



GETTING AHEAD OF THE GAME

**Implementing Unique Device Identification
without Derailing Production**



INTRODUCTION

For the sake of patient safety, the ability to track and trace medical devices at a global level is paramount. Currently there is no single global regulation for uniquely identifying medical devices in the supply chain. This means recalling devices is less efficient and more complex than it could and should be, negatively impacting patient safety and confidence.

The FDA's directive for Unique Device Identification (UDI) for medical devices offers a way of presenting information in a standard format or barcode, making trade, distribution and usage more secure. Compliance, however, can prove to be a time-consuming process, and if done incorrectly, can expose organizations to serious setbacks. Alignment to the directive may result in the need to change current product packaging and procedures; so getting ahead of the game is essential.

TOUGH CHALLENGES AHEAD

In the ever increasing interests of patient safety and efficient protection of public health, the FDA has adopted a rule for UDI in support of enhancing safety, with the aim of identifying errors involving medical devices and providing more rapid resolution of device problems.

The standardization of a common UDI mandate will increase visibility and improve the quality of information in medical device adverse event reports, improve traceability and security within the supply chain and reduce potential medical errors through consistent, unambiguous, harmonized data. Furthermore, UDI will facilitate the storage, exchange and integration of data and systems between suppliers and providers.

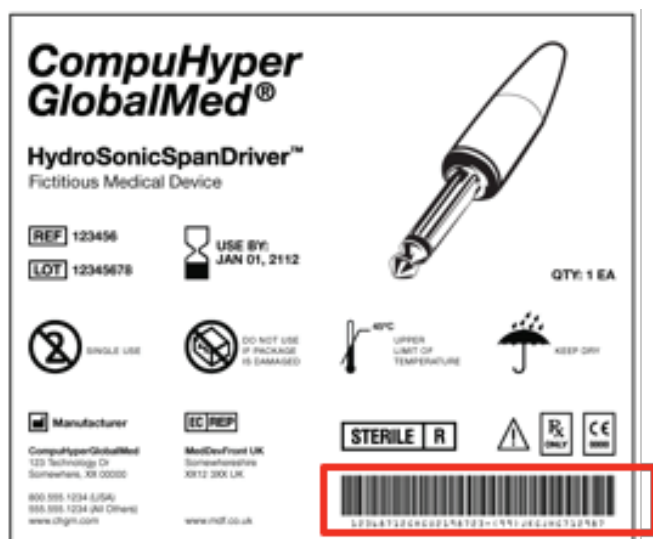
The true value of a UDI system lies in its broad adoption and subsequent use by manufacturers, distributors, providers, patients, and other stakeholders with important roles throughout the medical device lifecycle. UDI is expected to achieve this by providing electronic access to critical patient safety information relating to each medical device stored in a public database. The directive and proposed system aims to help users safely select and use the correct medical device for a patient, and for the FDA to identify product problems more quickly in adverse event reports and better target recalls.

Whilst the rule is a great reassurance for both patients and anyone who needs to use a medical device to improve health outcomes, the manufacturing and labeling industry is finding it a daunting task to prepare for and change their current processes in time.

SO WHAT IS A UNIQUE DEVICE IDENTIFIER?

A UDI is a unique numeric or alphanumeric code which allows the unambiguous identification of a specific product on the market. It represents the “access key” to device related information stored within a publically available Global UDI Database (GUDID), so that users of a medical device can easily look up information about that particular product.

The main framework for the production of a Unique Device Identifier is the combination of the UDI located on the label or directly on the product, and the storage of the UDI and additional device related information in the GUDID. The UDI itself contains two parts: the Device Identifier and the Production Identifier, both of which must be individually recognizable.



1) Device Identifier

The unique numeric or alphanumeric code specific to a medical device which is also used as the “access key” to information stored in a UDI Database.

2) Production Identifier

The numeric or alphanumeric code provides information that reflects how the device is controlled. The different types of Production Identifier(s) can include any combination of serial number, lot/batch number and manufacturing and/or expiration date. The different types of Production Identifiers included in the UDI will depend on the risks associated with the distribution and use of the device.

