FREQUENTLY ASKED QUESTIONS ABOUT UDI

Q: What is the purpose of the new UDI system by the FDA?

A: FDA is establishing a unique device identification system to adequately identify medical devices through their distribution and use. When fully implemented, the label of most devices will include a unique device identifier (UDI) in human- and machine-readable form. Device labelers must also submit certain information about each device to FDA's Global Unique Device Identification Database (GUDID).
The objective is to increase patient safety by

- harmonizing data between US health care providers, manufacturers, and the FDA
- introducing globally unique identifiers to prevent mix-up of device – ensuring the right device for the right patient
- improving traceability with electronic medical records
- enhancing effectiveness in management of recalls

Q: What products are included in the UDI scope?

A: Products registered in the US as Medical Device Class II (e.g. reagents, instruments, and stand-alone software) are required to comply with UDI requirements by September 24, 2016. Accessories (e,g, spare parts), classified as Medical Device Class I, will be included by September 24, 2018. Products sold in the US as Research Use Only (RUO) will not be UDI-labelled nor included in the GUDID database.
ThermoFisher Scientific has decided to not only apply UDI information on FDA-approved ImmunoCAP, EliA, and Phadia device labels, but also include UDI on labels for CE-marked device that are sold in other parts of the world.

Q: What information is contained in the UDI?

A: A UDI is composed of two parts:
<u>Device Identifier (DI)</u> - A unique numeric or alphanumeric code specific to a device version or model.
<u>Production Identifier(s) (PI)</u> - Numeric or alphanumeric codes that identify production information for a device and can include the following:
- The lot or batch number;
- The serial number;
- The expiration date;

Therefore, UDI = DI + PI

Q: What does UDI look like on ImmunoCAP-, EliA-, and Phadia device labels?

A: The UDI information will be provided on labels and packaging in both human- and machine-readable form. The exception is software, which will only carry the human-readable format.
1) AIDC = Automatic identification and data capture. A scannable GS1 Data Matrix (2D barcode) contains encoded data for DI number and PIs
2) HRI = Human Readable Interface. Provides DI and PIs in readable text format
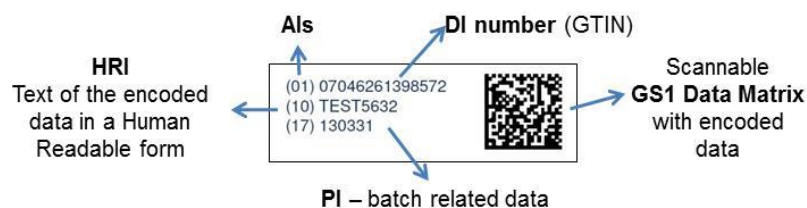
Example 2 GS1-128 (alternative barcode marking of instruments)

(01)10857674002017 (10)1152KMB

Q: What are the definitions of DI, PI, and AI?

A: See definitions below
DI = *Device Identifier*
 Global Trade Item Number (GTIN) e.g. 07046261398572
 - Static data that will remain the same for all units of a particular product
PI = *Production Identifier*
 The PI contains batch related data
 - Dynamic data that will vary from lot to lot
AI = *Application Identifier*
The AI tells what type of data that follows in the HRI
(01) = Device Identifier (GTIN), e.g. 07046261398572
(10) = Lot/batch, e.g. TEST5632
(17) = Expiration date, e.g. 130331

Q: Where can I learn more about the UDI system?

A: This page contains links to more information on Unique Device Identification System-related rules, guidances, training, and communications:
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/ChangesbetweenUDIProposedandFinalRules/default.htm

Q: How do I read the UDI 2D barcode?

A: Use a QR reader, e.g. by using an app on a smart phone or a dedicated barcode reader, to scan and read the GS1 Data Matrix. In addition, the unique GTIN-number, lot, and expiry date information are available on the label as human readable text.

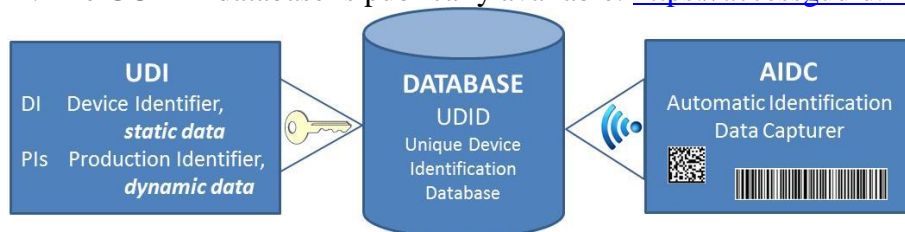**Q: Will the current barcode be replaced by the new UDI 2D barcode?**

A: Current barcodes on ImmunoCAP- and EliA products, which are read in Phadia instruments, are not affected by UDI labelling. They will remain on product labels and be used as before.

Q: What 'labels' are affected?

A: Section 201(k) specifies 'label' as a display of written, printed, or graphic matter upon the immediate container of an article. In addition to UDI appearing on all ImmunoCAP, EliA, and Phadia product labels, it will also be referenced on e.g. Certificates of Analysis (CoA), instrument certificates, and in Service- and installation records.

Q: How do I access the UDI database GUDID?

A: The GUDID database is publically available: https://accessgudid.nlm.nih.gov/

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Q: What type of information does the GUDID database contain?

A: The GUDID database only includes information on medical device registered for the US market. For ImmunoCAP, EliA, and Phadia devices classified as Medical Device Class II, all applicable device information will be uploaded and available by September 24, 2016.

Q: What will UDI information look like on ThermoFisher device labels?

A: Below are examples of a product label and a Certificate of Analysis.