



# UDI Implementation Reality – AIDC

How to identify/mark my medical device products?





# UDI Implementation Reality

...How to identify/mark my medical device products?...

## Moderator

Ms. Jackie Rae Elkin

Global Process Owner - Standard Product Identification

Global Regulatory Operations

Medtronic, Inc.

## Panelists

Mr. Dennis Black

Director, e-Business

BD - Becton, Dickinson and Company

Mr. Jithendra Nair

Director Information Technology, Asia Pacific

Cook Medical

Mr. Tom Werthwine

Global Process Owner - Auto ID Technology and Data Standards

Johnson & Johnson

## GS1 GO Staff

Chuck Biss

Senior Director, AIDC Healthcare



# UDI Implementation Reality – AIDC

...UDI in a GS1 “AIDC” world... the “theory” ...





# UDI

# Unique Device Identification

**...is enabled by...**

## GS1 Standards !!

**NOTE:** At the time of this presentation the US FDA Ruling has been published. As it is a detailed and in-depth document, it is recommended that you always refer to the final US FDA Ruling for all details specific to it at:

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/default.htm>



# Unique Device Identification

1. A standardized system to develop **Unique Device Identification numbers** (UDI)
2. **UDI** in human readable and/or **bar code/RFID** on a device, its label, or both
3. **UDI Database** will be created and will need to be maintained
4. **Users** need your help to implement. The FDA expects GS1 as an “Issuing Agency” to play a major role

**...the AIDC “bits” of UDI...**



# UDI system...

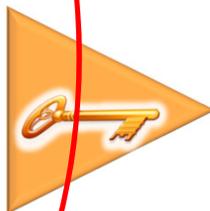
...AIDC "bits" ...

...the AIDC "bits" ...

## UDI/UDID - System

**AIDC Identifiers**

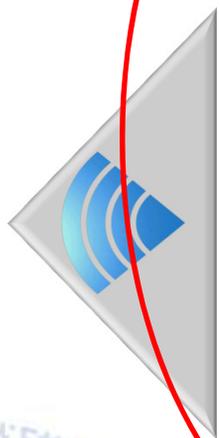
- **DI**  
(static data)
- **PI**  
(dynamic data)



**UDID**  
(database)

**Static Data Elements**

- **DI = primary access key**
- ...
- ...
- ...
- ...



**AIDC Data Carriers**  
Machine Readable

- 1D Bar Code
- 2D Bar Code
- RFID
- ...

**DI = Device Identifier**

**PI = Production Identifiers** (i.e. lot/batch no., serial no., expiry [use by] date, date of manufacture)



# UDI system...

...and some non-AIDC "bits" ...

GDSN discussed NOW in a parallel breakout session!!

## UDI/UDID - System

**AIDC Identifiers**

- **DI**  
(static data)
- **PI**  
(dynamic data)



**UDID (database)**

**Static Data Elements**

- **DI = primary access key**
- ...
- ...
- ...
- ...



**AIDC Data Carriers**

**Machine Readable**

- 1D Bar Code
- 2D Bar Code
- RFID
- ...

**DI = Device Identifier**

**PI = Production Identifiers** (i.e. lot/batch no., serial no., expiry [use by] date, date of manufacture)



# UDI in the GS1 system of standards

...UDI in GS1 terms...

## AIDC – Unique Device Identification (UDI)

Goal of unambiguous identification of a specific medical device. From an AIDC standpoint this identification has two (2) parts:

- The **Device Identifier (DI)** – Meant to be the identification of the “generic” medical device – GS1 **GTIN** enables this.
- The **Production Identifier (PI)** – Meant to be whatever “control” numbers or data a manufacturer uses in their process – GS1 **Application Identifiers (AI’s)** such as lot/batch number, serial number, expiry, in any combination with a GTIN) enable this aspect.

