Are you Ready for UDI Compliance?

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UDI Overview

- In 2013, Food and Drug Administration (FDA) released the final UDI rule
- Requires most medical devices distributed in the United States carry a unique device identifier, or UDI.
  - Also applies to certain combination products that contain devices and to devices licensed under the Public Health Service (PHS) Act (e.g., donor screening assays).
- Additional countries are looking at following suit in the coming years

UDI Requirements

Device label and package must bear a UDI, 21 CFR 801.20

Devices intended to be used more than once and devices intended to be reprocessed before each use must be directly marked with a UDI, 21 CFR 801.45

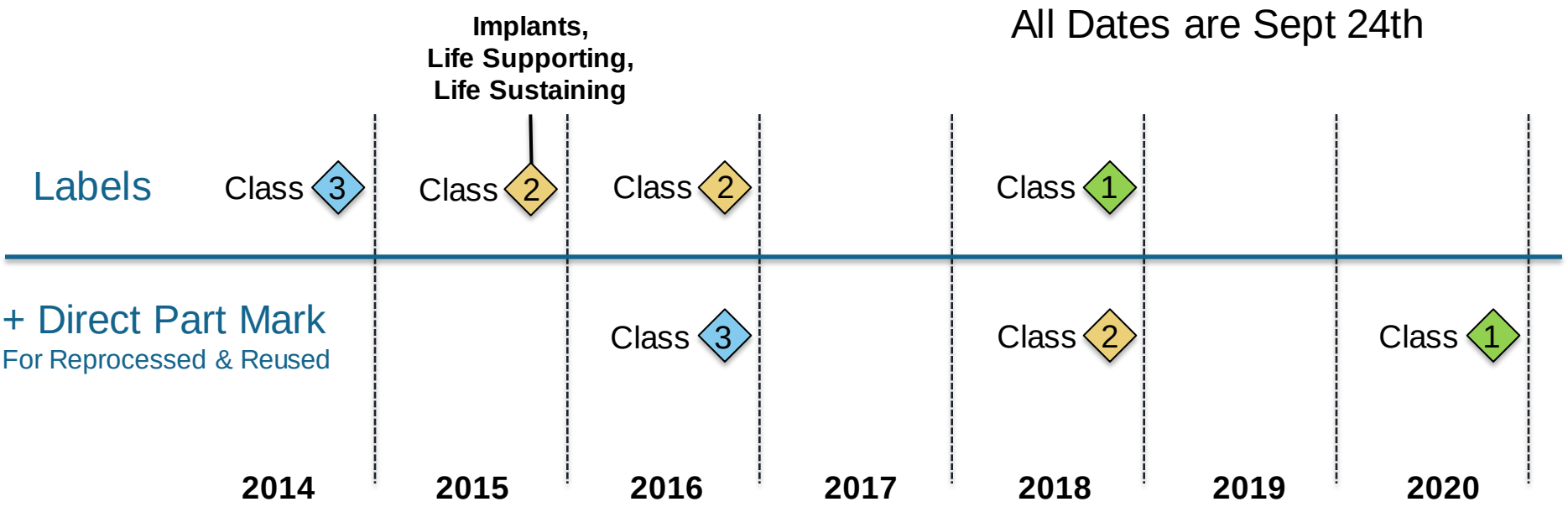
Data for these devices must be submitted to GUDID, 21 CFR 830.300

Dates on the labels must be in the correct format (YYYY-MM-DD), 21 CFR 801.18

Benefits of UDI

- Accurate reporting, reviewing and analyzing of adverse event reports to enable quick identification and correction of problem devices
- Enable clinicians to quickly obtain important information on devices, reducing medical errors
- Enhance analysis of devices
- Provide a standard and clear way to document device use in HIT systems.
- Increase effectiveness of management of medical device recalls
- Enable a global, secure supply chain, helping to address counterfeiting and diversion and prepare for medical emergencies.

FDA Compliance Schedule



Please Note: Healthcare Providers are asking Manufacturers to become compliant sooner, rather than later. Non-compliance could result in a Healthcare Provider choosing a product that is compliant over one that is not.

