



UDI Labeling Requirements for Medical Devices: Part 1



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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 requirements were posed to David Coons, vice president, Advanced Markets and Technology, Zebra Technologies:

Q: What are the compliance dates for the different types of products?

A: Class III medical devices and human cells, tissues, or cellular or tissue-based product (HCT/P) regulated as a device must be labeled with a UDI by September 24, 2014.

- Class II implants and life supporting / sustaining devices - September 24, 2015.
- Class II devices not included above - September 24, 2016.
- Class I - September 24, 2018.

Q: Can you explain the two elements that make up the UDI?

A: The UDI is comprised of a Device Identifier (DI) and a Production Identifier (PI). These two identifiers can be separate or integrated together, but they both must be present.

The DI is a fixed numeric or alphanumeric string that uniquely identifies the labeler and the specific version or model of a device. The PI holds variable production control data such as lot number, serial number, manufacturing date, and/or expiration date of a device identified by the DI.

Q: My company already uses barcode labels. Are we compliant?

A: Maybe, but probably not. Compliance involves the printing of a properly formatted label with a Device ID and

Product ID in both human and machine readable formats. The UDI is NOT a code that is self-generated or invented by your company. The code must be approved by the FDA and issued by one of three companies that have received special FDA accreditation.

In addition, the Device ID must be registered in the FDA's Global Unique Device Identifier Database (GUDID) before it may be used on a UDI label. Unless your company has satisfied all the requirements, you are not UDI compliant.

Q: Where do I get the Device Identifier?

A: To date there are three independent entities that FDA has accredited to develop and issue UDIs to the medical device industry.

1. GS1 (www.GS1.org)
2. Health Industry Business Community Council (HIBCC) (www.HIBCC.org)
3. International Council for the Commonality in Blood Banking Automation (ICCBBA) (www.iccbba.org)

Q: Do I need a Device Identifier (DI) for every product my company sells?

A: Yes, every product in a covered product category must have its own DI. In fact each packing level (each carton, case, etc.) will need its own DI. Remember that the law even covers software that is classified as a medical device. This means that companies may have hundreds or thousands of codes to obtain and manage.

Q: What information needs to be uploaded to the FDA database?

A: The FDA GUDID database currently requires approximately 60 data fields to be provided for every DI. These data fields include device descriptions, company information, packaging information, storage and handling conditions, sterilization information, etc. The FDA may modify or add to these required attributes periodically.

Q: How do I upload and maintain the data in the GUDID?

A: There are two possible ways to upload and manage your company's data in the GUDID.

1. **FDA Web interface** – The FDA provides a browser-based interface for manual entry and editing of small numbers of DI's. This option is only suitable for companies with very few products, as all data entry is manual.
2. **HL7 software interface** – The FDA has published a specification that enables companies to electronically submit device information one DI record at a time as an HL7 Structured Product Labeling (SPL) xml file. This specification has been incorporated into software applications that companies can use to help manage the upload and editing of larger numbers of items. These applications typically interface with a company's product repository system or even data tables in Microsoft Excel.

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