



UDI – Unique Device Identification – Barcode Specifications

FDA - UDI Description

"The UDI Rule establishes a UDI system. It requires the labels and device packages of medical devices distributed in the United States include a unique device identifier (UDI), unless we grant an exception or alternative to UDI label requirements. As will be explained later, this UDI will be in both easily readable plain-text and **Automatic Identification and Data Capture (AIDC) technology—usually a bar code.** The UDI Rule also requires specified product information be submitted to FDA's Global Unique Device Identification Database (GUDID)."

Barcodes must be inspected with a verifier that compares print quality to a set established ISO / ANSI standards (ISO 15416 for linear barcodes, ISO 15415 for 2D barcodes).

Overall an ISO/ANSI grade of **1.5/06/670** (**C/06/670**) or higher should be maintained on an on-going basis on the final symbol on the package. HIBC recommends that wherever practical, the symbol grade as printed should equal or exceed 2.5/06/670 (B/06/660).

Code 128 Linear Barcode Dimensions

Over time, most labelers have used an X-dimension of 0.010 inches (0.25 mm). More recently, those labelers with high-resolution printing capability may utilize X-dimensions as low as 0.0067 inches (0.17 mm).

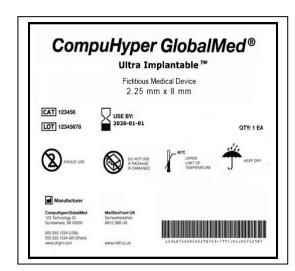
Any X-dimension greater than 0.0067 inches is allowable if the print quality requirement is met. The height of the bars should be at least 15% of the symbol length. Quiet Zones should be at least 10 times the X-dimension.

2D Code Dimensions (Data Matrix / QR)

Labelers should use an X-module dimension of 0.010 inches (0.25 mm). Any X-module dimension greater than 0.010 inches is allowable if the print quality requirement is met.

With our years of barcode/AIDC expertise, Symbology will help you ensure that your barcode technology meets established ISO/ANSI industry standards, and will scan throughout the supply chain. We provide a full range of verification equipment to grade your printed or DPM linear and 2D barcodes.

What is a UDI?



A UDI is a unique numeric or alphanumeric code that consists of two parts:

- a device identifier (DI), a mandatory, fixed portion of a UDI that identifies the labeler and the specific version or model of a device, and
- a production identifier (PI), a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of a device:
 - the lot or batch number within which a device was manufactured;
 - the serial number of a specific device;
 - the expiration date of a specific device;
 - the date a specific device was manufactured;
 - the distinct identification code required by §1271.290(c) for a human cell, tissue, or cellular and tissue-based product (HCT/P) regulated as a device