Becoming UDI Compliant

Drive the Two Work Streams Below, in Parallel

Identify, collect, validate and submit required data to GUDID

Assign UDI's to devices and place UDI on the devices label (and packaging) [and standardized date format]

IDENTIFY, COLLECT, VALIDATE & SUBMIT DATA TO GUDID

UDI Data Submission Requirement (GUDID)

The Primary Database Key is the Device Identifier (DI)

Global Unique Device Identifier Database

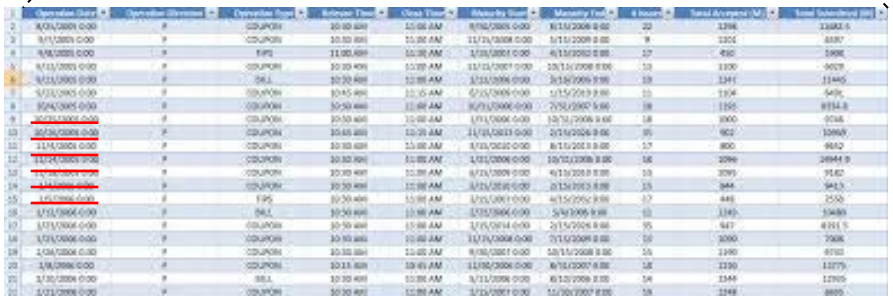
GUDID

60+ Attributes for each device

- One entry for each device SKU
  - ✓ Every size
  - ✓ Every color
  - ✓ Every flavor
  - ✓ Every packaging level

