



The NiceLabel Guide to UDI Compliance

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Introduction

In 2012 the United States Congress passed a bill called the [Food and Drug Administration Safety and Innovation Act \(FDASIA\)](#).

This bill was enacted in response to concerns over the safety of medical devices, and a perceived need to improve record keeping and tracking of these devices.

Each medical device must have a numeric or alphanumeric identification code assigned to it, often including a unique product identifier, either with a serial number, lot or batch number, expiration or manufacturing date, or a combination of these.

The US Food and Drug Administration (FDA) manages a central database of these Unique Device Identifier (UDI) numbers, called the [Global Unique Device Identification Database \(GUDID\)](#)—pronounced 'Good-ID'.

Every medical device marketed and sold in the United States will have to have its own UDI, once the full system has completed its roll-out in 2022. Class III devices had to include UDIs in September 2014 and 'implantable or life sustaining/supporting' devices were introduced in September 2015. Class II devices followed in September 2016 and Class I devices have a delayed compliance date of September 2022. Separate deadlines apply to products which are intended to be reused, with the final deadline of September 2022 for permanent marking of Class I devices.

Overall, the aim of the system is to give the medical profession and patients greater assurance over the safety and efficacy of medical devices, while protecting them from unapproved devices.

How to prepare for GUDID submission

Before you submit any data to the GUDID, there are several steps you must take:

1. Group your products according to:

- Product class - Find product classes at the [FDA's Product Classification Database](#)
- Exceptions and time extensions - More information can be found at the [FDA's UDI Exception Page](#)
- Direct marking - More information can be found in [21 CFR 801.45 - Devices that must be directly marked with a unique device identifier](#)

2. Acquire appropriate Dun and Bradstreet (D-U-N-S®) numbers for your products.

These are used to identify labeler organizations in GUDID. Make sure that your details in the D&B database are correct and update any information if necessary.

You can obtain a [D-U-N-S number from D&B without charge](#), which could take up to 30 business days to arrive. [If you pay a small fee](#), it will arrive sooner.

3. Determine how many UDIs you need.

Each type of device and every version or model of each type of device will require a separate UDI. Different sizes, colors, materials, styles and packaging sizes of a device also need different UDIs. [Registrar Corp has a blog post about how to calculate the correct number of UDIs.](#)

4. Get a Global Medical Device Nomenclature (GMDN) term for devices.

Labelers must identify a GMDN preferred code for each device submitted to the GUDID. The GUDID can support more than one code for a single device, so it may not be necessary for you to pick just one. Make sure you leave enough time to acquire this, since it can be a lengthy process. [GMDN codes can be obtained from the GMDN Agency.](#)

5. Select an issuing agency.

The Device Identifier (DI) portion of the UDI has to be issued by an FDA-accredited agency—either [GS1 in New Jersey](#), [HIBCC in Arizona](#) or [ICCBBA in California](#).

6. Identify data sources.

Understand the difference between the data you currently hold and what you will need to submit to GUDID.

How to choose a data management system

The next stage of UDI preparation is to compile your own database of all product codes and catalog numbers. This will enable you to determine what products are relevant for UDI listing and how they are labeled.

For some smaller manufacturers, this will be a straightforward task. For larger companies, which have acquired other businesses, it may mean a long and complex review of products and naming conventions.

Your database should include all of the codes for packages of multiple units and kit forms. You will have to decide whether a product is really a medical device, or whether it is a spare part or an accessory. If it is a device or an accessory it needs its own UDI, if it is a spare part it doesn't need a UDI. RAPS has an article about [how to classify accessories](#).

Here are some further steps that you must take as a part of data management:

- Decide what changes need to be made to your existing quality assurance procedures.
- Ensure that your electronic records are validated, as part of the submission process, so that they comply with [21 CFR Part 11](#).
- Ascertain who the labeler is for each of your products. For some manufacturers, multiple companies handle a medical device before it reaches the user, so they must identify one party who will be responsible for the UDI and the GUDID submission. Original Equipment Manufacturing (OEM) and distributor contracts will need to include this information.
- Check the changes and additions to the Code of Federal Regulations. As of December 2013, several modifications to this code took effect. The UDI requirement was added to Medical Device Reporting, Reports of Corrections and Removals, Medical Device Recall Authority, Premarket Approvals, Quality System Regulation, Medical Device Tracking Requirements and Postmarket Surveillance. [Boston Biomedical has a blog post on these changes](#).
- Once you have created your own database and determined how you will manage it, you will be ready to form a strategy for UDI implementation.

