US

The US FDA Unique Device Identification (UDI) Regulation

How the program works, compliance requirements, and deadlines for compliance



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August 2017

An Introduction to UDI Regulations

The US Food and Drug Administration (FDA) issued the final Unique Device Identifier (UDI) rule and implemented it into the US Federal Register on 24 September 2013. The UDI rule was designated as 21 CFR Part 830. UDI compliance is mandatory, and compliance deadlines vary by device classification and type (reference Table 1).

This white paper will discuss the basics of the regulation, some key points to consider, and recommended preparations to ensure proper implementation of a UDI system.

What is the purpose of the UDI?

The purpose of this regulation is to encompass various FDA concepts to provide safe and effective products to the public. The UDI system final rule provides standard device identification and accompanying identifying information to support various public health initiatives, including support to the FDA's Post-Market Surveillance (PMS) activities.

The FDA enumerated a few reasons for the UDI regulation, including:

- Reducing medical errors caused by healthcare professionals using the wrong device
- Rapidly identifying a medical device for adverse event reporting (Medical Device Reporting per 21 CFR Part 803)
- Rapid deploying, identifying, and resolving recalls or market corrections
- Ability for manufacturers to develop solutions to device issues through the identification of finished medical devices
- More effective communication with the FDA for device identification
- Providing sourcing information related to the device, such as inventory management or input into health care records

Unique Device Identification (UDI) is the key to accessing a wealth of information for medical devices around the world. The basic premise of UDI is to generate a number that can be attached to each medical device for quick identification. The UDI identifies the labeler and information that is specific to the product, and ties into a database that provides even more detail and important features of that specific product.

The UDI regulation requires that all medical devices have UDI numbers located on their packaging and/or directly marked on the actual device, with limited exceptions. The UDI must be in both plain text (human-readable interpretation/HRI) and encoded in the form of Automatic Identification and Data Capture (AIDC) technology, such as a barcode or Radio-Frequency Identification (RFID).

Labelers must enter device UDI information into the publically accessible FDA's Global Unique Device Identification Database (GUDID) before distributing the product. This database is public and allows hospitals, clinics, and healthcare professionals to look up the identification information for any medical device. The GUDID only requires companies to provide information on the device identifier and the general type of production identifier included in the labeling – not the actual production identifier for every device manufactured.

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Important UDI Compliance Deadlines

The FDA determined that a phase-based approach to implementing the UDI regulation would be more feasible and allow companies the time to change their labeling, packaging, and internal documentation to comply. Refer to Table 1, which provides a timeline of when devices must have the UDI number applied to their device.

Table 1: Compliance Dates for Implementation of UDI

Class of Device	UDI Placement	Compliance Date
Class III	Labels and packages of devices, including software-only products.	24 September 2014
	Direct marking of devices.	24 September 2016
Class II	Labels and packages of devices, including software-only products.	24 September 2016
	Direct marking of devices.	24 September 2018
Class I	Labels and packages of devices without existing barcode and UPC. Includes software-only products.	24 September 2020
	Direct marking of devices.	24 September 2022
Life-supporting or life-sustaining	Labels and packages of devices, including software-only products. Direct marking of devices.	24 September 2015

It is important to note that any device that was physically labeled before the compliance date does not require a UDI. Medical devices intended for more than one use, reprocessed for continued use, or that can be separated from their packaging prior to use require direct marking (on the device itself). This ensures that durable product and devices used more than once can be readily identified at any time during the life of the product.

Implantable devices *do not* require UDI marking directly on the device.

Some categories and device types are exempt from UDI regulations:

- Class I devices (and only Class I) that have a UPC number and barcode assigned are not required to obtain UDI numbers.
- Custom devices, research use only, and investigational devices that fall under 21 CFR Part 812 are not required to obtain UDI numbers.
- Veterinary or Export Only products are also exempt from UDI requirements.

Note that if a medical device is a single-use product or homogenous product bundled into a single package until removed for use, such as a box of gloves, Band-Aids, solutions in bottles, or gels, that device only requires a UDI number on its packaging. Further exemptions from the UDI regulation may be requested from the FDA based on needs of the company or possible technological features of the device that would make UDI placement difficult.