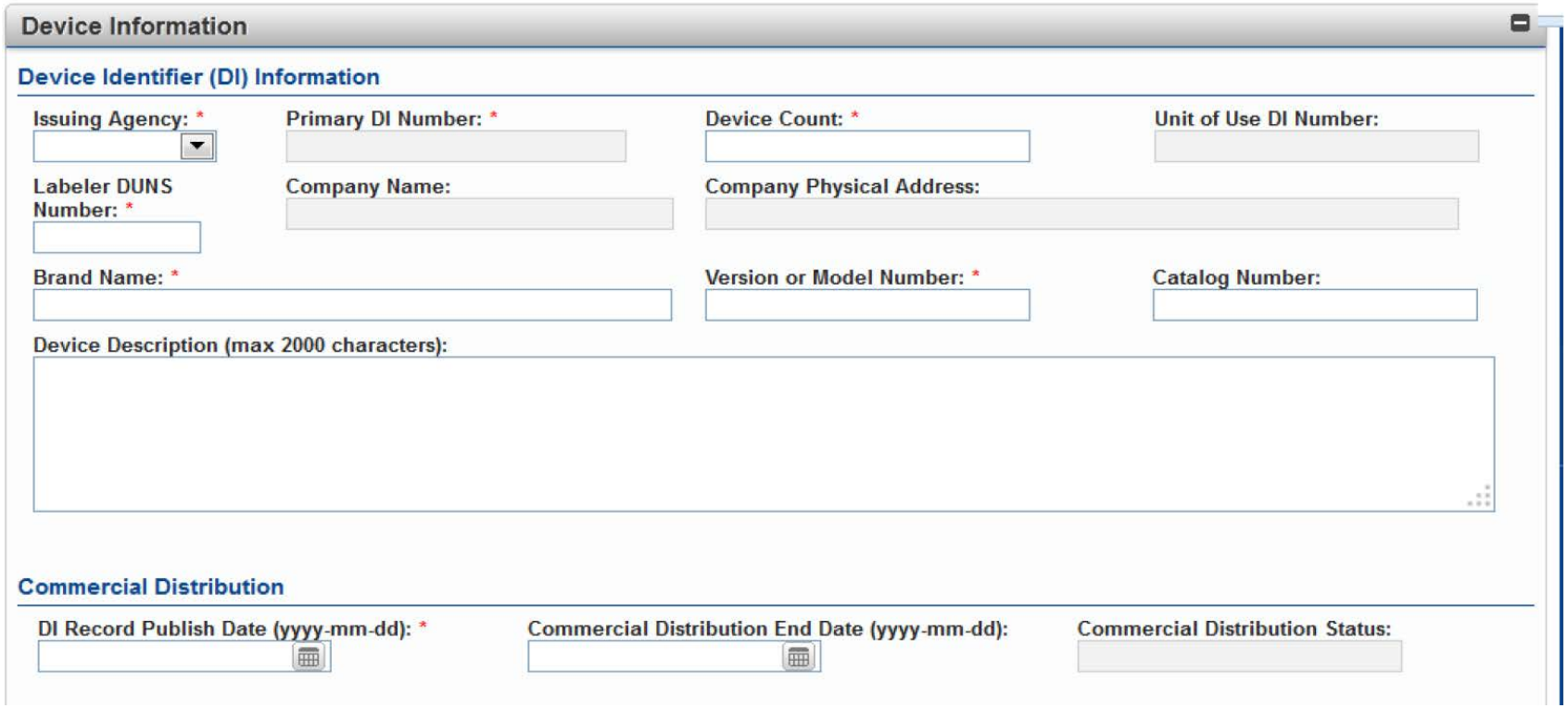
Attributes

Devices



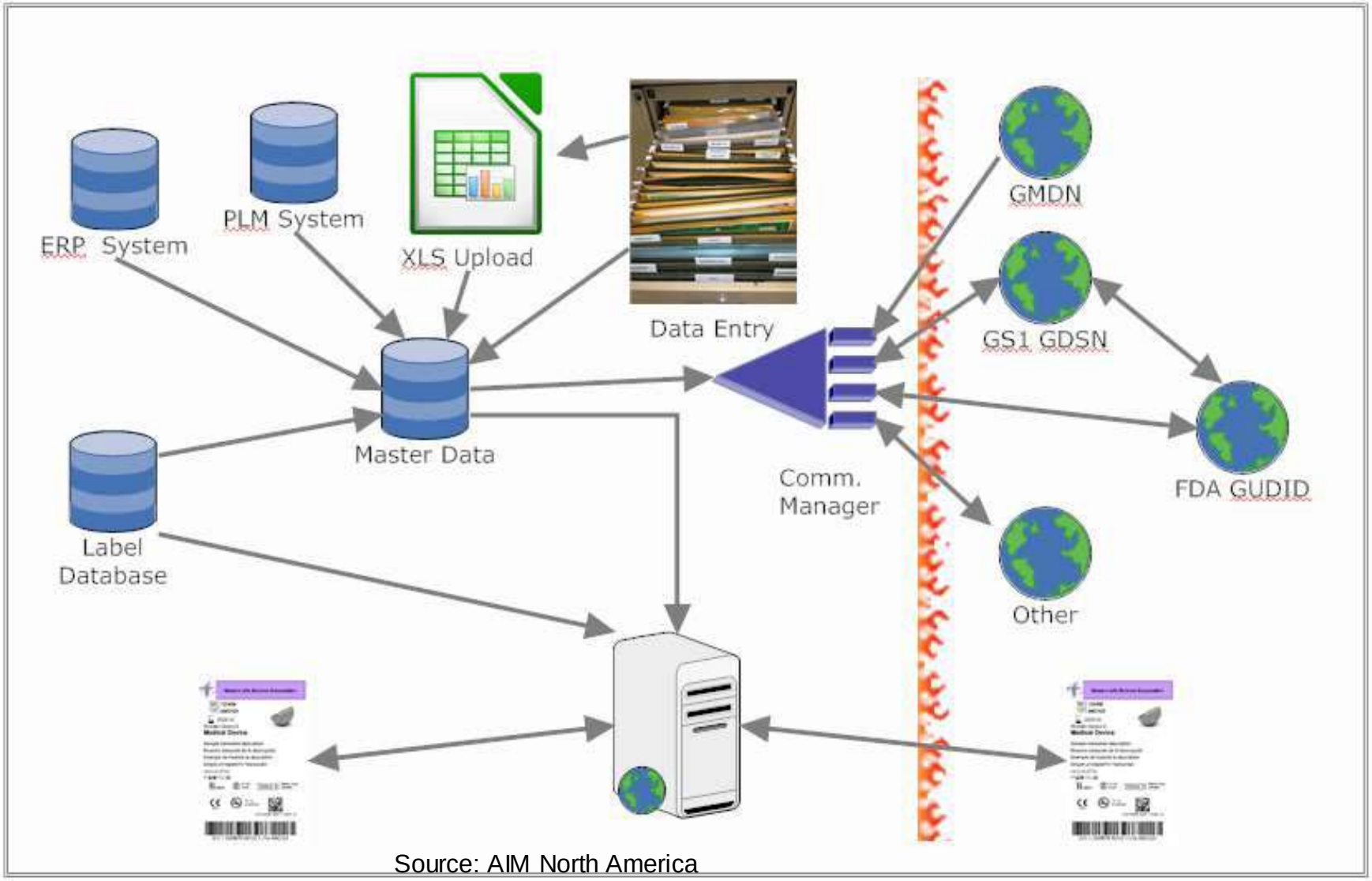
UDI Data Submission Requirement (GUDID)