**GTIN + AI(s) = UDI**

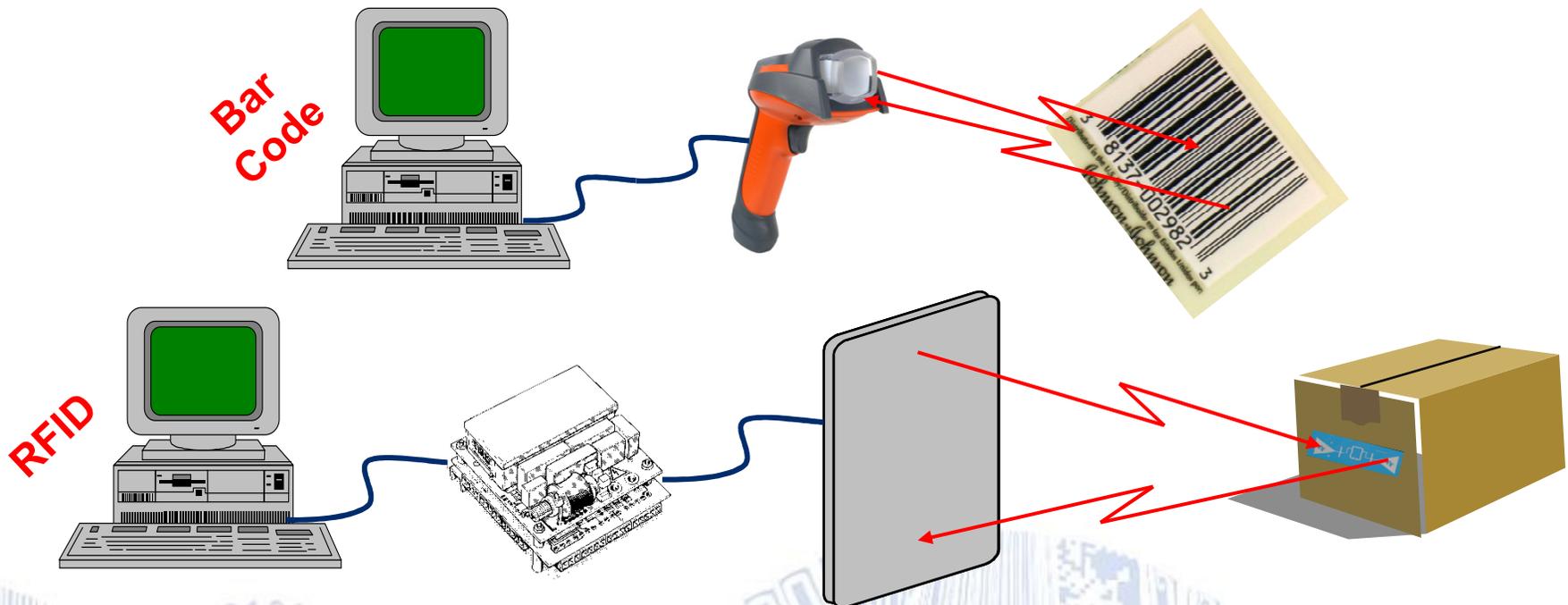


# UDI in the GS1 system of standards

...UDI in GS1 terms...

## AIDC - Data Carriers

ISO compliant machine-readable **Data Carriers** on the product (via label or DPM... Direct Part Marking) or it's packaging, which contain the UDI – 1D / Linear & 2D / Matrix bar code symbols, RFID.



**NOTE:** Though “any” ISO compliant machine-readable Data Carrier is applicable... GS1 Healthcare members have agreed to focus at this time on the use of bar code technology before considering other data carriers...



# UDI in the GS1 system of standards

...Bar Code Data Carriers “most” typically seen in UDI...



5 012345 678900  
**EAN/UPC**



(01)00012345678905(21)12345678  
**GS1 DataBar**



(01)00012345678905

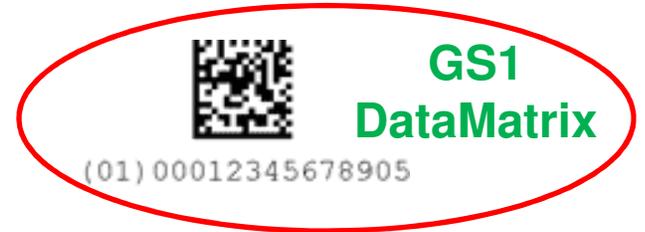


(00) 0 0123456 123456789 6  
**GS1-128**

**Composite Component**



(00) 0 0123456 123456789 6  
(02) 5 0123456 78901 7 (37) 000288 (02) 5 0123456 11111 5 (37) 000045



