What is a UDI?

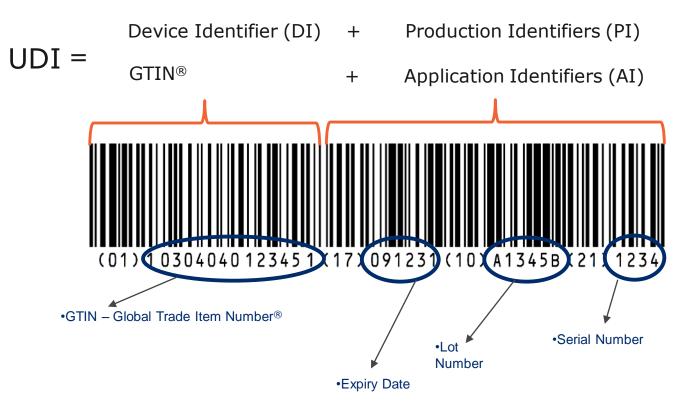


- Code on the device label, packaging or product, in both easily readable plain-text and automatic identification and data capture (AIDC) format
- Two parts : UDI = DI+PI
 - Device Identifier (DI) (static) specific to a device version or model
 - Production Identifier(s) (PI) (dynamic) one or more currently used control/production information, such as lot/batch, serial number, manufacturing date, expiration date



UDI Components



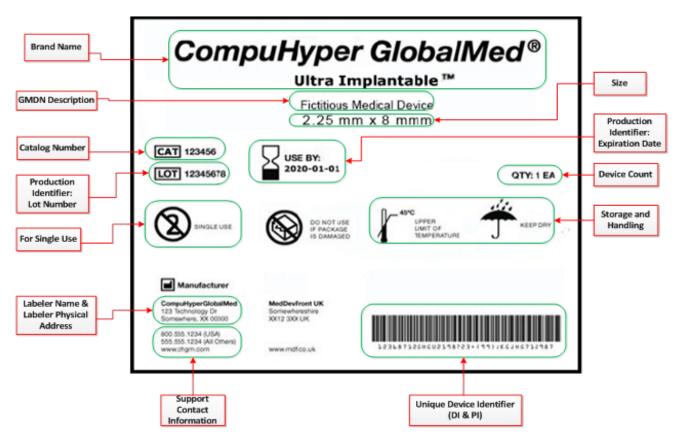


*Another Production Identifier is Manufacture Date



UDI Components





Reference:

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/UDIBasics/default.htm



UDI Example of GTIN[®] Plus Expiry Date, Lot, and Serial Number



 Healthcare best practice is to utilize the GS1-128 and/or GS1 Data Matrix to carry the UDI for Class III and Class II items.



GTIN with Serial, Lot & Expiration Date encoded in a GS1-128 Barcode

(01) 1 0304040 12345 1 (17) 101231 (10) ABCD12345 (21) 54321DCBA GTIN with Serial, Lot & Expiration Date encoded in a GS1 DataMatrix

Note: UPC and ITF-14 barcodes can only encode the GTIN and not Application Identifiers

* Symbols are not to scale for illustration only

