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When Experience Matters.

TOPFLIGHT INNOVATIONS

UDI Labeling is Here ….. Are you in Compliance?

The FDA developed the new Unique Device Identifier (UDI) in an effort to improve the accurate identification of all medical devices and the critical information that goes along with these devices. When fully implemented, the label on most devices will include a unique device identifier (UDI) in human- and machine-readable form.

Topflight Does the Hard Work for You

This change will likely affect all labeling associated with your medical device, from the UDI and prime label to the barcode and shipping labels. Topflight can print all of these labels for you, making this transition effortless. Our digital printing option gives you perfect ink-to-ink registration, type down to 1 point, and incredible detail in images, all while contributing to a greener and more sustainable environment.

- Variable content and serialization are highly cost effective with database-driven print files
- Shorter runs with lower quantities are more economical with digital
- Enjoy shorter lead times, as files go directly from computer to press
- Minimal to no waste of material and time
- Achieve efficiencies with no plates, minimal make-ready and no inventory
- In-line rotary die-cutting option; no need for an additional processing step

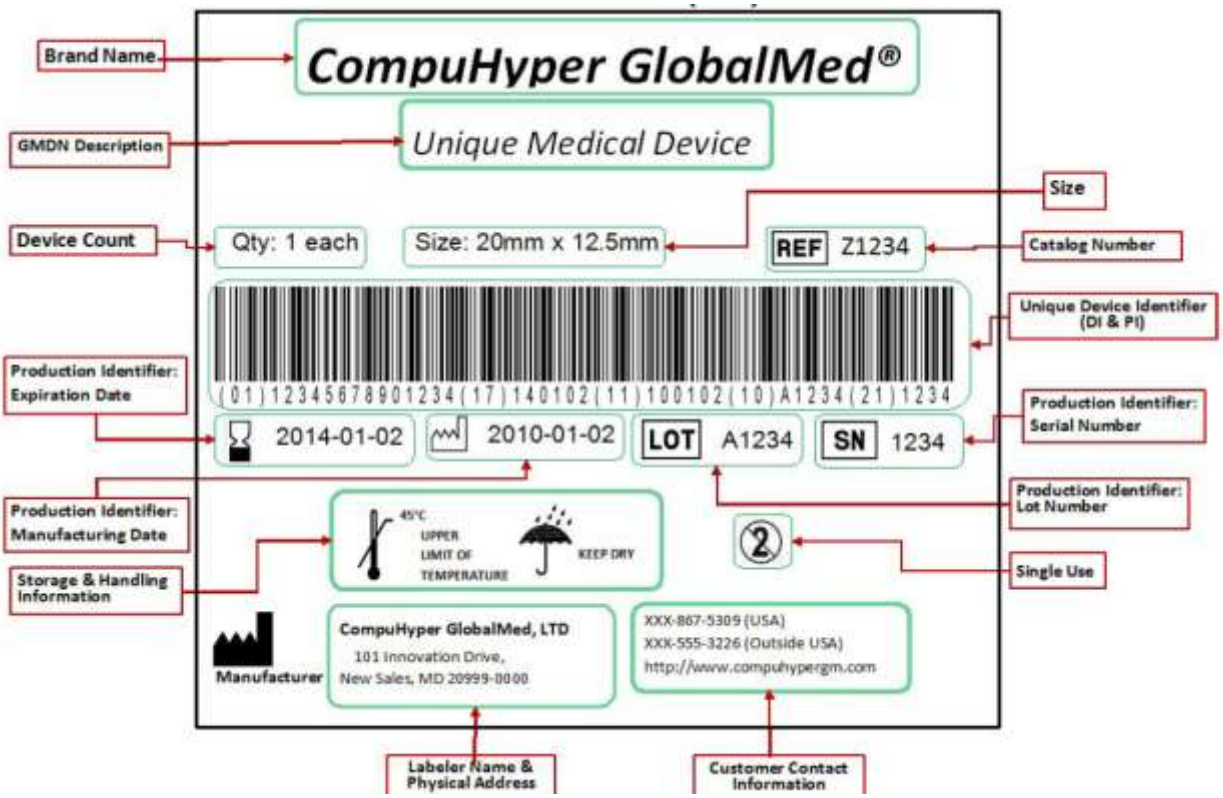
What are the effective dates for the new rule?

Product Classification	Due Date	Product Classification	Due Date
Class III	Sept. 2014	**Direct Marking Requirements (multiple use and reprocessed)**	
Implantable/ Life Supporting & Sustaining	Sept. 2015	Implantable/ Life Supporting & Sustaining	Sept. 2015
Class II	Sept. 2016	Class III	Sept. 2016
Class II – Convenience Kits *	**Sept. 2018**	Class II	Sept. 2018
Class I	Sept. 2018	Class I	Sept. 2020

*** RECENTLY EXTENDED: Class II Convenience Kits include collections of two or more different devices packaged together in which the devices in the package are not individually labeled, and repackaged single-use devices, other than implants.**

Why Choose Topflight?

Topflight Corporation is an independently held, ISO 9001:2008 and 13485:2003 certified company that manufactures labels, shrink sleeves, conductive parts and die-cut components for the Medical Device and Pharmaceutical markets. Our high quality labeling includes piggyback, island-placement and expanded content configurations, as well as serialized barcodes, QR codes, and variable content printing. For more information, visit www.topflight.com or call 717-227-5202.



***NEW* FDA Requirements:**

All medical devices will require specific new labeling, which includes the UDI, among other mandatory new markings. The manufacturer must also submit various device and production identifiers, such as lot numbers and expiration dates to FDA's Global Unique Device Identifier Database (GUDID). This global repository, which is available to consumers, will hold all requisite data from all devices currently on the market.

The system will require that the label and package of each medical device include a UDI, and that each will be provided in a plain-text version and in a form that uses automatic identification and data capture (AIDC) technology. The UDI must be marked directly on the device itself if the device is intended to be used more than once and intended to be reprocessed before each use. The final segment of the new rule includes a standardized date format which will be all numeric, YYYY-MM-DD (2016-10-20).

Benefits of a UDI System:

Once fully implemented, the UDI System will offer many benefits to consumers, health care providers, health care systems, industry and the FDA.

- Provides more accurate reporting, reviewing and analyzing of adverse events so problem devices can be quickly identified and corrected.
- Reduces medical errors by enabling health care professionals to more precisely identify a device and it's characteristics.
- Provides a standard method to document device use in electronic health records, clinical information systems, claims data sources and registries. A more robust post market surveillance system will be possible to support premarket approval or clearance of new devices and new uses of currently marketed devices.
- Allows for more effectively managed device recalls.
- Provides a foundation for a global, secure distribution chain, helping to address counterfeiting and diversion and prepare for medical emergencies.
- Leads to the development of a global medical device identification system.

Any questions regarding this information can be directed to Regina Todd, 717.227.5202, rtodd@topflight.com.