**GS1 DataMatrix**

(01)00012345678905



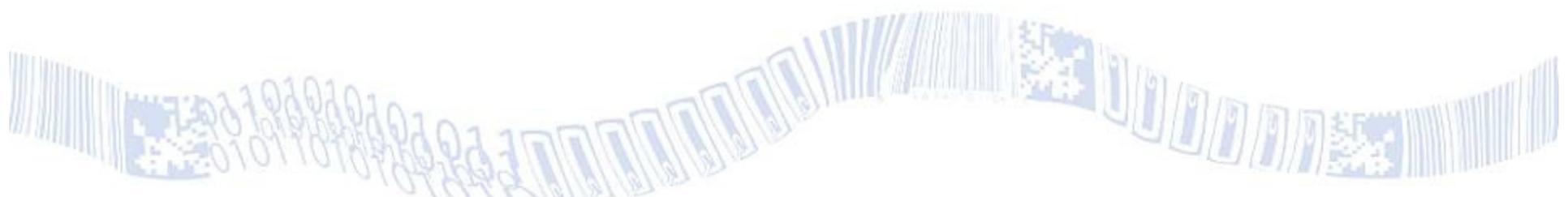
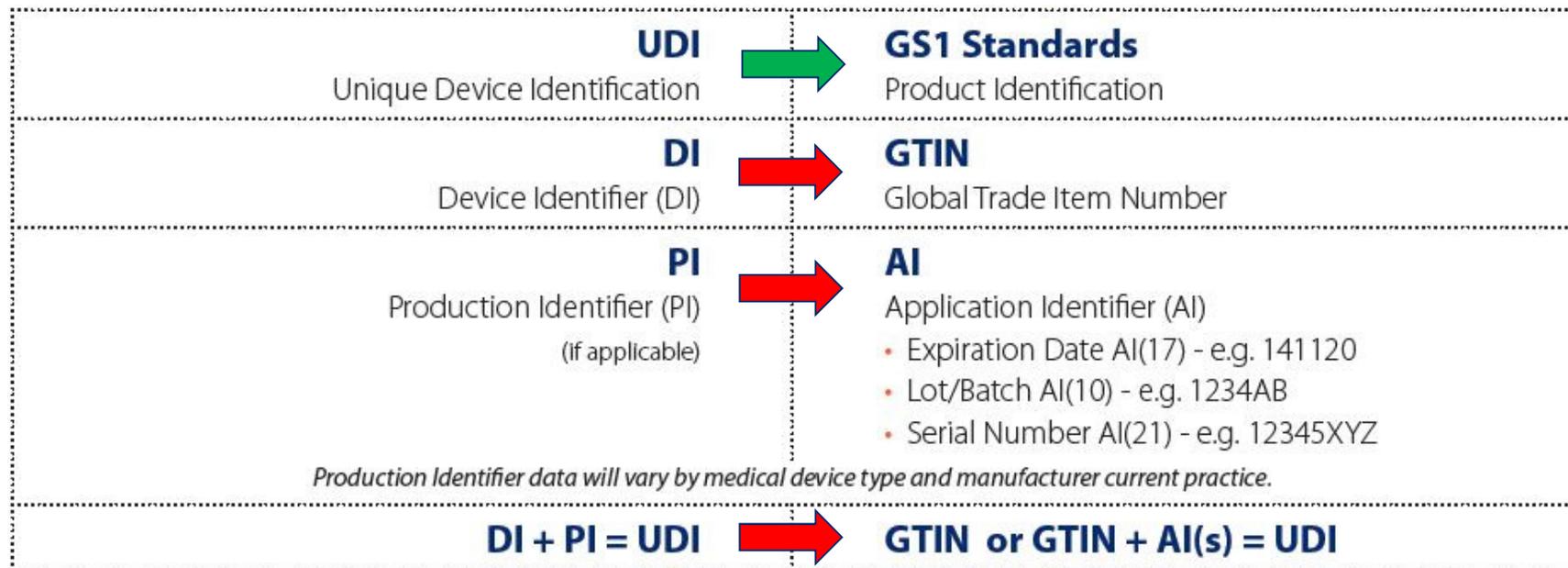
00012345678905

**ITF-14**



# UDI in the GS1 system of standards

...UDI in GS1 terms...