How Will UDI Work?

The application of the UDI number assignment can be quite tricky, and the regulation does not provide much clarification. What the FDA has made clear is to "identify devices through distribution and use" so that devices can be identified quickly. Table 2 provides some brief examples of how UDI numbers are assigned to the version or model of a device.

Table 2: Examples of UDI Assignment to Medical Devices

Device	Model	UDI Number
Laser Hair Removal Device	100	1234ABC1234
Laser Hair Removal Device	200	3456EFG3456
Laser Hair Removal Device	300	7890JKL7890
Infusion Device including accessories and software	34XJRT	3434TYU3434
MyTelehealth software only product	Version 2.3	8765VBD8765
Wound Healing device, single unit package	60	5656CVB5656
Wound Healing device, 10 unit package	606	7878CVB7878
Wound Healing device, 25 unit package	626	9090CVB9090

The FDA is clear that software-only products must also contain UDI numbers either in their splash screens or their "About" options. This may present challenges for companies with multiple SKUs, multiple part numbers, or multiple packaging configurations for their devices. Again, the application of the UDI number must identify the product through distribution and use, so if different packaging can be confused by the user, these may need separate UDI numbers. Remember the intent of the UDI number is to assist in quick identification during use, adverse event, or recall situation.

Manufacturers must consider the impact on the device's UDI number when introducing device changes (e.g., a new model, changes to the device packaging, or changes to the "look" of the device). Many companies already have a change management system, but they must also establish criteria for the impact on UDI numbering.

Some changes to device packaging also require a new UDI. Since the FDA contends that the identification of the device needs to be known throughout distribution and use, the company must define a good rationale for not assigning a new UDI number if aspects of the packaging are changed. If the company changes their OTC device from one style to a different style, resulting in a slightly different look, yet maintain the same model number, this may require a new UDI number. The company's change management process must be able to identify changes through the entire packaging level of the device and the device itself.

Standardized Date Format

The UDI requirements in the final rule have requirements that dates '…intended to be brought to the attention of the user…' must be in the all-numeric format. According to the UDI regulation, the mandated date format for manufacturing and expiration dates must be in the numeric format YYYY-MM-DD; as an example, January 15, 2020 would be formatted as 2020-01-15. A day (DD) must always be included.

Changing the date format will be a key challenge for many companies. This requirement may cause confusion for healthcare professionals in the US and some other countries that commonly use the format: DD-MM-YY. When presented with the date 2018-06-07 there will be confusion—is that June 7, 2018, or July 6, 2018? It will be advantageous to medical device manufacturers to educate their customers about these changes. Otherwise, manufacturers will face many complaints entered for "Used beyond expiration date" that could easily be avoided with some preemptive explanation.

UDI components

The actual UDI number is separated into two parts: the Device Identifier (DI), the static information assigned by FDA, and the Production Identifier (PI), which is considered the "dynamic," variable information, including serial/lot number and expiration/manufacture date. The labeling organization (or legal manufacturer) can determine what information should be included in the PI depending on the medical device, whether the device is disposable or reusable, and the packaging configuration.

All devices that must comply with the UDI requirements must contain a Device Identifier (DI).

Any Class I device does not require the PI as part of the UDI. Therefore, Class I devices only require the DI portion. Although this is not required, a Class I device labeler can include PI information for their own internal requirements.

On the device packaging, the UDI number (composed of either the DI or the DI and PI) must be in both Automatic Identification and Data Capture (AIDC) format, such as a barcode and human-readable form. An example of a UDI number in both AIDC and human readable form is shown in Figure 1.

The UDI must be applied at all levels of packaging, from the direct device label to unit-level packaging, and the numbers will be different for each packaging level. The UDI number does not need to be on the shipping box. When direct marking of the UDI number on the device is required, it must be in AIDC and human-readable format. This might be a challenge for companies requiring direct marking that cannot be in the form of labels or tags. Again, the main purpose of the UDI is to have a unique identity for rapid identification of a finished medical device.