How to implement a GUDID submission strategy

Labelers may submit UDI data records to the GUDID via either the FDA's GUDID Web Application or the Electronic Submissions Gateway in SPL format.

A. Manual GUDID submission

The FDA provides a free, secure online portal known as the [GUDID Web Application](#), which enables medical device labelers to enter UDI data directly into the GUDID database, one record at a time.

Device labelers can submit, search and retrieve information about their devices through this interface. However, if data is entered via the [GUDID Web Applications](#), it can only be managed through this system.

Manual submission makes the system suitable for smaller companies with less than 100 different stock keeping units (SKUs) or catalog items. For larger companies, a more automated system will save time and money, so this could be a better choice.

B. Health Level 7 Structured Product Labeling (HL7 SPL)

This enables companies to submit device information one DI record at a time, as an [HL7 SPL xml](#) (extensible markup language) file.

[HL7 is a standards development organization](#), accredited by the American National Standards Institute, which provides messaging standards for the healthcare sector. This enables the exchange, management and integration of data to support clinical patient care and management delivery, along with the evaluation of healthcare services.

If you plan to make HL7 SPL submissions, you must [establish a GUDID account](#) and then use the [FDA Electronic Submissions Gateway](#) (ESG) to submit your files (having first completed the ESG account establishment and testing process). Read more on [FDA's page about HL7 SPL submission](#).

C. A hosted solution, or Software as a Service (SaaS)

The majority of GUDID submission options available today are hosted, or SaaS options. These cloud-based solutions create data silos between your enterprise-based systems and a third party. The advantages of employing SaaS include benefiting from third-party expertise, predictability of cost and automatic technology upgrades. However, multiple connections may be needed between your enterprise systems and the product labeling system, which may in turn cause data synchronization issues between labeling and upload systems.

Using a hosted solution or SaaS may also increase the complexity of tracing and auditing the history of submissions for [21 CFR Part 11](#) compliance, due to the split location of data in cloud and other storage systems.

[Reed Tech](#) and [PTC](#), among others, offer hosted solutions.

D. An outsourced service

Outsourced service providers ease the burden on device labelers of submitting to the GUDID. They may do this by using the Web Interface on your behalf, or by using an SPL tool.

[Global Data Synchronization Network](#) (GDSN), services allow labelers to submit data through a single route via the GDSN, thus accommodating current and future data submission needs. For each UDI record, HL7 SPL-formatted submission data is transmitted to the GUDID, with FDA responses tracked for each submission. Data management and synchronization are provided, including data staging, pre-submission data validation and bi-directional workflow technology. Companies will be prepared for FDA audit and compliance reviews, providing documentation and evidence of system and data integrity.

Regardless of submission method, an outsourced partner may also be able to assist you in organizing internal teams, processes and data governance into a sustainable compliance program to achieve high UDI data management standards.

[Reed Tech](#), [GHX](#), and, [1worldsync](#) among others, offer outsourced services.

Practical steps for GUDID submission

You are now ready for the next stage in GUDID submission, where you take the following steps:

1. Appoint a regulatory contact

All device companies must designate a regulatory contact for UDI and GUDID purposes. This contact will set up the company's GUDID account, help to determine the UDI requirements applicable to its specific products and facilitate communication between the FDA and the company.

2. Create a GUDID account

Once a labeler has decided how they will submit data to GUDID, they should create an appropriate GUDID account. If you plan to submit through the GUDID Web Application, you should familiarize yourself with the system by creating draft submissions, which will not be visible to the FDA.