# UDI in the GS1 system of standards

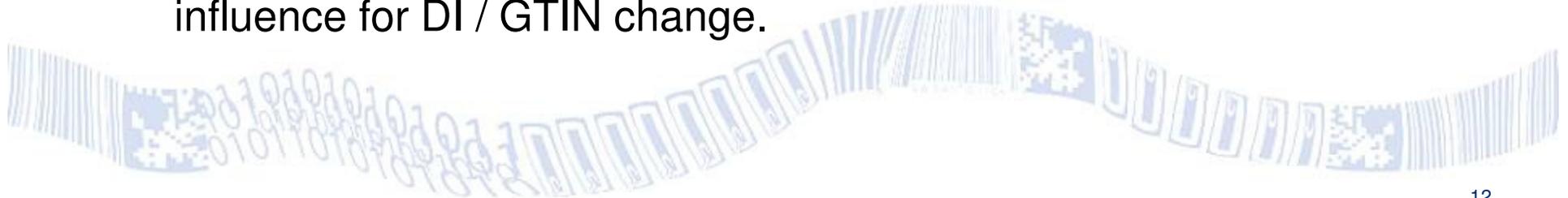
...UDI in GS1 terms...

## Device Identifier / GTIN Allocation

Some (but not all) common reasons for a Device Identifier (DI = GTIN) to change are:

- Change in quantity of a device package
- Change to package sterility
- Re-labeling of the original labeler's (mfg.) device
- Change labeling languages for different global markets
- Change in certification mark, e.g., CE Mark

Refer to the appropriate UDI regulation in your area and the GS1 GTIN Allocation Rules for complete details on any regional influence for DI / GTIN change.





# UDI in the GS1 system of standards

...UDI in GS1 terms...

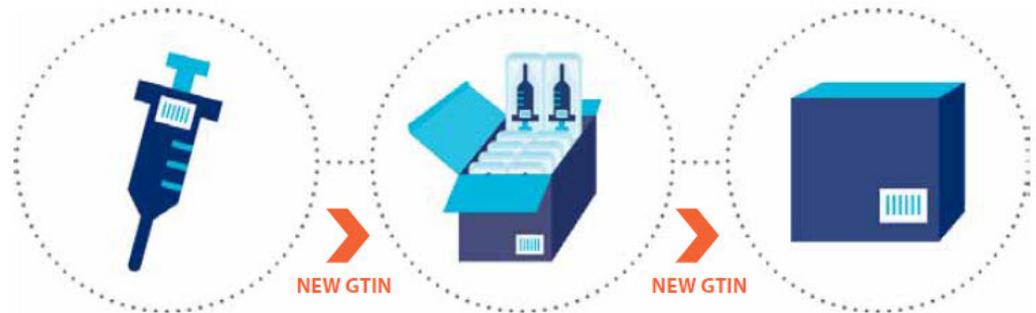
## Package Levels/Hierarchy

Packaging Levels –The UDI (a DI, i.e. GTIN and PIs i.e. AIs) should be in the AIDC data carriers (i.e. bar code symbol) and also in human-readable form on each applicable packaging level as defined by regulation. Each designated packaging level that is a trade item must have its own DI (GTIN). Logistics items are exempt.

### Common industry practices

**Packaging Levels** - The GTIN (DI) & AIs (PIs) should be in bar code & in human-readable form on each applicable package level as defined by regulation. Each designated package level must have its own GTIN (DI).

**Placement** - Bar code symbols are to be positioned to allow ready access for scanning when the product is stored or stocked on shelves.



NOTE: GTINs below for illustration only

Single Unit Package	Multiple Unit Package	Case
GTIN A	GTIN B	GTIN C
00857674002010	10857674002017	40857674002018



# UDI in the GS1 system of standards

...UDI in GS1 terms...

## Kits

Medical Device “kits” have their own UDI. The general rule is that only the packaged kit/combination product needs a UDI on its label, and that the individual devices contained within do not.

(NOTE: Refer to the FDA Rule for details and/or refer members to their compliance team for guidance specific to their products. Within GS1 additional definition & allocation rules for Healthcare kits are presently being clarified through the GSMP AIDC Healthcare Application Standard Updates Mission Specific Work Group.)

## Data Carrier Placement

As with any AIDC data carrier in any sector overall placement is important. Bar code symbols, with their associated HRI, should be positioned to allow ready access for scanning when the product is stored, stocked on shelves or handled for PoC use.