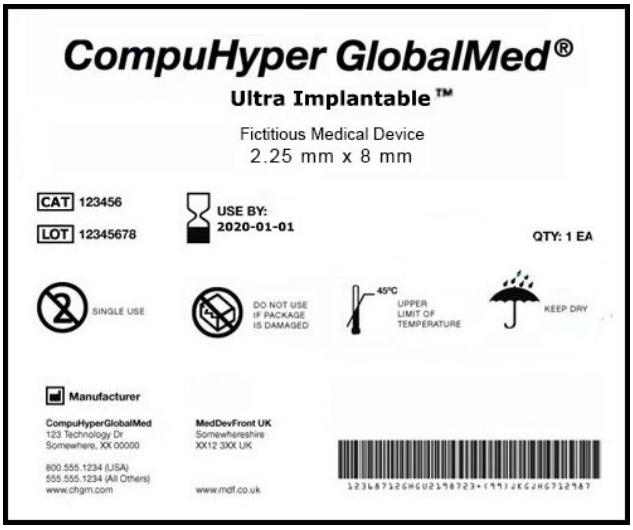

Figure 1: *An example provided by the US FDA*

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UDI Issuing Agencies

Once a manufacturer has determined the model or version groupings for its medical devices, the firm will then contact an issuing agency to obtain the UDI number. There are currently three issuing agencies accredited by the FDA:

- GS1 US – Lawrenceville, NJ
- Health Industry Business Communication Council (HIBCC) – Phoenix, AZ
- ICCBBA – San Bernardino, CA

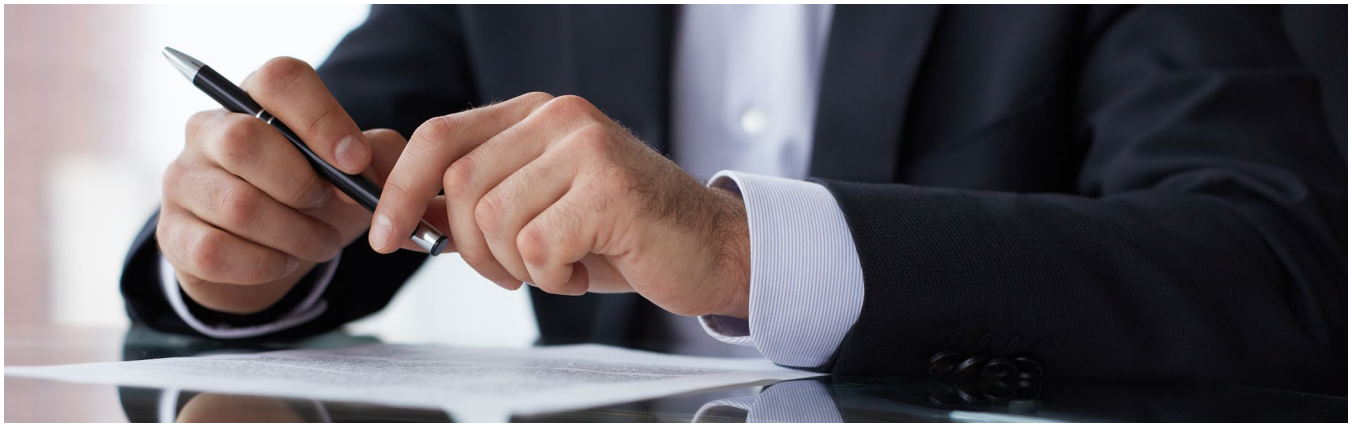
A company selects one of these third-party providers, completes an application, and pays the applicable fee. As part of the application, the company must provide all of the pertinent information related to the product model or version that will be included in the Global Unique Device Identification Database (GUDID).

The information can be transmitted electronically from the third-party provider to the FDA's GUDID database. This database is publically available to search for a company's product information, or users may enter a UDI number to look up the applicable information. The GUDID database should truly become a global database that contains a company's device information to quickly identify their products.

