or the DataMatrix code. RFID can also be used, although can be cost prohibitive for some applications.

The linear barcode may be the most recognizable barcode representing data by varying the widths and spacings of parallel lines. Here is a sample of the linear barcode:





#### Scalable and Small Data Matrix

Typically 1/10th to 2/10th of an inch, 2D symbologies contain a substantial amount of data and error correction characteristics making it easier to mark parts, accurately and process quickly.

Example of a DataMatrix code compared to the size of a dime. (not shown to actual size.)



Some applications require more data to be encoded in the barcode. The more data, the larger your barcode will be, and may exceed the limitations of the linear barcode.

Two-dimensional (2D) symbologies are designed for applications where space is an issue. 2D bar codes offer greater data storage capacity using high-density identification and error correction features, 2D symbologies are commonly used to store much more data in a much smaller area, such as data needed to track parts, WIP, traceability and compliance with the UDI rule.



GS1 Standard combines the advantages of the DataMatrix barcode with the GS1 data structure – the result being called GS1 DataMatrix.

For more information, GS1 has an introduction to the GS1 DataMatrix code that can be downloaded at the GS1 Site.

The HIBCC allows more barcode choices such as the Aztec and the PDF417 composite barcode.

#### What kind of Auto ID carrier will you use?

The FDA doesn't dictate which type, so you can use a linear bar code, 2D matrix or RFID. However, hospitals, clinics, and other healthcare organizations use all types of technologies for auto ID, so it makes sense to know how your label is going to be read by the end user.

To comply with the FDA's UDI rule, your choice of barcode is driven by the issuing agency you choose to base your UDI compliance.

# Parts of the UDI

The UDI is defined as consisting of 2 parts:

#### -The Device Identifier - DI

The fixed component, or static part of the UDI consists of the company prefix and the item number.

**Note:** The company prefix will depend on the Standards being used.

#### -The Product Identifier - PI

The dynamic information about the device such as the lot or batch number, manufacturing date, expiration date, or the serial number, if required.

Both parts of the UDI, the Device Identifier and the Product Identifier make up the UDI and can be one long barcode or split into two barcodes.

# Standard Date Format

The format of the dates on medical device labels needs to conform to the standard format of Month Day, Year (e.g. JAN 1, 2012) to ensure dates are unambiguous and clearly understood by device users.

Proposed Rule: Required US format (Jun 19, 2013) and implementation in 1 year if label includes a date (ie: expiration):

- All numeric: YYYY-MM-DD (2013-06-19)
- Day must always be included
- Same Compliance Date as other UDI requirements
- Applies to all labels (even if exempt from UDI)
- If not subject to UDI applies at year 5
- A combination product with NDC number is exempt.

# Standards Available for UDI Labeling

Global data standards are necessary so that each party within the supply chain identifies the same products in the same way.

The FDA does not mandate which auto ID carrier to use, but consider your customers. Not all healthcare providers have the capabilities to handle all of the different carriers. Select the appropriate standard and technology for your product and customers.

The primary standard identifiers for medical-surgical products available are:



GS1's Global Trade Item Number (GTIN) is a fixed length numeric code of up to 14 digits in length. The GTIN has traditionally been used in the pharmaceutical industry.



HIBCC's Labeler Identification Code (HIBC-LIC) is an alphanumeric code of up to 18 characters, and has been used historically in the medical device supply chain.



ISBT 128 is the International Standard for Blood and Transplant organs and can contain up to 128 characters.

# GS1 (Global Standard 1) and UDI

Today, The GS1 is an accepted issuing agency for the FDA's UDI initiative.

Under the GS1, the Global Trade Item Number™ (GTIN™) is used for the unique identification of trade items worldwide. Integrity of these numbers throughout the item's lifetime is a key to maintaining uniqueness for manufacturers, wholesalers, distributors, hospitals, regulatory bodies and other Supply Chain stakeholders.

Brand Owners or manufacturers must allocate and maintain their GTINs according to the rules of the FDA UDI mandate and the GS1 Standard. The label/direct mark must survive for the life of the product to preserve the link back to the database.

A change to one aspect, characteristic, variant or formulation of a trade item may require a new GTIN.

Some common reasons for a GTIN (DI) to change are:

- Change in quantity of a device package.
- Change to package sterility.
- Re-labelling of the original labeler's (manufacturer) device.
- Change labelling languages for different global markets.
- Change in certification mark, e.g., CE Mark.