- Submit product information into Global Unique Device Identification Database (GUDID)
  - Users of a medical device can easily look up information about the device



Source: UDI Implementation Workshop

Data Submission Flow



Source: AIM North America

GUDID Submission Software Solutions

ASSIGN UDI'S TO DEVICES AND PLACE UDI ON THE DEVICES LABEL

Assigning UDI's to Devices

Create a UDI (a unique numeric or alphanumeric code) that consists of two parts:

Device identifier (DI)

A mandatory, fixed portion that identifies the labeler and the specific version or model of a device

-Global Trade Item Number (GTIN)

Production identifier (PI)

A conditional, variable portion that identifies one or more of the following when included on the label of a device:

-lot or batch number

-serial number

-expiration date (date format must be YYYY-MM-DD)

-date of manufacture (date format must be YYYY-MM-DD)

-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.

Assigning UDI's to Devices

Use of Device Identifier (DI) and Production Identifier (PI)

- Class I: Device Identifier (DI) ONLY
- Class II and III: Device Identifier (DI) + Production Identifier (PI)

The UDI must be presented in two forms

- (1) Easily readable plain-text
- (2) Automatic identification and data capture (AIDC) technology

Issuing Agencies Currently Accredited by FDA for UDI

Each uses proven AIDC technologies

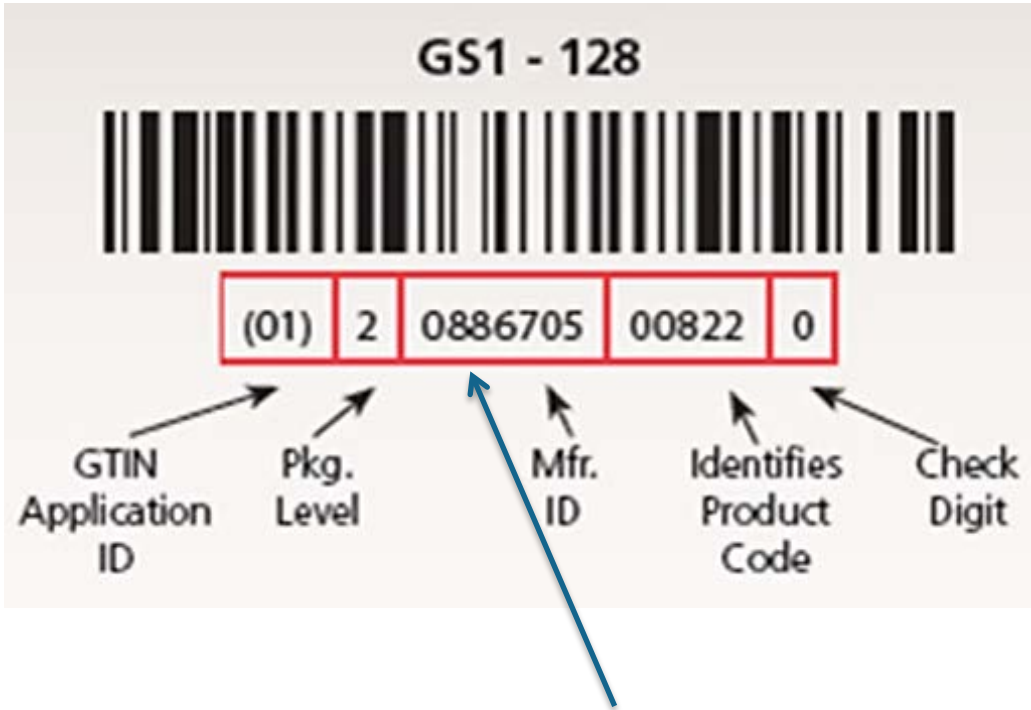
- GS1-128
- GS1 Data Bar
- GS1 Data Matrix
- RFID EPC Gen 2 UHF Tag

- Code 128 and Code 39
- Data Matrix, QR Code, Aztec Code
- RFID ISO 18000-6c UHF Gen 2 tag

