

UDI and Healthcare
(Sunrise 2013)

The FDA has mandated the use of a Unique Device Identification (UDI) system to identify medical devices. Identifying medical devices using this standardized method will provide benefits in several areas including patient safety, supply chain efficiency and regulatory compliance once the FDA finalizes its product marking standard.

The FDA has not decided on which bar code standard will be used to carry the UDI. The two leading contenders are GS1 and HIBCC. Both GS1 and HIBCC have their proponents who will argue the merits of each. Fortunately for our customers, EASYLABEL has supported both of these standards for some time.

A majority of Group Purchasing Organizations (GPOs), device manufactures and hospitals are not waiting for the FDA to make a decision and are already announcing their support of GS1 before the UDI mandate is even finalized.

GS1 is new for Healthcare but it is a time tested and proven system. The EAN/UCC, now known as GS1, system of global standards has been in use for over 30 years in the supply chain and logistics industries. GS1's Global Trade item Number (GTIN) has long been established in every country for uniquely identifying trade items .

Thanks to EASYLABEL, creating a GS1-128, GS1-Databar or GS1-Datamatrix Bar Code is easy! EASYLABEL's GS1 Bar Code Wizard makes creating GS1 Bar Codes a simple 4-step process. The Wizard prompts you for the required information and then builds the bar code automatically!

Link to the FDA's page on Unique Device Identification

- <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/ucm207973.htm>

If you would like additional information about GS1's use in Healthcare there are some helpful links from GS1 on the Healthcare Industry's Sunrise Initiative and GTIN:

- GS1's Healthcare main page – www.gs1us.org/healthcare
- GS1's Sunrise page which includes definitions and implementation plans – www.gs1us.org/hcsunrise
- GS1's webinars on Sunrise – www.gs1us.org/hcedu
- GTIN information including: Tool Kits, Use Cases and Guidelines for its use in Healthcare [http://www.gs1us.org/sectors/healthcare/product_identification_\(gtin\)](http://www.gs1us.org/sectors/healthcare/product_identification_(gtin))