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UDI: A Guide to Device Identifiers

The FDA released its Final Rule for a Unique Device Identification System in 2013, requiring medical devices marketed in the U.S. to be assigned a UniqueDevice Identifier (UDI) that will allow it to be better tracked throughout its lifecycle.
Since that time, medical device labelers have sent us thousands of questions about how to implement UDI.

Introduction

One topic that comes up over and over again in conversations with industry members is how to go about obtaining, assigning and maintaining UDIs for device product portfolios. How do you choose an issuing agency? How many codes should you purchase? What types of changes to a device warrant a new code? This guide is intended to help you begin to answer these questions for your device portfolio and point you to FDA and other resources around the web that can help. While the FDA and others have provided the information below in various forms elsewhere, we hope this guide will serve as a single place to access the essential information needed to get started.

The Anatomy of a UDI

Before we discuss how to obtain, assign and maintain UDIs, we should review the makeup of a UDI. How is an individual UDI crafted?

Each UDI is a code made up of two basic parts, the Device Identifier (DI) and the Production Identifier (PI). This guide is focused on the DI, since it has been the source of so many questions from industry members. While The PI for a given device varies based on lot and serial numbers, manufacturing and expiration dates, etc., the DI remains fixed. For this reason, only the DI portion of the UDI is submitted to and maintained in the FDA's **Global Unique Device Identifier Database (GUDID)**. The DI is the frame of reference for all instances of a device. It is also the backbone of an individual data record in the GUDID, holding together all of the numerous data fields and connecting them to each other to communicate essential information about the device.

How do I obtain DIs?

FDA has approved three agencies, GS1, HIBCC and ICCBBA, to issue DIs in accordance with the final rule. A device labeler must purchase or license a DI from one of these agencies before constructing the UDI and assigning it to a device. Each agency offers different benefits that device labelers will want to weigh when choosing the standard for their DIs.

The FDA-approved DI issuing agencies are:

GS1 – A nonprofit standards agency, GS1 sets international standards for supply chains, electronic data exchange, healthcare and more. GS1 numeric code licenses must be renewed at set periods. The pharmaceutical supply chain has historically utilized GS1 codes but the agency has also been gaining momentum in the medical device sector in recent years. DIs issued by GS1 are known as GTINs, Global Trade Item Numbers.

HIBCC – Health Industry Business Communications Council is a nonprofit organization focused on setting standards for the healthcare industry. HIBCC codes are alphanumeric and are acquired after paying a one-time fee. Historically, the healthcare industry supply chain has utilized HIBCC codes.

ICCBBA – A non-governmental organization, ICCBBA focuses exclusively on standards for medical products of human origin, such as blood products, tissues and organs for transplant. It manages the ISBT 128 standard used in more than 75 countries. The FDA has approved the organization to issue codes for blood bags and human cells, tissues, and cell/tissue-based products. ICCBBA codes have historically been used by blood, tissue and organ transplant banks.

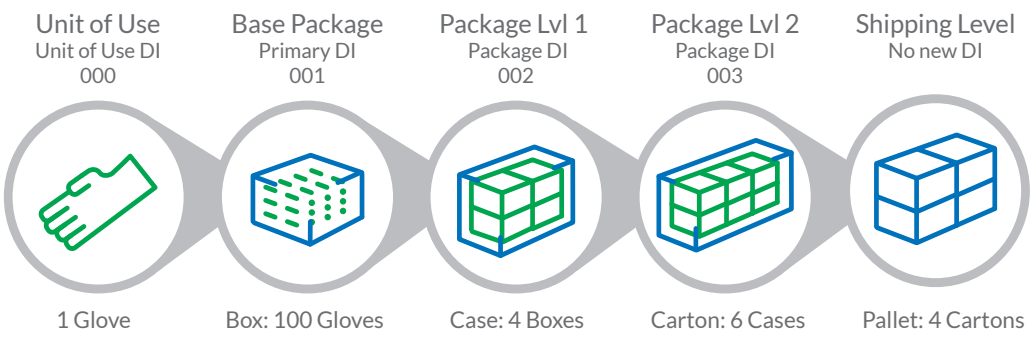
As you consider which agency is best suited to your company's needs, be sure to consider the following questions:

- **Do you already use existing codes from one of these agencies?** If you do, utilizing the same agency for your UDI labeling needs might make sense.
- **Are you feeling pressure from downstream customers to choose a particular agency?** If most of your business goes to customers who already use one set of standards, they may request that you use the same standards to better coordinate with their processes.
- **Are your products sold internationally?** If so, you may want to investigate whether the primary markets in which you do business require or strongly encourage a particular agency's code.
- **How many DIs will you need?** Each agency has different pricing structures. Cost may be a factor when deciding whether to license or to purchase a code outright.

How do I assign DIs?

After determining your issuing agency and obtaining a sufficient number of DIs, you will need to assign those DIs to the devices in your portfolio and report them as part of the DI record submission to the GUDID. Each DI record contains at least a Primary DI and possibly more:

1. **Primary DI.** Every DI record contains a Primary DI, which is assigned to the base package level. This is the smallest packaging configuration in which a device is sold (e.g., a box containing 100 rubber exam gloves).
2. **Secondary DI**. The Secondary DI is an optional field in the DI record, designed to accommodate a DI from an issuing agency other than the Primary DI agency. For instance, if your company has historically used HIBCC codes for other purposes but decided to use GS1 GTINs as your Primary DIs, you should associate the HIBCC code with the DI record in the Secondary DI field.
3. **Unit of Use DI.** This is a virtual DI assigned to some devices, meaning it is reported as part of the DI record but does not appear on the device or label. Unit of Use DIs are assigned when the base package contains more than one useable device. For example, each glove in a box of 100 rubber exam gloves is a device, so the glove would receive the Unit of Use DI.
4. **Package DI**. If your device is sold in package configurations containing multiple base package units, each package configuration up through (but not including) the shipping level receives its own DI. For instance, the box of 100 rubber exam gloves may be sold in a case containing four boxes. The cases may in turn be sold in a carton containing four cases and the cartons shipped four to a pallet. In this case, the glove would receive a virtual Unit of Use DI, the box would receive the Primary DI and the case and carton would receive Package DIs. No DI would be assigned to the pallet. Seethe graphic below.
5. **Direct Marking DI.** If your device is subject to **Direct Marking requirements**, your device will have a DI marked directly on the product. This may be the same or different from the Primary DI.



When is a new DI needed?

Device labelers often ask about when they need to create a new DI for a device. In other words, what changes to a device warrant the assignment of a new DI? The short answer is that a new DI is needed when either or both of the following changes occur:

1. Change in the version or model number. Every labeler maintains its own system of version/model numbers for its devices, as well as limits for what changes constitute an updated version or model of the device. **If the version/ model number changes, a new DI is needed.**
2. **Change to a non-editable field of the GUDID record.** Of the 62 data elements that make up a GUDID record, some can be edited after the grace period has ended and the record is made public, while others are fixed. For example,the fields containing contact information for customer use can be edited at any time in the lifecycle of a GUDID record. However, others are non-editable, such as the device brand name or the field indicating whether a device is packaged as sterile. If changes are required to a non-editable field, a new DI (and GUDID record submission) is required.

More DI Questions?

While this guide is by no means exhaustive, we hope it has provided you with a basic understanding of Device Identifiers and what you need to do to get started. If you have additional questions about how to apply these guidelines to your device portfolio or about UDI in general, please contact us. Our team of UDI experts is ready to help.

About Reed Tech

Since 2005, Reed Tech has been helping Life Sciences companies successfully submit their regulatory data to the FDA and other authorities electronically in Structured Product Labeling (SPL) format. Reed Tech has successfully submitted more than 750,000 unique records to the GUDID, annually about 34% of all published records. More than 450 Class III, II and I device labelers of all sizes trust Reed Tech as their UDI record submissions partner. As the number of global entities requiring medical device UDI information grows, Reed Tech will add selectable channels for data submission to regulatory bodies and data syndication to commercial trading partners.

For More Information, Contact: **MedDevice**@ReedTech.com **215-557-3010**

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