**Note:** Refer to the appropriate UDI regulation and the GS1 Healthcare GTIN Allocation Rules for complete details on regional influence for GTIN change.

Single Unit Package	Multiple Unit Package	Case
GTIN A	GTIN B	GTIN C
00857674002010	10857674002017	40857674002018



#### **Barcode Standards**

UDI Unique Device Identification	GS1 Standards Product Identification	
DI Device Identifier (DI)	GTIN Global Trade Item Number	
PI Production Identifier (PI) (if applicable)	AI Application Identifier (AI) • Expiration Date A1(17) - e.g. 141120 • Lot/Batch A1(10) - e.g. 1234AB • Serial Number A1(21) - e.g. 12345XYZ	
Production Identifier data will vary by medical device type and manufacturer current practice.		
DI + PI = UDI	GTIN or GTIN + AI(S) + UDI	

Unique Device Identification as it relates to GS1 terms



GTINs may be 8, 12, 13 or 14-digits in length. Their data structures require up to 14-digit fields, and all GTIN processing software should allow for 14 digits.

Any label or RFID tag must also display human-readable text in case AIDC scanning or reading tools are unavailable.



### UDI Compliance Using GTINs

Both linear or 2D barcodes can be used for compliance with the UDI automatic ID identification requirement.

There are two ways use linear barcodes:

- 1. Use one linear with GTIN (DI) and Production Identifier (AI)
- 2. Use 2 separate barcodes, one for GTIN (DI) and one for Production Identifier (AI)

The third illustration here shows using the 2D barcode to combine all the data into one barcode.



GS1-128



GS1 DataMatrix

(01)10857674002017 (17)141120 (10)1234AB

Standard can be correlated with UDI requirements. Since GTINs may be 8, 12, 13 or 14-digits in length, their data structures require up to 14-digit fields. Therefore, all GTIN processing software should allow for 14 digits.

### HIBCC Standards for UDI

HIBCC stands for the Health Industry for Business Communication Council. Historically, the medical device industry has used HIBCC UPNs (Universal Product Numbers), and the supply chain and supporting systems of many device manufacturers have been built using HIBCC codes.

- HIBCC codes are alphanumeric and up to 18 characters in length.
- They generally have a smaller label footprint as compared to the GS1 option.
- At present, HIBCC requires a one-time fee scaled against gross sales with no annual recurring fees a benefit for small device manufacturers.

One of the drawbacks of HIBCC is the perception that it is primarily U.S.-focused and less global than other options.

#### Use Linear or 2D Barcodes

The information to be encoded in the automatic ID includes the LIC and the product code for the item, level of packaging, and then the last digit is a check digits (calculated by the barcode to be sure it is encoded properly.)

Labeler Identification Code (LIC) Assigned by HIBCC. Identifies the labeler. It is four alphanumeric characters.

Product Code / Catalogue ID Assigned by the labeler. Identifies the item/drug/device. 1-18 alphanumeric characters.

Package Level / Unit of Measure Assigned by the labeler. Identifies the packaging configuration level of the item; e.g. Unit-Dose, Carton, Case, Master-Case, Pallet, etc. 1 numeric character. Shown below are the symbols for the HIBC LIC Primary Data Structure





HIBC LIC Concatenated Primary and Secondary Data in a 2D Symbol



### \*+A99912345/ \$\$59901510X3J\*

+ EXP DATE

+ LOT/BATCH

+ SERIAL NUMBER

The data structure of the HIBCC SLS was designed to accommodate identification of multiple levels of packaging from pallets down to individual units of measure, using a standardized code and consistent format. This allows for easier identification within various packaging configurations, as well as consistency throughout the global marketplace.



# About ICCBBA

ICCBBA stands for International Council for Commonality in Blood Banking Automation, Inc.

ICCBBA enhances safety for patients by managing and promoting the ISBT 128 international information standard for use in transfusion and transplantation.

ISBT 128 is the global standard for the terminology, identification, labeling, and information transfer of medical products of human origin (including blood, cell, tissue, and organ products) across international borders and disparate health care systems. It is used in more than 70 countries across six continents. The standard has been designed to ensure the highest levels of accuracy, safety, and efficiency for the benefit of donors, patients, and ISBT 128 licensed facilities worldwide.



