UDI: KCI PRODUCT LABEL CHANGES

What is UDI?

Unique Device Identification (UDI) is a new regulation that was released by the United States Food and Drug Administration (FDA) on September 24, 2013.

This regulation requires medical device manufacturers to label their products with a unique device identifier (DI) and additional conditional production identifiers (e.g., serial/lot numbers, manufacturing date, expiration date, and donation identification numbers). The UDI must be present in both plain text (human-readable) and barcode (machine-readable) formats on the product labels.

Manufacturers are also required to upload certain information associated with the product into the Global UDI Database (GUDID) maintained by the FDA. This database serves as a reference catalog for every device with an identifier and is accessible by the public.

For more information on the full rule, visit the FDA website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/

Benefits of UDI

The UDI system allows for more accurate reporting, reviewing, and analyzing of adverse event reports so that problem devices can be identified and corrected more quickly than in the past. It also allows distribution systems to have a more standardized way of identifying products and for hospitals to document use of devices in electronic health records.

Timelines

A phased implementation has been mandated by the FDA for medical device compliance as follows:

- September 24, 2014: Class III medical devices
- September 24, 2015: Implantable, life-supporting, and life-sustaining medical devices
- September 24, 2016: All other Class II medical devices
- September 24, 2018: Class I, exempt, and unclassified medical devices

The deadline specifically applicable to KCI products is **September 24, 2016**.

KCI USA, Inc., is currently compliant to the UDI regulation for all its products that are commercially distributed in the United States.

GS1 Standards

The FDA allows for manufacturers to follow the barcode formats of specific accredited issuing agencies.

KCI USA, Inc., uses GS1 formats for all its UDIs and associated barcodes.

GS1 is an international global standards organization that offers manufacturers a standardized way to encode product information and to track and identify products in the supply chain.

The device identifiers issued by GS1 are known as Global Trade Item Numbers (GTINs) – a unique 14-digit number assigned to each product.

Labeling Changes

Here are some examples of KCI's new UDI-compliant product labels. If you currently scan KCI barcodes to manage and track your inventory, you will need to update your systems to recognize the new formats.

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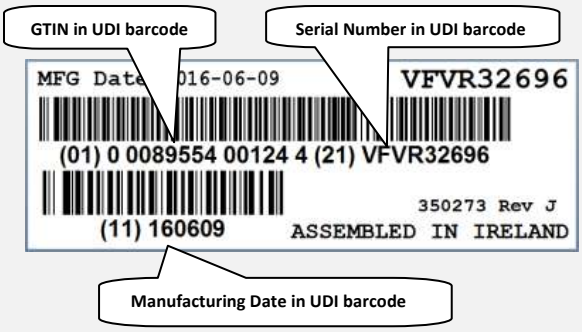
Reusable Product Label Example:

These labels are present on serialized, reusable device assemblies and include the GTIN as the device identifier with the serial number and manufacturing date in the production identifier.



Single-Use Product Label Example:

The labels on lot-controlled disposable products include a GTIN as the device identifier with the lot number and expiration date in the production identifier.

The expiration data is included in the barcode only when present in human-readable form.