All manufacturers must request a GUDID pre-production account from the FDA. The Account Request Form asks for detailed information, which may involve some investigation on the manufacturer's part, along with internal corporate approvals. Once submitted, the FDA may take up to a week to respond to a submitted Account Request Form, according to industry sources. Creating a user account and receiving credentials from the FDA may take another day or two.

3. Select a product identifier

UDIs for all devices other than Class I devices have to contain a production identifier (PI). One or more of the following can make up the PI:

- Lot or batch number
- Serial number
- Expiration date
- Manufactured date
- Distinct identification code for a human cell, tissue or cellular and tissue-based product (HCT/P) regulated as a device

How to set up your system for GUDID submission

In this section, we detail the steps you need to take to ready your system for GUDID submission. You should:

- Amend label and packaging components and their composition to comply with submission criteria
- Develop a label template for your organization. This can easily be done with NiceLabel technology.
- Develop a label sign-off process which covers all relevant areas of your business
- Ensure that you understand the technological capabilities of your trading partners
- Detail the packaging changes you will need to make to accommodate new labels
- Consider the requirements of non-US regulators, in Europe or elsewhere, to ensure that your label changes will be as widely accepted as possible

How to set up your labeling system

Here is a final checklist of points to consider to help you select the best labeling software for UDI compliance and GUDID submission.

- Make sure that the application provides [21 CFR Part 11](#) compliant technologies: medical device manufacturers are required to implement controls, including system validations, electronic signatures and documentation, for any software and systems involved in processing the electronic data that must be maintained by the predicate rules (the underlying requirements) or submitted to the FDA.
- Ensure that the label design software can print the GS1 and Health Industry Bar Code (HIBC) and generate the automatic identification and data capture (AIDC) technology for placing a UDI on labels for medical device packaging. It is crucial that the solution you choose provides an efficient, easy-to-use way of meeting UDI requirements. The best practice is, if space permits, use the linear Code 128 barcode type, but make sure it meets the size requirements. If you are unsure or if you have very limited space on the label, use the two dimensional DataMatrix code. Either way it's a good idea to check the barcode quality with verification equipment or with your issuing agency. They may require you to pay a small fee for the verification. Explore the [NiceLabel Label Management System](#) to get started.
- Consider thermal transfer labels as a means of putting UDI on device packaging. These are cost effective and use high-resolution printing capabilities for barcodes, graphics and text. The completed label is high contrast for easy scanning.
- Consider implementing [a label a management solution that includes a document management system that adheres to 21 CFR Part 11](#), to simplify label creation, revision control and label approvals. This will give you the ability to manage document storage, user access and print history.
- Consider using a label management solution that includes quality management features such as an electronic label catalog of all of your labels and the ability to graphically compare label revisions or label variations.

The hardware you may need

1. Windows Server

Use a server that hosts the document management system and integration software (if you are going to connect to MES, PLM or ERP systems) for your label management solution. You will also need Windows PC's for the label designer and print operators.

2. Printers

Thermal transfer printers offer the best support for self adhesive labels and on-demand label printing in production environments. Consider equipment from a supplier such as [Zebra](#) or [SATO](#).

3. Direct Marking Equipment

Here too, you may need new hardware, including laser etching equipment (for marking reusable devices). Consider equipment from [Videojet](#), [Hitachi](#), [Domino](#) and [Markem Imaje](#).

4. Vision Inspection System

Select an in-line verification system to ensure that print quality for your label is maintained to the standards required by your issuing agency. Consider equipment from a supplier such as [Microscan](#) or [QualiVision](#).

The final stages

You should now be ready to submit data to the GUDID, but first go through a final checklist to ensure that your organization is prepared:

- Have you developed a protocol for obtaining missing attributes?
- Who is responsible for compiling the information?
- Who is responsible for managing the information once it is collected?
- Have you established a verification and validation process (and who is responsible for this)?
- Are you ready to process ACK (acknowledgement) messages from the FDA?

