Promoting the Inclusion of Device Identifiers and the Global Unique Device Identification Database (GUDID) in MDEpiNet Demonstration Projects

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FDA UDI Rule

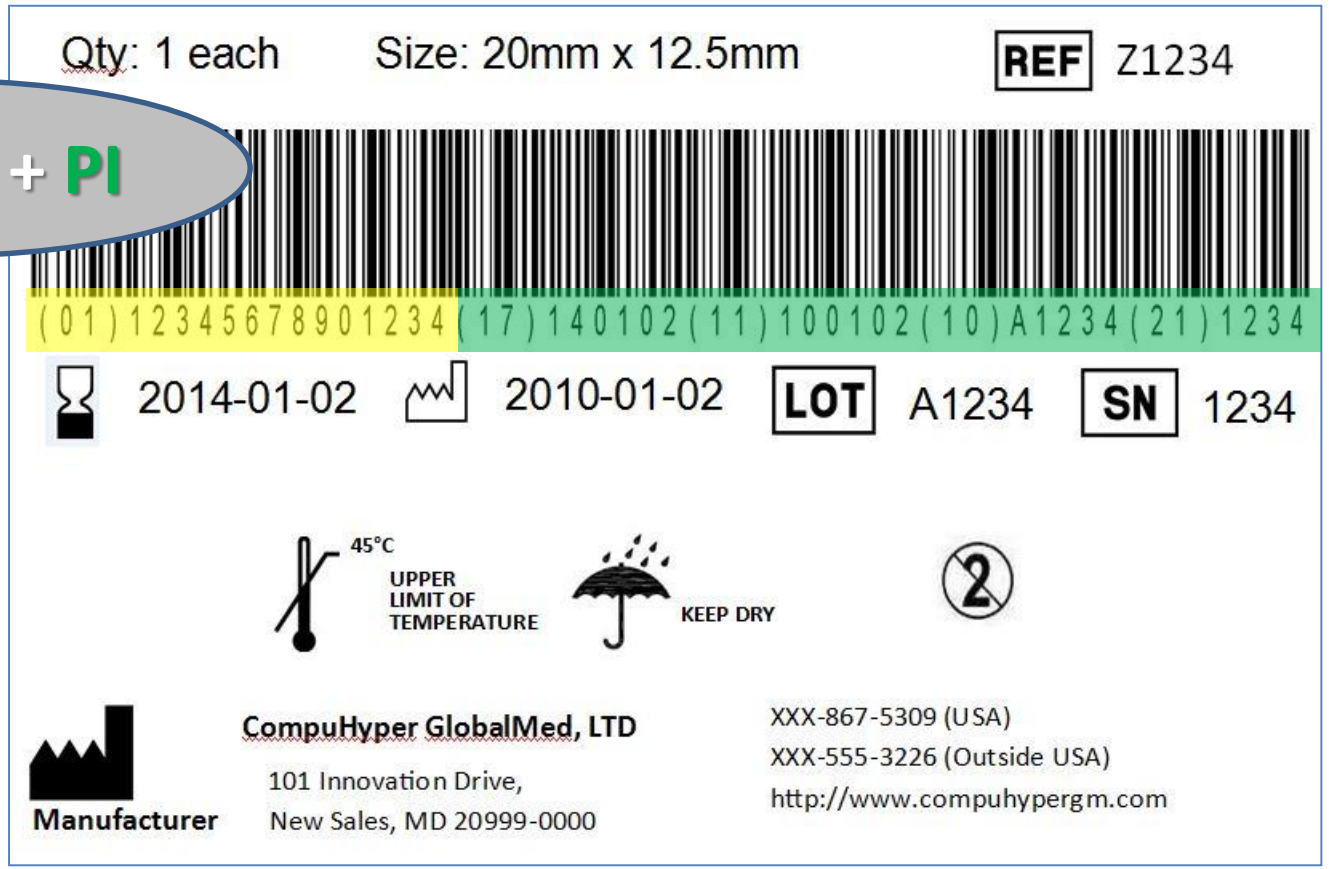
- *Unique device identifier (UDI)* means an identifier that adequately identifies a device through its distribution and use by meeting the requirements of § 830.20 of this chapter. A unique device identifier is composed of:
  - (1) A *device identifier*—a mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the labeler of that device; and
  - (2) A *production identifier*—a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of the device:
    - (i) **The lot or batch within which a device was manufactured;**
    - **(ii) The serial number of a specific device;**
    - **(iii) The expiration date of a specific device;**
    - **(iv) The date a specific device was manufactured;**
    - **(v) For an HCT/P regulated as a device, the distinct identification code required by § 1271.290(c) of this chapter**.

Where is the UDI?

Found on the device label, packaging or, in some cases, on the device itself

Both in plain text and machine readable format (AIDC) - subset

UDI = DI + PI



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FDA

AccessGUDID is in beta!

Contact us with your comments and suggestions for the site.

ACCESS GUDID

IDENTIFY YOUR MEDICAL DEVICE

peripheral artery stent

multiple **peripheral artery stent**, bare-metal

ABOUT AccessGUDID

The **Global Unique Device Identification Database (GUDID)** contains key device identification information submitted to the FDA about medical devices that have **Unique Device Identifiers (UDI)**.

The FDA is establishing the unique device identification system to adequately identify devices sold in the U.S. from manufacturing through distribution to patient use. You can use AccessGUDID to search for specific medical devices or download all the GUDID data at once. We anticipate the release of additional web services for testing by the end of 2015. Please see the API Documentation for more information.

MORE INFO

ABOUT UDI

ABOUT GUDID

DOWNLOAD

Download Data

Download the latest full releases and update files provided to the NLM by the FDA.

API

API Documentation

Coming Soon!

Resources for application developers to get the most out of AccessGUDID.

HELP

Help using AccessGUDID

Searching AccessGUDID