# UDI in the GS1 system of standards

...UDI in GS1 terms, carriers you might see at...



## The Warehouse

GS1-128  
"Concatenated" data



GS1-128  
"Non-Concatenated" data



ITF-14



## The Hospital

GS1-128  
"Concatenated" data



GS1-128  
"Non-Concatenated" data



GS1 DataMatrix



(01)10857674002017  
(17)141120  
(10)1234AB

All data carriers are for illustration only, not to scale and not in proportional size to one another. Please refer to GS1 General Specifications for detailed & up-to-date GS1 System information. UDI requirements may vary by geography -please refer to regional UDI regulations.



# UDI in the GS1 system of standards

...UDI in GS1 terms, carriers you might see at...



The Point-of-Care



The Retail POS

GS1-128  
"Concatenated" data



EAN 13



UPC-A



GS1 DataMatrix



(01)10857674002017  
(17)141120  
(10)1234AB

ITF-14



All data carriers are for illustration only, not to scale and not in proportional size to one another. Please refer to GS1 General Specifications for detailed & up-to-date GS1 System information. UDI requirements may vary by geography -please refer to regional UDI regulations.



# UDI example - #1

**16G Dual Lumen Oocyte Recovery Set** **wallace**<sup>TM</sup>

<b>de</b> 16 G doppellumiges Eizellenentnahmebesteck	<b>pt</b> Conjunto de colheita de oócitos de duplo lúmen de calibre 16
<b>da</b> 16G dobbeltløbet oocyttagningsæt	<b>sv</b> 16 G hämtningsset för oocyter med dubbellumen
<b>es</b> Equipo de doble luz para recogida de ovocitos de 16 G	<b>fi</b> 16G Kaksi kanavainen munasolun keräyspakkaus
<b>fr</b> Jeu à double lumière pour récupération d'ovocytes 16 g	<b>cs</b> Souprava k odběru oocytů s dvoulumenovou jehlou 16 G
<b>el</b> Σει ανάκτησης ωοκυττάρων διπλού αυλού 16G	<b>pl</b> Dwukanałowy zestaw do pobierania oocytów 16 G
<b>it</b> Set per prelievo oociti a doppio lume da 16G	<b>hu</b> 16G kettős lumenű oocyta begyűjtő készlet
<b>no</b> 16G Dobbeltlumensett for uthenting av oocyter	<b>tr</b> 16G Çift Lümenli Oosit Alma Seti
<b>nl</b> 16 G dubbellumenset voor het verzamelen van oöcyten	<b>et</b> 16G kahe valendikuga munarakkude kogumise komplekt
	<b>ro</b> Set cu lumen dublu pentru recoltarea ovulelor, 16G
	<b>bg</b> Набор за събиране на яйцеклетки с двоен лумен 16 G
	<b>sk</b> Dvojlúmenová súprava na odber oocytov 16 G
	<b>lt</b> 16 G dvigubo spindžio oocitų ėmimo sistema

**REF DNS1633-500**

**STERILE EO ONLY** **Rx CE** 0473

**Caution.** Do not reuse. Latex free.  
Do not use if package is damaged. Sterilised using ethylene oxide. **Caution:** Federal (USA) law restricts this device to sale by or on the order of a physician.

**Smiths Medical International Ltd.**  
Hythe, Kent, CT21 6JL, UK.  
Australian Representative:  
**Smiths Medical Australasia Pty. Ltd.**  
Brisbane, QLD 4113, Australia.  
www.smiths-medical.com.

Wallace and Smiths Medical design mark are trademarks of the Smiths Medical family of companies. The symbol ® indicates the trademark is registered in the U.S. Patent and Trademark office and certain other countries. Made in UK.