The UDI system requires manufacturers to provide the information to the user in both plain-text format and code format - such as a linear, 2D DataMatrix barcode or RFID tag based on International Organization for Standardization (ISO) that can be read by Automatic Identification and Data Capture (AIDC) technology. Although not mandated by the FDA, these will more than likely be a GS1 code format especially considering the mandate for GS1 standards by major healthcare providers (e.g. The NHS in England). This information will need to then be ‘fed up’ to the UDI database from the ERP system and the labeling management system.

The proposed information to be stored in the GUDID is as follows:

- Device Identifier Type/Code [GTIN]
- Make/model; Brand/Trade Name
- Clinically relevant size
- Device version/model number (or reference number)
- Unit of Measure/Packaging level/quantity
- Controlled by – Lot and/or Serial Number; Exp. Date
- Labeler contact name, phone, email
- GMDN Classification code/term
- Whether packaged sterile
- Contains latex
- FDA premarket authorization (510k, PMA)
- Listing number

With the following administrative attributes:

- DUNS Number
- Brand Name or Model/Version – Device Family
- FDA product code (procode)
- Marketing Status/date
- For single-use
- Contain Human Tissue
- Kit Product
- Combo Product
- Higher levels packaging
- Rx - OTC

IMPROVING PATIENT SAFETY, REDUCING ERRORS & INCREASING EFFICIENCY

The definition of a medical device is typically an object that physically enters the human body and in many cases remains there for a period of time. Consequently direct marking on the product is not always possible for a number of reasons such as size of the device, design, materials, or performance issues. These life saving devices come with an extensive amount of critical information; so it is no easy task to try to convey this through a single label. Therefore, having UDI for each and every applicable medical device product that electronically stores its critical information in an accessible database will bring a number of significant and enormously valuable benefits for both the medical device manufacturer and the patient.

For the medical device manufacturer, benefits will include improved supply chain management such as:

- a) Enhancing device traceability improving post market surveillance with the ability to rapidly and definitively identify a device and key attributes that affect its safe and effective use
- b) Eliminating unnecessary and costly product scrapping where devices which are not implicated by the problem are less likely to be 'swept up' in an over-broad attempt to remove potentially hazardous devices
- c) Better security of devices through more effective detection, which in turn could lead to the removal of counterfeit devices

For the healthcare provider and patient, benefits will include:

- a) Consistent coding to identify products will enable wider use of automated inventory management systems, thereby reducing inventory cost and the expense of consignment stocks
- b) Helping to ensure that the intended device will be used in the treatment of a patient, rather than a similar device that may not fully meet the requirements of the health care professional who ordered its usage
- c) Reducing medical errors that result from misidentification of a device or confusion concerning its appropriate use

THE KEY CHALLENGES FOR MANUFACTURERS

Getting equipped in time is the biggest challenge for medical device manufacturers. Although all data stored in the GUDID will be publicly available with no cost element to access, buying in the correct systems and skilled staff for the job will mean initial extra expenditure, potentially putting a financial strain on many of them.

As the marking of UDI is an additional labeling requirement and not a replacement of any other form of product marking, substantial time needs to be allocated to ensure the process is implemented and managed correctly without a negative impact on the organization. Failure to comply with the UDI rules of marking every medical device product under their name correctly will result in a manufacturer's reputation being seriously damaged, not to mention inspection and a warning letter from the FDA.

The implementation of UDI requires both knowledge of the process and collaboration between departments within a medical device manufacturing organization. Finding the most effective way of communicating the new rule will require careful consideration and planning. All parties involved in the process will need to truly understand the implications and perceived benefits, to meet their own requirements as well their organization and the overall industry.

