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# UDI White Paper

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In conjunction with: GS1, Zebra and Motorola

# Unique Device Identification White Paper

**Summary**

This white paper has been produced to help readers understand the US Food and Drug Administration (FDA) final ruling on Unique Device Identification (UDI), describes how the ruling will impact the medical device industry and provides recommendations of how businesses can comply with its requirements.

**Introduction**

The Food and Drug Administration (FDA) has released a final ruling requiring that most medical devices distributed in the United States carry a unique device identifier, or UDI. It also applies to certain combination products that contain devices and those licensed under the Public Health Service (PHS) Act (e.g., donor screening assays).

A UDI system has the potential to improve the quality of information in medical device adverse event reports, which will help the FDA identify product problems more quickly, better target recalls and improve patient safety.

**When fully implemented, a UDI system can:**

- Allow more accurate reporting, reviewing and analysis of adverse event reports so that problem devices can be identified and corrected more quickly.
- Reduce medical errors by enabling health care professionals and others to more rapidly and precisely identify a device and obtain important information concerning the characteristics of the device.
- 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, and registries. A more robust post market surveillance system can also be leveraged to support premarket approval or clearance of new devices and new uses of currently marketed devices.
- Provide a standardised identifier that will allow manufacturers, distributors and healthcare facilities to more effectively manage medical device recalls.
- Provide a foundation for a global, secure distribution chain, helping to address counterfeiting and diversion and to prepare for medical emergencies.
- Lead to the development of a medical device identification system that is recognized around the world.

**What is a UDI?**

A UDI is a unique numeric or alphanumeric code that consists of two parts:

- A device identifier (DI), a mandatory, fixed portion of a UDI that identifies the labeller and the specific version or model of a device, and
- A production identifier (PI), a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of a device:
    - the lot or batch number within which a device was manufactured;
    - the serial number of a specific device;
    - the expiration date of a specific device;
    - the date a specific device was manufactured;
    - the distinct identification code required for a human cell, tissue, or cellular and tissue-based product (HCT/P) regulated as a device.

**UDI Compliance**

The UDI ruling impacts manufacturers and distributors in two areas:

Labels: Compliant labels are required for all products and at all stages of packaging (i.e. from large cartons to individual packages)

Data: A set of data for each product and package sent to the FDA Global Unique Device Identification Database (GUDID) in the USA to be approved

ONLY WHEN YOU HAVE ACHIEVED THE ABOVE ARE YOU COMPLIANT

NON-COMPLIANT GOODS WILL NOT BE ALLOWED TO BE SOLD OR USED IN THE USA

The FDA has declared that UDI requirements are likely to change, therefore medical device manufacturers will need to ensure that they remain UDI compliant over time.

Also, other countries are planning to release their own standards for identification of medical devices and products. It is likely that these standards will be primarily based on the FDA's standards with minor amendments to meet the specific regulatory requirements of each country.

**Summary of compliance dates for the FDA UDI Requirements**

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

Medical devices are defined in different classes, according to risk with regard to patient safety and need to be marked clearly according to these risk classes. Due to the extensive diversity of medical devices, a gradual risk-based approach to implementation has been agreed. 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. (NB: These classifications are the US device classifications, not the European classifications)

| Compliance Date | Requirement |
|---|---|
| 24/09/2014 | The labels and packages of Class III medical devices and devices licensed under the Public Health Service Act (PHS Act) must bear a UDI. |
| 24/09/2015 | The labels and packages of implantable, life-supporting, and life-sustaining devices must bear a UDI. |
| 24/09/2016 | A Class III device required to be labelled 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 |
| 24/09/2018 | A Class II device that is required to be labelled 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 |
| 24/09/2020 | A Class I device, and devices that have not been classified into Class I, Class II, or Class III that are required to be labelled with a UDI, must a bear a UDI as a permanent marking on the device itself if this is a device intended to be used more than once and intended to be reprocessed before each use |

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|---|
| **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 |

**The trend towards global standards to ensure compliance**

The FDA's final ruling is a major part of the trend towards common global standards in the medical device and products industry. In healthcare as in other industries, GS1 standards for identification and bar coding are recognised as the industry benchmark. In December 2013 GS1 became the first FDA-accredited UDI issuing agency.