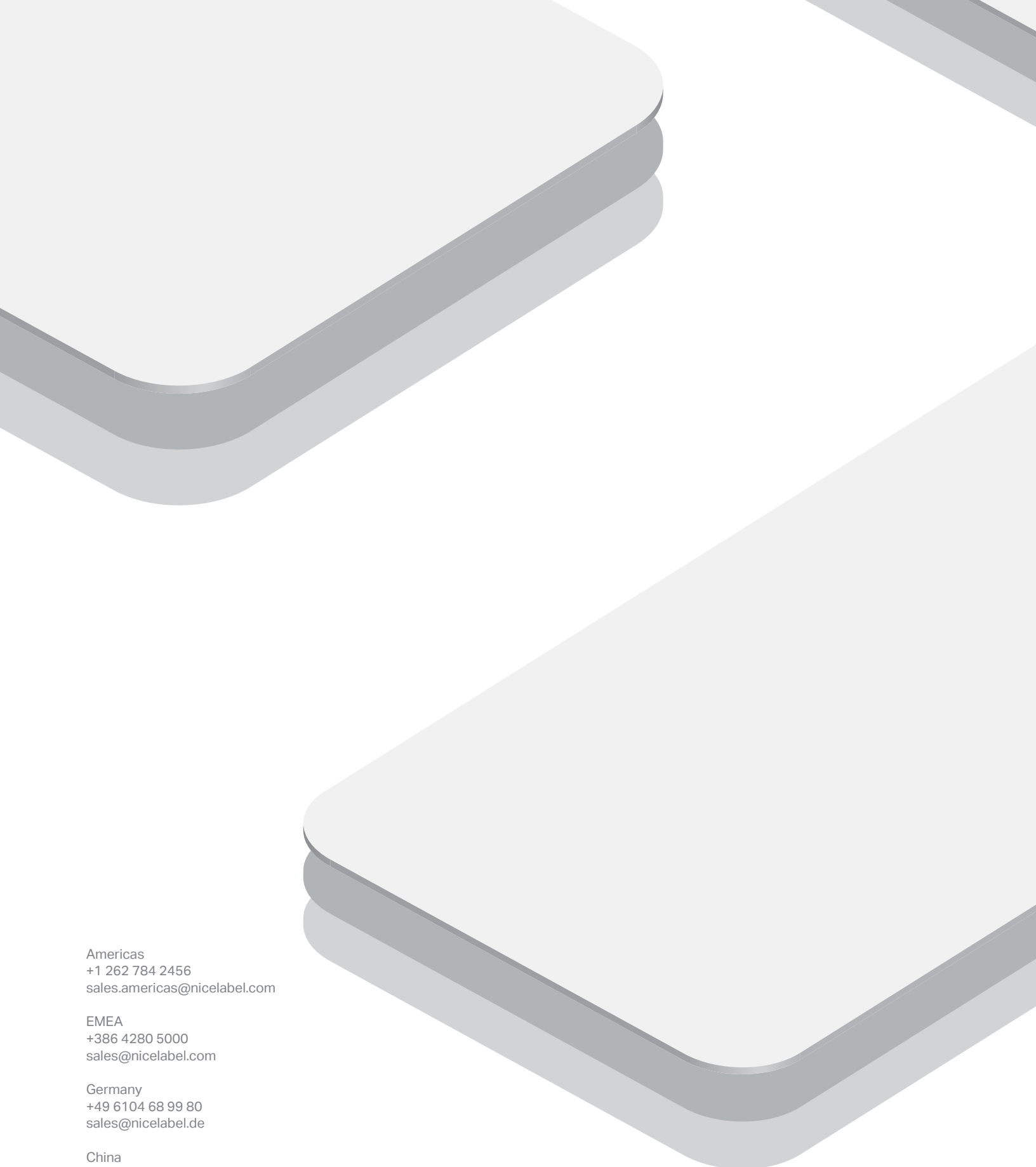
Now you can submit GUDID data to the FDA.

Good luck!

About NiceLabel

Established in 1993, NiceLabel is a leading global developer of label design software and label management systems that help companies of all sizes improve the quality, speed and efficiency of their labeling, while reducing cost.

With the help of our label management systems, organizations are able to digitally transform their entire labeling process, from design to printing to label management. The result is a leaner, more agile operation that enables companies to respond more quickly to changing market conditions and requirements, get products to market faster and compete more effectively in the sectors where they do business.



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