TAKING RESPONSIBILITY

Organizations should already be seeking best practices in managing labeling lifecycle processes to meet the new requirements. Many medical device manufacturing organizations who still use paper-based methods and outdated labeling systems will struggle to manage the increased amount of data and information that will be generated. Organizations should be carefully planning their future labeling operations strategy now and consider implementing a validated, secure label lifecycle management solution.

'Label Lifecycle Management' refers to the provision of discipline and control throughout the lifetime of the label. This includes security controls, auditing, the provision of editing tools, maintaining data integrity, support for review and approval, supply of objective evidence, ability to represent customer processes and the storage of historical content for future reference making it much simpler to become UDI compliant.

Key areas are:

- **Regulatory Compliance**
 - 21 CFR Part 11, Part 812, Part 820, EU Annex 11, MHRA, GMP V
- **Security Enforcement**
 - Password controls, user restrictions, group management, access controls
- **Content Creation**
 - Labels, Inserts, IFU's, Product Data, Batch Data, Logos, Glyphs, Symbols, Product Images
- **Version Control**
 - Enforce access control and content editing restrictions across the system
 - Provide and maintain one source of the truth
 - Preserve Data Integrity throughout the lifecycle
- **Review & Approval Management**
 - Prevent unapproved content being printed
 - Streamline review cycles
 - Extend access beyond traditional production system users
- **Printing**
 - Production Printing, Re-printing, Re-Labeling, mapping customer workflow processes within the software
 - Using external systems to source production data as required
- **Reconciling**
 - Electronic reconciliation of every document printed from every workstation anywhere in the system.
- **Auditing**
 - Complete secure audit trail of every transaction preserved within the software

Because UDI only succeeds if the integrity of the label data is assured to be correct, protected, and ultimately published to the GUDID, it is recommended that these data elements are to be managed by those persons who have the permission and credentials to enter, approve, and version control these label data elements in a secure database.

So for the Device Identifier, it is recommended to manage these data elements in a secure, closed, validated, labeling solution which offers a mechanism to enter, review, approve, and systematically version control each data element.

In the industry it is common knowledge that labels and label data live in a state of change for multiple reasons, and it's how these changes are managed that impacts the ability to achieve success, and further, the ability to ensure UDI compliance.

Likewise, for the Production Identifier, the LOT or Batch number should be generated and controlled in an ERP system, and preferably data-driven at time of print, as the integrity of these elements is critical to the ability to uniquely identify each product in the marketplace for proper traceability and post market surveillance. Other Production Identifiers such as serial numbers, the date of manufacture, and the expiry date, should be generated and controlled either in an ERP system and/or secure labeling lifecycle management system and converted into a barcode format at the time of print.

TIMESCALES

The FDA's final rule for UDI compliance was published in September 2013.

From this publication of the rule the clock is ticking for medical device manufacturers to meet compliance regulations within specific timeframes dependent on the class that their medical device products are categorized.

Medical devices are defined by different classes, according to their risk with regard to patient safety, and need to be marked clearly according to these risk classes to meet compliance. Due to the extensive diversity of medical devices, a gradual risk-based approach to implementation is essential. As a rule, the FDA will normally require compliance for Class III devices within one year after the final UDI publication, Class II medical devices in three years, and Class I medical devices up to five years.

Below is the Effective Dates for UDI Requirements.