The FDA views human tissue as a medical device. Therefore, the new UDI Rule applies.

#### **ICCBBA ISBT 128 Unique Donor** Identification Number W 1234 07 Blood **Black and White** 123456 Type Bar Code **Print Only** W1254 07 123456 E X **Expiration Date** BLOOD SYSTEMS 22 Jan 2007 Scotladale, AZ 85257 DA Regultration Number 2071464 US License Number 183 Collection AB Facility. Registration Rh POSITIVE Number and Special R only Testing License VOLUNTEER DONOR Number Information 22 Jan 2007 RED BLOOD CELLS Special Testing Label goes he Name of From 500 etc. CPD Whole Blood Blore at 1 to 8 C Further Processing By label car Placed here Facility that Descriptive modifies BADARTADA CM9682904 Product Code original product 0316 V 00

# UDI at The Unit and Packaging Level

Different UDIs are required at each unit of measure. Each level of the packaging requires its own UDI.

Direct part marking provides UDI on some products, such as devices that are implantable, or devices that can be sterilized and reused.

Packaging levels means the various levels of device packages that contain a fixed quantity of medical devices, e.g. each, carton, case. This does not include shipping containers such as pallets

The UDI-DI (e.g., GS1 GTIN, HIBC-LIC, ISBT product code) should be globally unique at all levels of packaging.

Apply the UDI on the base package label and the device package level.

The FDA requires a unique UDI at each unit of measure. So each individual product has its own UDI, as would the same product in a box of 12, and in a case of 12 boxes.

The GTIN (DI) & Als (PIs) should be in bar code & in humanreadable form on each applicable package level as defined by regulation. Each designated package level must have its own GTIN (DI).

Placement - Bar code symbols are to be positioned to allow ready access for scanning when the product is stored or stocked on shelves.

Barcodes are to be displayed on the product packages to allow ready access to scanning equipment when the product is stored or stocked on shelves.

- 1. Orientation: Display the barcode on the package so the human readable portion is viewed when in storage or stacked.
- 2. Display Panel: Display the barcode on the panel or label most likely to be seen when the package is stored.



There should be a UDI at every level of packaging except at the logistics unit level.

# The Label Design Software

Barcode label software makes it easy to produce the barcodes and labels for UDI compliance.

Most modern label software packages are able to print the GS1 or HIBCC barcodes. Here at ID Technology, we can provide label templates for our BarTender and NiceLabel software. It is simple to connect the software to external databases to populate labels with the correct data.



GS1 Datamatrix in BarTender

HIBCC Aztec Codein NiceLabel

# Printing The UDI - The Label or Direct Mark

The FDA's UDI Rule requires a UDI on the medical device, and/or packaging according to the specifications within the rule.

Compliance guidelines do not specify using a label or require a direct mark for most products. (For exceptions, refer to the FDA's Ruling.) Each has it's own pros and cons. Issuing agency requirements, costs, available equipment/services, and internal business processes are the main factors in your decision on how to mark your product with the UDI.

The symbol marking technologies most suited for UDI compliance are:

- Thermal Transfer Labels (for products, packaging and pallets)
- Thermal Transfer Overprinter (for printing on flexible packaging)
- High Resolution Inkjet (cases)
- Laser Marking (DPM & cartons/ Cases)

#### Thermal Transfer Labels

- High resolution print for barcodes, text and graphics.
- High contrast output For scanning reliability.
- Durable label materials and printing for harsh environments.
- Cost effective .
- Print in color.



Print and accurately apply thermal transfer labels to products, cases or cartons in a single step in production.

#### Direct Mark Laser

- When using a label is not feasible.
- Permanent Mark.
- Withstands harsh environments.
- UDI Mark compliance for reprocessed implantable devices.
- Stands up to sterilization processes.
- Can be used For marking cartons.



#### High Resolution Inkjet

- Can Be Used In high-volume, end-ofline operations.
- Cost effective, no labels.
- Inkjet printers produce high quality, high resolution text, barcodes and graphic images at 300 dpi.



High Resolution Case Coding Inkjet Systems marks a four-inch high block of information and graphics, including barcodes, use by/sell by dates, lot numbers, product names, descriptions and product ingredients.

# Greydon Systems Primary Packaging

Greydon systems can print UDI compliant barcodes to both GS1 and HIBCC standards.