**LOT** 1111111 **2008-10** **2010-10**

**smiths medical**

FC835-A 127

**UDI Bar Code symbol**

**Device Identifier (DI)**  
"Static" portion  
GTIN (product identifier)

**Production Identifier (PI)**  
"Dynamic" portion  
Application Identifiers (e.g. serial, lot number & expiry date)



# UDI example - #2

UDI Bar Code symbol

Device Identifier (DI)  
"Static" portion  
GTIN (product identifier)

Production Identifier (PI)  
"Dynamic" portion  
Application Identifiers (e.g. serial, lot number & expiry date)

MOSAIC® 305 CINCH® II  
21 MM

REF → 305C221  
Rector Number  
Size → 21 MM  
Use By → 2016-07-12  
SN → 21A11F4855  
Serial Number

MOSAIC® 305 CINCH® II  
Porcine Bioprosthesis Aortic Valve

Aortic

UDI Bar Code symbol

(01)00643169001763 17160712(21)21A11F4855

STERILE LC  
Sterile LC; Device has been sterilized using Liquid/Chemical Sterilants according to EN ISO 14190.

PYROGEN  
Nonpyrogenic

Do Not Resterilize

Do Not Reuse

Quantity: 1

Temperature Limitation: 43°C / 111°F

USA Rx only  
For US Audiences Only

www.medtronic.com/manuals  
Consult Instructions for Use

Check temperature indicator prior to use

Manufacturer: Medtronic, Inc. 710 Medtronic Parkway Minneapolis, MN 55432 USA

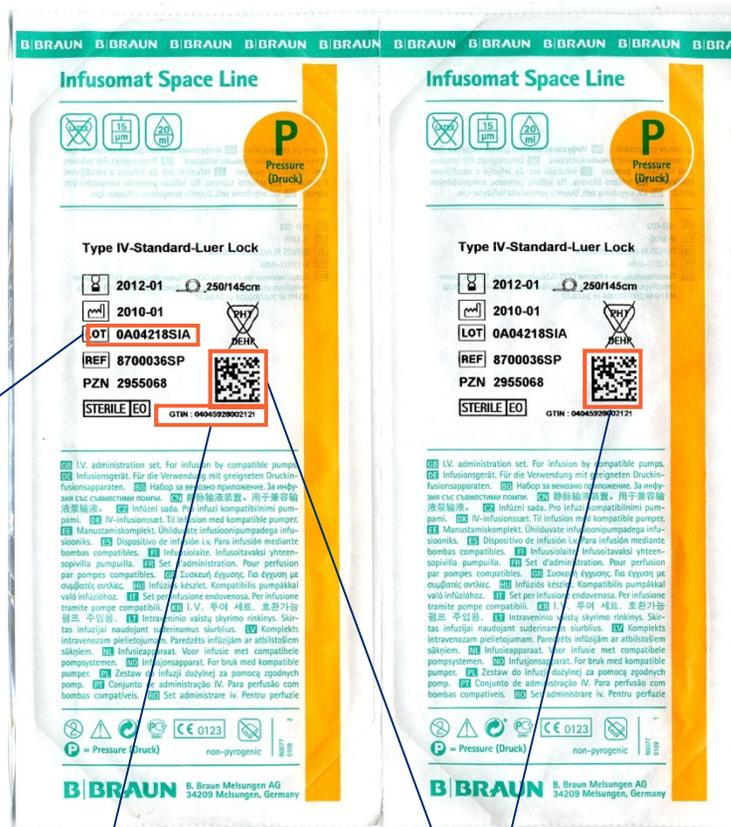
Manufactured at: Santa Ana, CA USA  
© 2011 Medtronic 1211533002 Rev. 1B

MOSAIC® 305 CINCH® II  
21 MM

REF → 305C221  
Rector Number  
Size → 21 MM  
Use By → 2016-07-12  
SN → 21A11F4855  
Serial Number



# UDI example - #3



**Production Identifier (PI)**  
"Dynamic" portion  
Application Identifiers (e.g. serial,  
lot number & expiry date)

**Device Identifier (DI)**  
"Static" portion  
GTIN (product identifier)

**UDI Bar Code**  
symbol



# UDI webpage

[www.gs1.org/healthcare/udi](http://www.gs1.org/healthcare/udi)

GS1 The global language of business

Contact your local GS1 office MO Zone Login Search >>

Home About Us Standards Products & Solutions Services Sectors

Healthcare

About GS1 Standards Implementation AIDC UDI GDSN eCOM Traceability Resource Library Events Contact us healthcare\_gdsn\_editor My account Log out

View Edit Revisions

Sectors > Healthcare > Implementation > UDI

### UDI - Unique Device Identification

The GS1 System of standards enables all stakeholders to efficiently and effectively meet UDI requirements by ensuring interoperability and compatibility within an organisation, between organisations and across borders.

