Health Industry Business
Communications Council

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What is the HIBC Device Identifier?

The HIBC Device Identifier (DI) is the portion of the Unique Device Identifier (UDI) that you are required to submit to the FDA's GUDID. The Production Identifier (PI) is the other portion of the UDI that is not submitted to the GUDID.

The HIBC DI has the following components: the Labeler Identification Code (LIC), the Product/Catalog Code, and the Unit of Measure (also referred to as Package Level Indicator). For more information on Unit of Measure see HIBCC's Guide to Understanding Unit of Measure.

Example:

LIC = A999
Product Code = ABC123
Unit of Measure = 0 (single unit)

DI that is entered in to the GUDID = A999ABC1230

DI that appears on the device label =

+A999ABC1230V

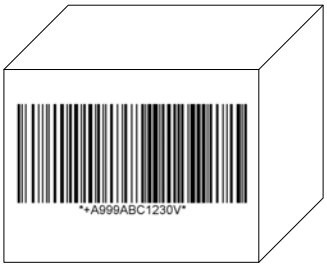
Note: The UDI on the device label includes additional characters (Stop/Start Characters "*", HIBC Flag "+", Check Character, and all other Data Identifiers/Delimiters). Refer to the HIBC Supplier Labeling Standard for more information.

What do I include in the GUDID?

Primary DI:

The Primary DI is the DI located on the lowest package level that contains a UDI.

Example 1: The package below contains a single device that is exempt from the Direct Marking UDI requirement.

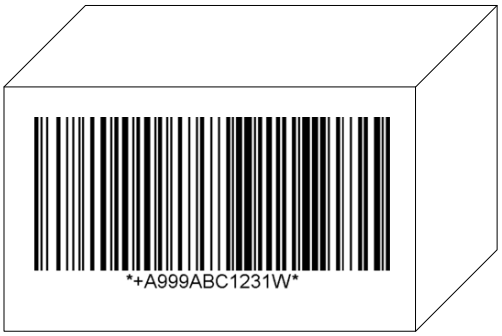


Primary DI = A999ABC1230

Example 2: The device below does not have a package and is Directly Marked with with a UDI.

Primary DI = A999ABC1230

Example 3: The package below contains two devices with that are exempt from the Direct Marking UDI requirement (i.e. they are not individually labeled with a UDI).



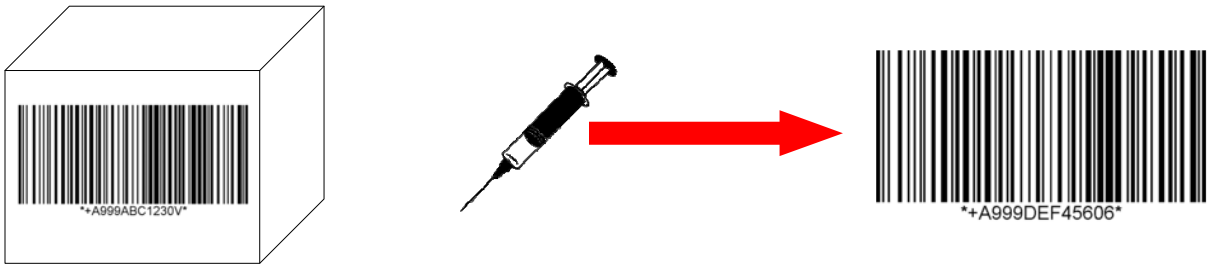
Primary DI = A999ABC1231

Direct Marking DI:

The FDA general rule is that all devices be directly marked with a permanent UDI.*

The Direct Marking DI component of the UDI can be the same as that which appears on your device label. However, you may choose to use a different DI for direct marking in order to distinguish the unpackaged device from the device packaging. If so, then you must enter *both* the Primary and Direct Marking DIs in the GUDID.

Example: The device below has a Direct Marking DI that is different from the DI on the device packaging. The red arrow points to the DI that is directly marked on the device.



Direct Marking DI: A999DEF4560

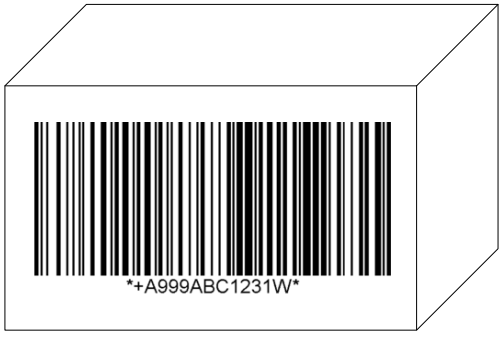
Note: The Direct Marking DI must include the LIC, Product/Catalog Code, and Unit of Measure.

*The FDA does provide some exceptions to the direct marking requirement which can be found on the FDA's UDI webpage.

Unit of Use DI:

A Unit of Use DI is required to be entered in the GUDID when the Primary DI contains more than one device and those devices are not individually labeled with a UDI (see Example 3 under Primary DI).

Example: The package below contains two devices with that are exempt from the Direct Marking UDI requirement (i.e. they are not individually labeled with a UDI).



Primary DI = A999ABC1231
Unit of Use DI= A999ABC1230
Note: The Unit of Use DI does not appear on any of the device labeling.

For an explanation of all GUDID fields refer to the FDA's GUDID Data Elements Reference Table.

For additional questions contact HIBCC by email at info@hibcc.org

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