Greydon's flexo and digital printers allow printing of UDI data, as well as other information, directly onto the packaging. In addition, the Greydon printer can often print the complete package, eliminating the need to purchase and manage an inventory of pre-printed packaging material.





Greydon's Flexographic printers produce the best possible print at minimum cost. These printers can be configured as single color or two color and use quick change photo-polymer print plates to create the image on the packaging. The variable data, including UDI barcodes is printed with a secondary digital printer. This can be a thermal transfer printer, HP based TIJ inkjet or a Genesis digital printer.



# Thermal Transfer Label Materials

The FDA's final UDI rule affects medical device manufacturers in the U.S. and worldwide. Manufacturers must now label most medical devices distributed in the United States with a "unique device identifier" (UDI). The label materials must comply with UL/IEC 60601-1 3rd edition marking and durability rub tests and potentially are UL 969-certified.

Finished labels must be compliant with Title 21 - Food and Drugs, Chapter I - Food and Drug Administration, Subchapter H - Medical Devices, Part 801 Labeling.

Work with ID Technology to be sure the label materials you choose will be 100% compliant with the FDS's UDI ruling.





#### MedFlextm Labeling Material

MedFLEXtm is a series of labeling materials for the labeling of FDA Class II and III medical devices and can provide alternative labeling materials for UDI compliance.

All products are VBS Supreme and all are immediately adoptable into your UL file.

- Choose 2 mil gloss topcoated polyesters in clear, white and silver matte;
- All products utilize a new, more universally printable topcoat printable via resin and wax/resin thermal transfer; UV & solvent screen; UV, solvent & water flexo; and UV inkjet;
- The high-performance permanent acrylic adhesive bonds well to low- and high-surface energy plastics, painted metal, powder paint, polycarbonate and fiberglass;
- Backed with a 50 lb. semi-bleached kraft roll form release liner.

These products are UL-recognized and certified with inks from four leading manufacturers.

## UDI Database - GUDID

A requirement of the UDI rule is the management and transmission of UDI related data in to the FDA's global database, the GUDID or Global Unique Device Identification Database.

The GUDID is based on universal standards for medical device identification and includes a standard set of basic identifying elements for each UDI.

For each Device Identifier (DI):

The proprietary/trade/ brand name of the device.

- Previous DI if a new version or model
- The version or model number
- If direct marked, DI if different than label
- The size of the version or model
- The type of production identifiers on the label
- FDA premarket submission and listing number(s)
- Global Medical Device Nomenclature (GMDN) term
- FDA product code (procode)
- The number of individual devices in each package
- Commercial distribution status
- Higher levels of packaging
- Whether it is a kit, combination product, HCT/P

Whether the device is labeled:

- As sterile or sterilize before use (and how). Higher levels of packaging
- As containing natural rubber latex
- With MRI compatibility (safe, conditional, unsafe)
- As Rx and/or OTC



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Figure D1: GUDID Attributes Mapped to a Fictitious Medical Device Label

# Other Helpful Resources for FDA UDI

Listed here are some resources that may be helpful. Labeling News: <u>http://www.labelingnews.com</u> FDA and UDI: <u>FDA's UDI Site</u> GS1Healthcare: <u>http://www.gs1.org/gsmp/kc/healthcare</u> HIBCC UDI & Standards: <u>http://www.hibcc.org/</u> There are currently three ways to upload the required data:

- 1. Use the web tool.
- 2. Upload HL7 XML file. Tools already exist to help.
- 3. Pay a 3rd party.

Most information will be available to the public so that users of a medical device can easily look up information about a device around the world. The UDI does not indicate and FDA's database will not contain any information about who uses a device, including personal privacy information.

# **PRO**MACH



Shaded regions represent areas served by our Label Converting Facilities



#### Nationwide Service & Support

We pride ourselves in providing responsive nationwide customer service and support from any of our 17 regional sales, service and stocking facilities.

ID Technology technicians are PMMI Certified Trainers to ensure the highest standards of quality training are being met and unparalleled value is being given to the customer.

Our field service personnel are factory trained to service and support our full range of labeling, coding and marking equipment.

In addition to the field service team, ID Technology employs factory trained bench service technicians to accommodate timely depot service.

ID Technology boasts six label converting plants across the US and Canada that produce top quality labels and tags with local support.



For customers using ID Technology labels with our labeling systems, we provide a lifetime limited equipment warranty free of charge. Just ask us for details!



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