Compliance Date	Requirement
1 year after publication of the final rule (September 24, 2014)	The labels and packages of class III medical devices and devices licensed under the Public Health Service Act (PHS Act) must bear a UDI. § 801.20. Dates on the labels of these devices must be formatted as required by § 801.18. Data for these devices must be submitted to the GUDID database. § 830.300. A 1-year extension of this compliance date may be requested under § 801.55; such a request must be submitted no later than June 23, 2014. Class III stand-alone software must provide its UDI as required by § 801.50(b).
2 years after publication of the final rule (September 24, 2015)	The labels and packages of implantable, life-supporting, and life-sustaining devices must bear a UDI. § 801.20. Dates on the labels of these devices must be formatted as required by § 801.18. A device that is a life-supporting or life-sustaining device that is required to be labeled with a UDI must bear UDI as a permanent marking on the device itself if the device is intended to be used more than once and intended to be reprocessed before each use. § 801.45. Stand-alone software that is a life-supporting or life-sustaining device must provide its UDI as required by § 801.50(b). Data for implantable, life-supporting, and life-sustaining devices that are required to be labeled with a UDI must be submitted to the GUDID database. § 830.300.
3 years after publication of the final rule (September 24, 2016)	Class III devices required to be labeled with a UDI must bear a UDI as a permanent marking on the device itself if the device is a device intended to be used more than once and intended to be reprocessed before each use. § 801.45. The labels and packages of class II medical devices must bear a UDI. § 801.20. Dates on the labels of these devices must be formatted as required by § 801.18. Class II stand-alone software must provide its UDI as required by § 801.50(b). Data for class II devices that are required to be labeled with a UDI must be submitted to the GUDID database. § 830.300.
5 years after publication of the final rule (September 24, 2018)	A class II device that is required to be labeled with a UDI must bear a UDI as a permanent marking on the device itself if the device is a device intended to be used more than once and intended to be reprocessed before each use. § 801.45. The labels and packages of class I medical devices and devices that have not been classified into class I, class II, or class III must bear a UDI. § 801.20. Dates on the labels of all devices, including devices that have been excepted from UDI labeling requirements, must be formatted as required by § 801.18.

Effective Date	Requirement
	Data for class I devices and devices that have not been classified into class I, class II, or class III that are required to be labeled with a UDI must be submitted to the GUDID database. § 830.300. Class I stand-alone software must provide its UDI as required by § 801.50(b).
7 years after publication of the final rule (September 24, 2020)	Class I devices, and devices that have not been classified into class I, class II, or class III that are required to be labeled with a UDI, must bear UDI as a permanent marking on the device itself if the device is a device intended to be used more than once and intended to be reprocessed before each use. § 801.45.

Compliance dates for all other provisions of the final rule. Except for the provisions listed above, FDA requires full compliance with the final rule as of the effective date that applies to the provision.

SUMMARY

So the real questions for medical device manufacturers are; based on your current system capabilities:

- a) Are you able to properly control the elements and execution of your print jobs and then capture the data elements of every label printed?
- b) Will you be positioned to efficiently capture and submit the necessary data to the GUDID?
- c) Have you factored in the training of your staff and allocated sufficient time to integrating this additional labeling requirement to your current processes?

If you can't give a definitive yes, then you need to start thinking about it sooner rather than later. Although the delayed timelines from the FDA for final rulings are frustrating for many, it should by no means indicate that any organization can afford to delay their preparation. By planning and implementing a label lifecycle management strategy with the right processes and right solution, you will guarantee UDI readiness for your organization in time and without derailing your production.

About GS1 UK www.gs1uk.org

GS1 is an international not-for-profit association with Member Organizations in over 100 countries. GS1 is dedicated to the design and implementation of global standards and solutions to improve the efficiency and visibility of supply and demand chains globally and across sectors. The GS1 system of standards is the most widely used supply chain standards system in the world.

Our Member Organizations handle all enquiries related to GS1 products, solutions and services.

- GS1 has close to 40 years' experience in global standards
- GS1 offers a range of standards, services and solutions to fundamentally improve efficiency and visibility of supply and demand chains.
- GS1 standards are used in multiple sectors and industries.

About PRISYM ID www.prisymid.com

PRISYM ID designs and delivers turn-key labeling solutions for organizations that need complete product auto-identification and lifecycle traceability. With the continual tightening of labeling regulations and audits, PRISYM ID empowers its clients to safeguard their reputation by ensuring compliance, and significantly reduce costs by eliminating recalls through labeling errors. For over 30 years, PRISYM ID has been the market leader in world-class label lifecycle management, and is trusted for delivering personalized service excellence to clients in varied sectors including medical device, life sciences, healthcare, automotive, chemical and manufacturing.



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