UDI Compliance To-Dos

1. Read the FDA's UDI final rule: https://www.federalregister.gov/articles/2013/09/24/2013-23059/unique-device-identification-system
2. Read the GUDID guidance document: http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM369248.pdf
3. Establish and implement a Unique Device Identification (UDI) System procedure in your quality system.
4. Understand your device's distribution patterns throughout the globe and keep an eye on global implementation steps as they develop for UDI.
5. Train employees on the UDI requirements, the regulations, new procedures, and document training on the training records.
6. Assemble and designate the project team or core team, which includes a cross-functional team representing marketing, production, quality, regulatory, and development. Assign UDI tasks to personnel to tackle the transition and address the ongoing maintenance tasks.
7. Evaluate labeling related equipment (e.g., printers, scanners, etc.) for appropriate capabilities. Update or replace as needed. Identify any equipment installation or qualification requirements.
8. Select an Accredited Agency to obtain the UDI numbers, in accordance with Supplier Evaluation Procedure to obtain your company prefix.
9. Define and list all of the attributes associated with the product version to be included in the GUDID database (e.g., sterile, packaging levels, direct marking).
10. Populate the GUDID database, including the UDI number and the attributes defined, according to the FDA web interface or through third-party provider.
11. Update the product labeling with the UDI number in human readable format and AIDC format.

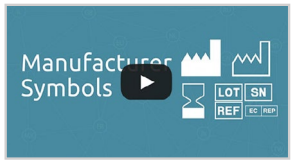
    Note: *All product versions or part numbers of the finished medical device will have an assigned UDI number located with direct marking on the product, on the product labeling, and/or the product packaging, unless exempt. Exempt devices must be identified and documented with the rationale consistent with the regulations.*
12. Assign identification information to your devices.
13. Communicate the information on the new UDI labeling and how to use it both inside your organization and throughout your distribution channels.



Conclusions

The FDA's Unique Device Identification Regulation provides a way for patients, users, and healthcare professionals to readily identify any medical device they are using. As this is a new regulation, eventually all companies must comply, so this is not a question of whether a company will implement a UDI system, but when. Emergo recommends that companies generate a quality plan for how they will transition and implement a UDI system within their organization.

If a company has two or three models or versions of their products, they may not find compliance too difficult. However, a company with 400 models or versions of their products has a significant amount of work ahead. One of the largest challenges will be that the entire product labeling and packaging of the company will likely need to be changed with the implementation of the UDI number and date format.



Learn more about device labeling requirements

If you enjoyed this white paper about the FDA UDI system, our video about device labeling and symbols might be useful to you. We discuss regulations for symbol usage in the US and EU, the benefits and challenges of using symbols, and the most common symbols and their meanings.

WATCH VIDEO

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- FDA QSR implementation and audits
- FDA 510(k) preparation and submission

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About the Author

Carrie Hetrick is a Senior RA Consultant at Emergo. Carrie is a trained dental surgeon with over 15 years of experience in medical device regulatory management. Her expertise includes FDA premarket notifications, premarket amendments, technical files, clinical evaluation reports, OUS regulatory submissions, FDA QSIT, and Notified Body audits, as well as implementing quality systems. She previously held executive positions at AQ Biomed and Grant Dental Technology Corporation. She received her doctoral degree from the University of Colorado Health Science Center School of Dentistry.

To Learn More...

Unique Device Identification System — FDA Final Rule
http://www.emergogroup.com/files/usa-udi-final-rule-2013-23059-pi.pdf

Unique Device Identification System: Form and Content of the Unique Device Identifier (UDI) - Draft Guidance for Industry and Food and Drug Administration Staff
https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM512648.pdf

Unique Device Identification: Convenience Kits - Draft Guidance for Industry and Food and Drug Administration Staff (January 4, 2016)
https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM479242.pdf

Global UDI Database (GUDID) - Guidance for Industry and FDA Staff
https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM369248.pdf

UDI System: Small Entity Compliance Guide - Guidance for Industry and FDA Staff
https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM409401.pdf

UDI System: Frequently Asked Questions, Vol. 1 - Guidance for Industry and FDA Staff
https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM410439.pdf