UDI Labeling Requirements for Medical Devices: Part II

SEE MORE. DO MORE.

Dave Coons

**Vice President,
Advanced Markets & Technology,
Engineering**

Sponsored by Zebra Technologies

In September 2013, the US Food and Drug Administration released its final ruling on legislation requiring all medical devices distributed in the United States to carry a Unique Device Identifier (UDI) label. The regulation covers all products classified as medical devices, including Class I, II, and III devices, InVitro devices, software, and some tissue-based products.

The UDI law will be implemented over the course of several years, beginning with Class III devices, which must be fully **compliant by September 24, 2014**. The FDA has provided a schedule that details the mandatory compliance deadlines for different types of products. Any company that is not compliant by the required date will be prohibited from selling or distributing covered products in the United States.

For more information about UDI, see the *FDA Medical Devices Regulations website*.

The following questions about UDI and FDA compliant labels were posed to David Coons, Vice President, Advanced Markets and Technology, Zebra Technologies:

Q: Can I integrate the UDI into an existing label or do I need a separate UDI label?

A: You may add the UDI to an existing label, as long as the existing label meets the requirements for quality and readability over the lifetime of the product.

Q: Will I need to redesign my labels?

A: Yes—It is very likely that you will need to redesign your labels. The UDI, in both human readable and machine readable form (typically a barcode), must be added to each label. Additionally, some of the current information on your labels may need to be reformatted to meet the UDI requirements. Many companies are finding that adding the UDI is difficult on smaller pre-existing labels. This means that some labels must be redesigned to make better use of space and/or use smaller fonts. Another option is to use a larger label.

Q: Do the product and the packaging both require a UDI label?

A: Generally, yes. If there is any chance that the product will be separated from its packaging or pouch before use, then both parts will require a UDI label. For example, many devices are shipped in sterile pouches inside a cardboard shipping carton. The cartons are often broken down or discarded when the pouches are put into a supply cabinet or on a shelf. In these cases, it is required that the pouch and the carton both carry a UDI label.

Q: Will I need to upgrade my printers?

A: You will probably be able to use your existing printing equipment. Most medical device manufacturers use thermal transfer printers to print their labels, and all Zebra thermal transfer printers are capable of printing UDI compliant labels. If you can fit the required elements on the label and maintain placement and readability, then you are probably set.

Some companies may choose to upgrade their equipment in order to move up to 300 or 600 DPI resolution, or to get better top-of-form alignment. These factors will come into play if label space is limited or if new labels need to be added. Some companies might take the opportunity to upgrade older printing equipment as part of the larger UDI readiness program.

Q: Will I need to upgrade my software?

A: There are two main software elements that need to be considered as part of your UDI program.

1. **Label Design and Printing** – As long as your current software can handle rendering and printing of GS1, HIBCC, or ICCBBA barcode formats, and if it can connect to a data source for production control variable data, then you should be able to continue using your existing software.
2. **GUDID Upload** – Unless your company has very few unique products and/or packaging levels, you will probably need to acquire software to help manage the data upload, as discussed in a previous question above.

Some vendors have software that combines both functions into a single workflow, but they can be separate applications.

Q: How does the law address print quality and readability of the UDI label?

A: Section 820.120 of the UDI regulation requires that the label be both human and machine readable for the lifetime of the product. This typically means that a barcode should be a "C" grade or better when the label reaches the end user. In order to verify compliance, many companies are using scanners to verify that the quality of their printed barcodes is a "B" or better on their production lines, thus giving allowance for some degradation as the carton moves through the distribution channel to the end user. One large company recently presented its findings from an internal audit of barcode quality and spec conformance across all of its labels. They were surprised to learn that almost 100% of their labels were not compliant. They addressed and corrected those issues as part of their UDI readiness program. Zebra can help you understand more about barcode quality and we can recommend products that can help you be sure your label quality stays high.

Q: What else do I need to consider when planning my labeling project?

A: Clearly, in order for a label to remain readable over the lifetime of the product, it must stay firmly adhered to the surface. You need to consider the surface material and the shape of surface the label application is intended for to ensure that the label remains adhered. Small curved surfaces can be difficult to label, since they require a flexible material with a tight mandrel adhesive.

Also, you need to consider the environmental conditions the label will encounter. Materials and adhesives are sensitive to very low and very high temperatures, humidity, sterilization, and chemicals. Labels must be specifically selected to meet stringent environmental requirements.

In almost all cases, thermal transfer technology will be needed due to the long life requirements for medical device labels. Other considerations include best practice for label layout and barcode orientation (ladder vs. picket fence), and forethought of how the barcode will present to a user using a hand scanner.

Q: Where can I get advice on selecting label materials that will meet my unique application needs and meet the UDI requirements?

A: With more than 25 years of experience working with thermal print technology, Zebra's Supplies R&D team has unparalleled knowledge of how to optimally pair label materials and ribbons for a range commercial applications. With access to all Zebra printers and thousands of different materials, we can recommend materials that will ensure the label is readable and scannable throughout the product's lifetime and is fully compliant with the UDI regulation.

For more information, contact:

Mark Borah
Zebra Technologies
Business Development Manager
mborah@zebra.com
800-423-0442

Corporate Headquarters
+1 800 423 0442
inquiry4@zebra.com

Asia-Pacific Headquarters
+65 6858 0722
apacchannelmarketing@zebra.com

EMEA Headquarters
+44 (0)1628 556000
mseurope@zebra.com

Latin America Headquarters
+1 847 955 2283
inquiry4@zebra.com

Other Locations / USA: California, Georgia, Illinois, Rhode Island, Texas, Wisconsin **Europe:** France, Germany, Italy, the Netherlands, Poland, Spain, Sweden, Turkey, United Kingdom **Asia Pacific:** Australia, China, Hong Kong, India, Indonesia, Japan, Malaysia, Philippines, Singapore, South Korea, Taiwan, Thailand, Vietnam **Latin America:** Argentina, Brazil, Colombia, Florida (LA Headquarters in USA), Mexico **Africa/Middle East:** Dubai, South Africa