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Date: August 1, 2016

UDI requirements for the brand owner of Class I products:

The FDA has issued the requirement that all medical devices utilize a unique device indicator (UDI) on all available levels of product packaging. In addition, they require all brand owners to submit product information into a central data base, GUDID. This action must all be completed by September 24, 2018. For greater detail please go to:

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/ChangesbetweenUDIProposedandFinalRules/ucm20038746.htm

In summary as pulled from FDA documents:
The UDI Rule is intended to create a standardized identification system for medical devices used in the United States. The main objective of the UDI system is to adequately identify devices through distribution and use. This system makes it possible to rapidly and definitively identify a device and some key attributes that affect its safe and effective use. The UDI Rule requires the label and device packages of every medical device distributed in the United States to bear a UDI.
The UDI must be presented in two forms on the label and device packages: easily readable plain-text and automatic identification and data capture (AIDC) technology. The easily readable plain-text form of the UDI may be presented as a single line or multiple lines of text and should be displayed below or near the AIDC (barcode) technology form of the UDI.
In addition to the UDI label requirements under 21 CFR 801 Subpart B, labelers must submit product information concerning devices to FDA's Global Unique Device Identification Database (GUDID). The labeler is the person who causes a label to be applied to a device.(The company name on the product) The GUDID contains ONLY the device identifier (DI), which serves as the primary key to obtain device information in the database. Production Identifiers (PI) are not submitted to or stored in the GUDID, but the GUDID will contain production identifier flags to indicate which PI attribute(s) are on the device label
In order to submit data to GUDID, first an Organization (Labeler) account needs to be established. (www.fda.gov/udi to obtain an organization account)
The UDI Rule also requires UDIs to be issued under a system operated by an FDA-accredited issuing agency (GS1 or HIBCC). Each labeler, therefore, must work with one or more FDA-accredited issuing agencies to develop UDIs for devices that are required to bear a UDI.

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General terms and descriptions:

Unique Device Identifier (UDI) An identifier that adequately identifies a device through its distribution and use by meeting the requirements of 21 CFR 830.20. A unique device identifier is composed of a device identifier (DI), any applicable production identifiers (PI)

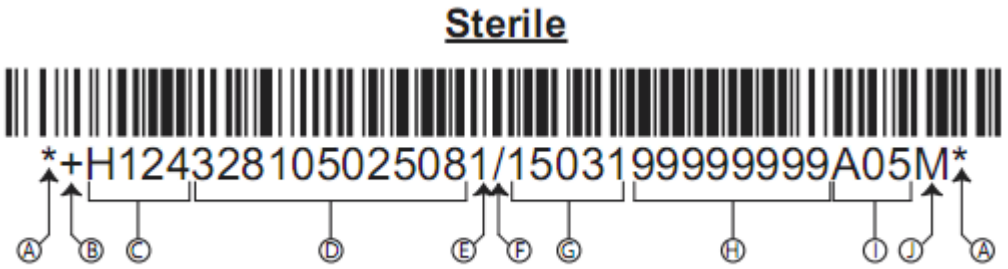
Device Identifier (DI): A mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the labeler of that device. **(Applies to all items: Class 1, II, III)**

Production Identifier (PI): A conditional, variable portion of a UDI that identifies one or more of the following when included on the label of the device: (a) The lot or batch within which a device was manufactured; (b) The serial number of a specific device; (c) The expiration date of a specific device; (d) The date a specific device was manufactured; **(Applies to Class II & III items)**

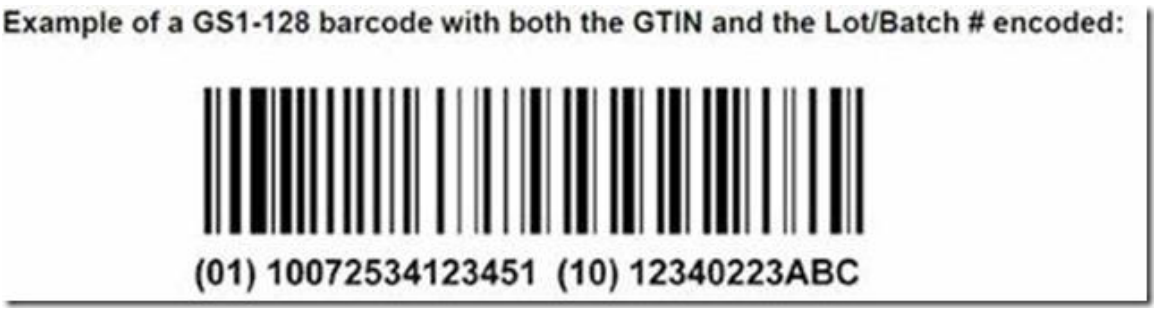
Data Delimiter

Within an encoded data string, a defined character or set of characters that identifies specific data elements.

HIBCC example:



GSI example



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