GS1 Standards meet all the requirements of the UDI rule including:

- Product identification at each level of the packaging hierarchy using the GS1 Global Trade
- Item Number (GTIN)
- Applicable bar code symbols
- Applicable product data to be included in bar codes
- All data that must be stored within the Global UDI Database specified by the FDA

In addition to the FDA's compliance timeline, NHS trusts in the UK and other major medical device consumers both in UK and globally will require suppliers to provide GS1 GTINS and associated data in their procurement processes**.**

NHS trusts in the UK propose to inform suppliers that use of GS1 standards will be evaluated positively in any competitive situation and will become a mandatory requirement over time. This is expected to expedite manufacturer's adoption of GS1 standards to identify and label their products.

In the UK, more details can be found at www.gs1uk.org.

**The Challenge**

The challenge for Medical Device Manufacture's is how to comply with this FDA UDI final rule within the above timeframe, as failure to do so will have a severe business impact as wrongly labelled products shipped to the US will not be accepted.

The size of the problem facing Medical Device Manufacturers varies. Costs of compliance will be greater for organizations that manufacture in multiple countries and use different enterprise reporting and labelling systems.

For small and medium size enterprises (SMEs), which constitute the majority of suppliers, UDI compliance is projected to be costly not just in terms of software and labelling system upgrades, but also in terms of management time and attention understanding and administering ever changing regulatory requirements.

**The Solution**

Kodit, a software solutions company based in the UK has developed a cloud based UDI compliant software and services solution with built-in flexibility to cater for future changes.

For the vast majority of medical manufacturers who need to demonstrate UDI compliance a cloud based UDI service may be the most viable and cost effective way forward as it will avoid costly in-house upgrades.

The Kodit UDI software solution runs on Fujitsu's global cloud infrastructure that is able to scale to meet demand of any medical manufacturer, it has built-in security, data disaster recovery and has a service level of 99.95% availability and can be accessed anywhere in the world.

The UDI solution can also include all the necessary components needed, including Zebra label printers/media and Motorola scanners for verification.

The Kodit UDI Compliance solution gives users the opportunity to realise the following benefits:

- Significantly reduced implementation costs
- Reduced costs of keeping up with GS1, FDA and other standards
- Reduced costs associated with product recalls and non –compliance
- Elimination of the costs associated with manual processes and errors
- Improved information for management and audit purposes.

If you are in need of a UDI compliant service and you would like more information contact Kodit via the following website: http://www.kodit.com

**About Kodit**

Kodit specialises in the creation of intelligent mobile data collection / verification solutions in areas such as; Healthcare, Asset Maintenance, Asset Lifecycle Management and Emergency Response Management. The solutions are deployed via our partners both locally and in the Cloud using internationally recognised standards for communications and data security.

**About Zebra**

A global leader respected for innovation and reliability, Zebra provides enabling technologies that allow customers to take smarter actions.

Zebra's extensive portfolio of barcode, receipt, kiosk and RFID printers and supplies, as well as real-time location solutions give a digital voice to assets, people and transactions that provides greater visibility into mission-critical information.

**About Motorola**

Motorola Solutions Inc. is the world leader in enterprise mobility with global sales offices, a huge network of authorised resellers, and specialist application partners.

As the world leader in the bar code scanning industry, Motorola Solutions is perfectly positioned to help Medical Device Manufactures comply with the FDA UDI final rule. Motorola offer the broadest and most fully featured portfolio of bar code scanners, including rugged, handheld, hands-free and fixed mount scanners.

For more information about Motorola scanners, visit www.motorolasolutions.com/barcodescanners

**About GS1 UK**

For more than 35 years GS1 UK has been working with its members to enable the efficient movement of goods and sharing of information. It drives supply chain efficiency alongside 111 other not-for-profit GS1 member organisations in 150 countries worldwide.

Having introduced the first truly global bar code numbering system in 1973, at least five billion GS1-compliant bar codes are now scanned everyday – making it the most widely used supply chain standards system in the world. GS1 identification numbers are now also commonly used in RFID tags, Electronic Data Interchange (EDI) messages and for real-time global data exchange.

Providing independent support, GS1's team of technical and business consultants also assist members with on-site implementation of appropriate supply chain information solutions.

Its 27,000+ UK members range from SMEs to major UK companies and include grocery retailers and food service companies, food manufacturers, healthcare and pharmaceuticals companies, and NHS Trusts. Its supervisory board includes senior directors from Tesco, Morrisons and Sainsbury's, as well as Unilever, P&G, Diageo and the NHS.

www.gs1uk.org