Unique Device Identification (UDI) Frequently Asked Questions

QTS Medical Device Outsourcing

Q What does UDI mean?

A Unique Device Identification (UDI). UDI is an FDA rule regarding unique package identification, part marking and a public database of medical device attributes.

Q What is a UDI?

A UDI is also jargon used to describe the barcode content; a combination of a device identifier (DI) and one or more production identifiers (PI).
This information is structured per requirements of the accredited standards. (GS1, HIBCC, ICCBBA)
Requirements can be found in various sections of the 21CFR800-series.

Q Why is the FDA requiring this?

A The FDA Amendments Act of 2007 and the User Fee Act of 2010 (FDASIA).

Q What is the public database?

A This is a database that is maintained by FDA, referenced as GUDID. The data you are required to submit to this database includes: The device identifier portion of your UDI and dozens of device attributes. (Examples of device attributes: address, device trade name, latex content, etc.)

Q Who is required to comply and when am I required to comply?

A For package barcoding and the public database information:
Class 3 Devices: 1 year from release of Final Rule (September 24, 2014).
Implants and life sustaining and life supporting devices: 2 years from release of Final Rule (September 24, 2015).
All other Class 2: 3 years from release of Final Rule (September 24, 2016).
Applicable Class 1: 5 years from release of Final Rule (September 24, 2018).
In addition, devices intended for re-use and requiring reprocessing are subject to direct part marking on a separate schedule.

Q How do I comply?

A **Step 1**
Select and partner with one of the accredited standards (ex. HIBCC, GS1, ICCBBA).

Step 2
Implement Quality System Procedures related to issuing and changing of device identifiers for the chosen method.

Step 3
Gather your list of products and establish device identifiers for each unique sales item (catalog #).

Step 4
Determine the production identifiers you will include in your product UDI.

Step 5
Implement Unique Device Identification into your product labeling system.

Step 6
Develop a procedure for and implement UDI process in Direct Part Marking, if applicable.

Step 7
Register device identifiers and device attributes in the public database.

Q What is a production identifier?

A Lot or Batch specific manufacturing attributes: (ex. lot or batch number, expiration date, serial number, date of manufacture).

Q What production identifiers will your company need to display in your UDI?

A All of the production identifiers that are already present on the label.

Q Do I have to upload my production identifiers to the database?

A No, the database is device attributes only, not lot attributes.

Q Why is my UDI required to include lot attributes?

A FDA is intending to use the UDI in complaint and adverse event reporting. However, UDI is not a track and trace system.

Q When do you need to roll (change) your device identifier(s)?

A FDA is allowing Manufacturers to determine their own change rules. GS1 customers should be aware of GS1 GTIN Healthcare allocation rules, which define change triggers.

Q When do I need to change my UDI?

A Production identifiers change with every lot.
The device identifier portion: See answer to previous question.

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Q How do I express my UDI on my product label?

A UDI is printed as a machine-readable symbol technology (barcode, RFID, etc.) AND the human readable (plain-text).

Q How do I pick my barcode type?

A **2D:** Square barcode similar to QR codes; specifically the Datamatrix format.
1D: Linear barcode, similar to those found on most consumer goods.
Note: This is not a regulatory question; it is determined by your supply chain requirements.

Q Who is responsible for maintaining the information in the database?

A The Manufacturer of Record. This is the manufacturer listed on the product label.
(Is NOT: The factory, contract manufacturer, or regulatory consultants).

Q We already created our own barcode, is that enough?

A No, you need to establish a barcode that is compliant with one of the approved accredited standards.

Q How do I know when my barcode is good enough?

A Quality requirements for the symbol are defined by your chosen accredited standard. Generally, the quality assessment requires calibrated optical verification equipment.

Q What tools exist to check my barcode content?

A **GS1:** ww.GEPIR.org
HIBCC: www.HIBCC.org

Q Where am I required to display my UDI?

A You are required to display your UDI on:
The lowest level unit of sale and higher level packaging units labeled for sale.

Q I have a small label, what do I do?

A UDI will be a required label element, no matter the size of the label.

Q What is DPM?

A Direct Park Marking (DPM) is physically marking your device, when required, or made available in your software(s) interface. DPM is only required for devices intended for re-use that require reprocessing before re-use.

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Q I have a tiny device which requires DPM; do I have to DPM it?

A No, FDA will allow self-exemption when either DPM is not technically feasible, or it negatively affects product safety or effectiveness.

Q What are allowed date formats on labels?

A When UDI is applicable to your device class, all labeled dates must be rendered as YYYY-MM-DD. Note: Date format within a UDI barcode is dependant on the accredited standard you've chosen.

Q What about product that is already in the field of distribution? Do I have to re-work existing product?

A Items that have been sold are not subject to this rule. Items packaged and labeled but unsold (finished good inventory, including consignment) are grand-fathered for 3 years after rule, effective dates per your device class.

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