A single standard ultimately accelerates implementation and increases compliance to the UDI regulations. GS1 has over 110 Member Organisations and more than 2,000 employees worldwide providing support to users on how to implement UDI in their local language and understanding the local situation.

- Introduction
- What is UDI?
- UDI Leaflet
- UDI's scope
- Benefits
- Information

Global GS1 Healthcare Conference Register now 1-9 October 2013 San Francisco, USA

Get ready for UDI Visit GS1 US website to find out how to meet FDA UDI requirements

#### Introduction

The IMDRF (International Medical Device Regulator Forum), the United States Food and Drug Administration (FDA) and the European Commission have made safety and integrity of the global Healthcare supply chain a strategic priority by proposing legislation for Unique Device Identification (UDI).

UDI is expected to improve patient safety and Healthcare business processes. A single, global system of standards is fundamental to enable an efficient and effective implementation of UDI by all Healthcare stakeholders worldwide.

#### What is UDI?

UDI – Unique Device Identifier

A common, worldwide system for product identification, to be applied to all medical devices placed on the market.

UDI	GS1 Standards
Unique Device Identification	Product Identification
DI	GTIN
Device Identifier (DI)	Global Trade Item Number
PI	AI
Production Identifier (PI) (if applicable)	Application Identifier (AI)
	- Expiration Date AI(17) - e.g. 141120
	- Lot/Batch AI(10) - e.g. 1234AB
	- Serial Number AI(21) - e.g. 12345XYZ
<i>Production identifier dates will vary by medical device type and manufacturer current practice.</i>	
DI + PI = UDI	GTIN or GTIN + AI(s) = UDI

#### UDI Leaflet

Are you ready for UDI? Click here to download the UDI Leaflet.



## UDI Leaflet

Are you ready for UDI? Click here to download the UDI Leaflet.

Are you ready for UDI?  
Unique Device Identification for medical devices

Introduction

The GS1 System of standards enables all stakeholders to efficiently and effectively meet UDI requirements by ensuring interoperability and compatibility within an organisation, between organisations and across borders.

A single standard ultimately accelerates implementation and increases compliance to the UDI regulations. GS1 has over 110 Member Organisations and more than 2,000 employees worldwide providing support to users on how to implement UDI in their local language and understanding the local situation.

UDI is expected to improve patient safety and Healthcare business processes. A single, global system of standards is fundamental to enable an efficient and effective implementation of UDI by all Healthcare stakeholders worldwide.

What is UDI?

UDI – Unique Device Identifier

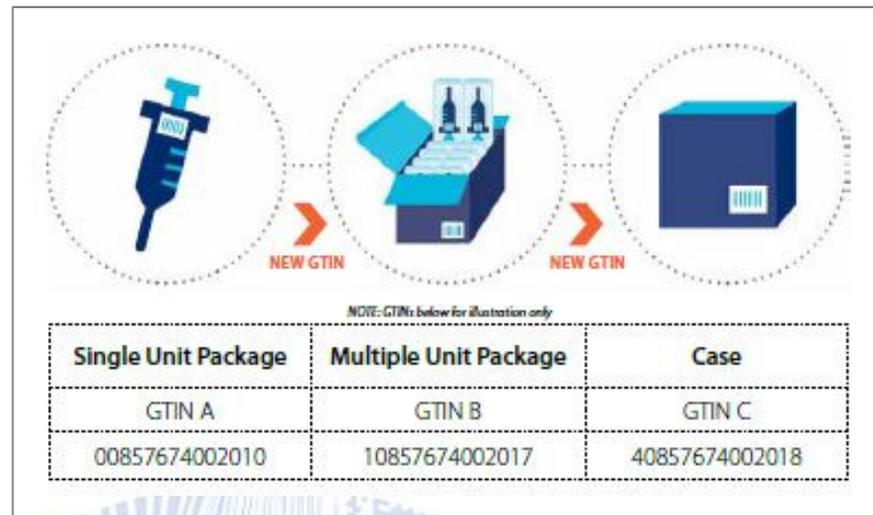
A common, worldwide system for product identification, to be applied to all medical devices placed on the market.