- *ISBT128*
- Data Matrix
- RFID ISO 18000-3 mode 1 HF tag

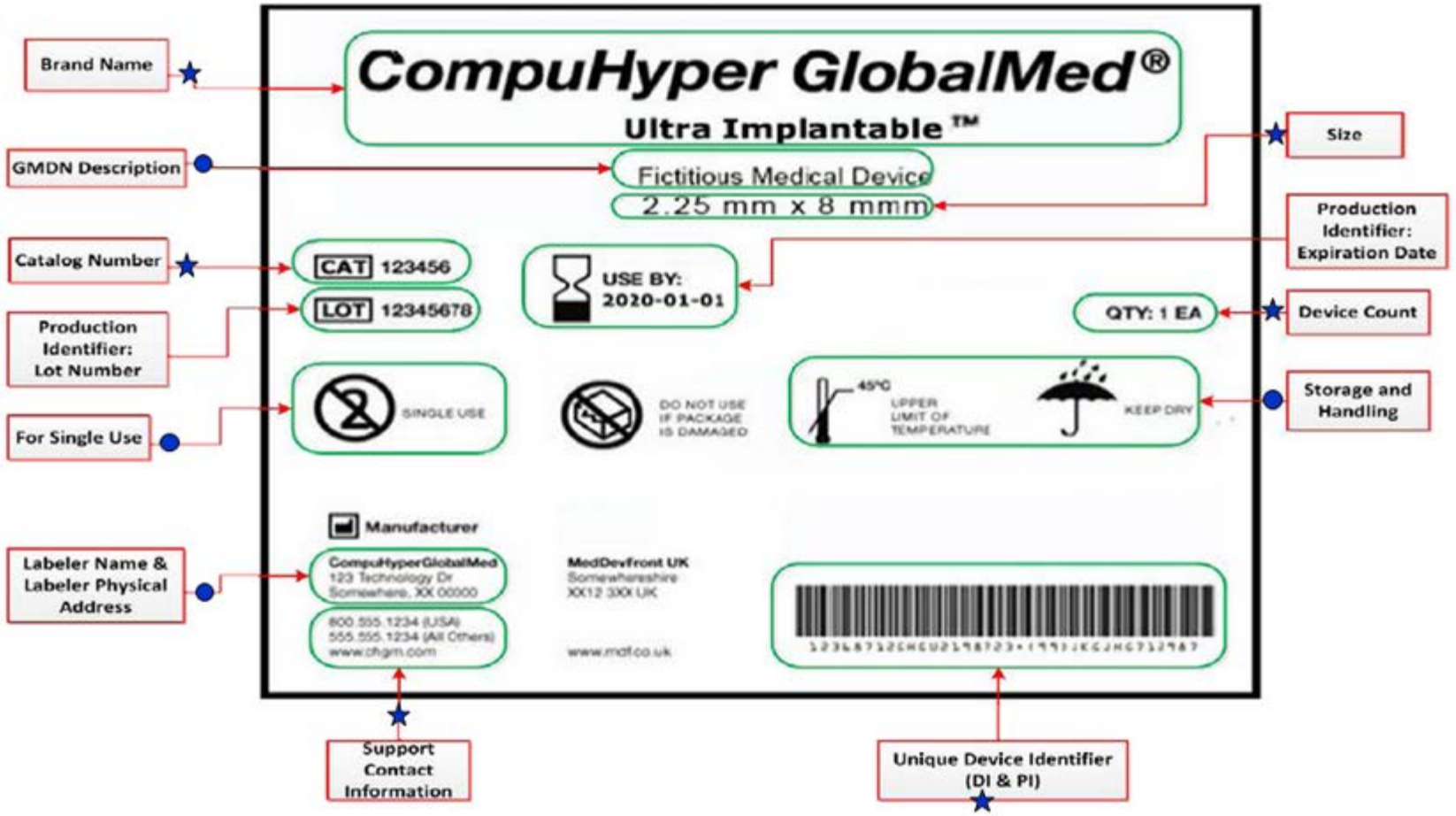
Globally Unique Device Identifier

GS1 Example



GTIN = Global Trade Item Number

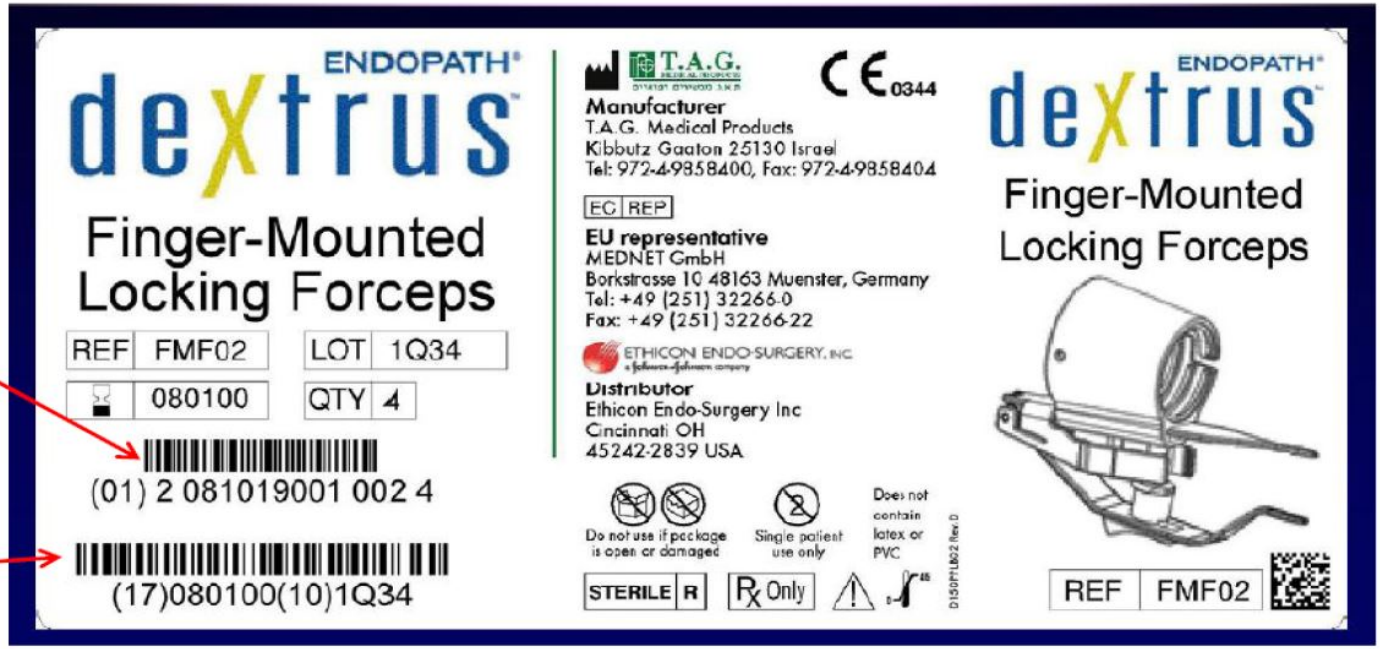
Medical Device Label Elements



Re-designing the Label
UDI Label Example

Device Identifier
(01) GS1 GTIN

Production Identifier
(17) Expiration
(10) Lot Number



Device Identifier and Production Identifier Concatenated in a GS1 Data Matrix symbol

Please Note: US Healthcare Facilities are requesting one Data Matrix barcode on the label. However, Data Matrix may not be acceptable in certain countries.

Determine UDI Labeling Levels

Direct Marking

Device Packaging

Inner Carton

Outer Carton

- UDI does not have to be on shipping container (ie. skid or tote)
- What is marked depends on how the device will be consumed and if it is reusable

Summary

- The FDA UDI Rule was Purposefully Written to Offer Implementation Flexibility to Manufacturers

- Focus on Driving the Two Work Streams Below, in Parallel
  - Identify, collect, validate and submit required data to GUDID
  - Assign UDI's to devices and place UDI on the devices label (and packaging) [and standardized date format]
    - Determine packaging levels requiring UDI
    - Re-design labels to fit barcode(s) and feature the standardized date format.

- Understand Your Customers - Healthcare Organizations are Establishing Their Own Compliancy Guidelines and Timelines

Global Medical Device Nomenclature (GMDN)

G·M·D·N AGENCY

- Internationally agreed descriptors used to identify medical device products.
- Uniform naming supports market surveillance, adverse event reporting, product recall and other healthcare management activities.
- Database lists all the terms, which are currently available to name and describe medical devices.
- New terms are regularly issued to cope with new medical devices innovations.

Q&A and Additional Information

UDI Compliance Management

Tue, May 12, 2015 2:00 PM - 3:00 PM Central Daylight Time

https://global.gotomeeting.com/join/631680037

Join the conference call.

(877) 416-0279, Code: 3826541998

UDI Labeling

Tue, May 19, 2015 2:00 PM - 3:00 PM Central Daylight Time

https://global.gotomeeting.com/join/995247997

Join the conference call.

(877) 416-0279, Code: 3826541998

UDI Verification

Tue, May 26, 2015 2:00 PM - 3:00 PM Central Daylight Time

https://global.gotomeeting.com/join/670061965

Join the conference call.

(877) 416-0279, Code: 3826541998

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