# UDI Support: “Are you ready for UDI?”



- Introduction to UDI
- UDI in GS1 terms
- Presentation of industry practices
- Benefits of UDI



[www.gs1.org/healthcare/udi](http://www.gs1.org/healthcare/udi)



# UDI / GS1 AIDC - the “snapshot”...

## Unique Device Identification in GS1 terms

<b>UDI</b> Unique Device Identification	<b>GS1 Standards</b> Product Identification
<b>DI</b> Device Identifier (DI)	<b>GTIN</b> Global Trade Item Number
<b>PI</b> Production Identifier (PI) <i>(if applicable)</i>	<b>AI</b> Application Identifier (AI) - Expiration Date AI(17) - e.g. 141120 - Lot/Batch AI(10) - e.g. 1234AB - Serial Number AI(21) - e.g. 12345XYZ  <i>Production Identifier data will vary by medical device type and manufacturer current practice.</i>
<b>DI + PI = UDI</b>	<b>GTIN or GTIN + AI(s) = UDI</b>

### Why GTINs change?

Some common reasons for a GTIN (DI) to change are listed below. Refer to the appropriate UDI regulation and the GS1 Healthcare GTIN Allocation Rules for complete details on regional Influence for GTIN change:

- Change in quantity of a device package
- Change to package sterility
- Re-labelling of the original labeller's (manufacturer) device
- Change labelling languages for different global markets
- Change in certification mark, e.g., CE Mark

### Reference tools

- GS1 General Specifications (current version)
- GS1 Healthcare GTIN Allocation Rules
- GS1 US Healthcare Provider & Supplier GTIN Tool Kits

For any question regarding the use of GTINs contact your local GS1 Member Organisation: <http://www.gs1.org/contact>

## Common industry practices

**Packaging Levels** - The GTIN (DI) & AI (PIs) should be in bar code & in human-readable form on each applicable package level as defined by regulation. Each designated package level must have its own GTIN (DI).

**Placement** - Bar code symbols are to be positioned to allow ready access for scanning when the product is stored or stocked on shelves.



NOTE: GTINs below for illustration only

Single Unit Package	Multiple Unit Package	Case
GTIN A	GTIN B	GTIN C
00857674002010	10857674002017	40857674002018

## A few examples of Data Carriers across the supply chain

### The Warehouse

GS1-128 "Concatenated" data

GS1-128 "Non-Concatenated" data

ITF-14

### The Hospital

GS1-128 "Concatenated" data

GS1-128 "Non-Concatenated" data

GS1 DataMatrix

Data may be carried in a single "concatenated" GS1-128 (best practice) or in two GS1-128s (allowed alternate).

GS1 DataMatrix is particularly suited to small spaces on Single Unit or Multiple Unit Packages and Direct Part Marking (DPM) on Single Units.

### The Point-of-Care

GS1-128 "Concatenated" data

GS1 DataMatrix

### The Retail POS

EAN-13

UPC-A

ITF-14

UPC-A is used primarily in North America. EAN-13 is used throughout the world on Secondary (retail) packaging. UPC-A, EAN-13 and ITF-14 do not encode "Attribute Data" (Application Identifiers).

ITF-14 usually seen at POS by "warehouse" retailers and commonly in the warehouse on cases.

All data carriers are for illustration only, not to scale and not in proportional size to one another. Please refer to GS1 General Specifications for detailed & up-to-date GS1 System information. UDI requirements may vary by geography - please refer to regional UDI regulations.

**NOTE:** Check out the GS1 Healthcare UDI web page at: <http://www.gs1.org/healthcare/udi>



# UDI Implementation Reality – AIDC

...our Panelists and the “reality” ...





# UDI Implementation Reality

...How to identify/mark my medical device products?...

## Panelists

**Mr. Dennis Black**

Director, e-Business

BD - Becton, Dickinson and Company

**Mr. Jithendra Nair**

Director Information Technology, Asia Pacific

Cook Medical

**Mr. Tom Werthwine**

Global Process Owner - Auto ID Technology and Data Standards

Johnson & Johnson

## Moderator

**Ms. Jackie Rae Elkin**

Global Process Owner - Standard Product Identification

Global Regulatory Operations

Medtronic, Inc.





## IMPLEMENTATION REALITY

**“Medical Devices: How to identify/mark my products?”**

**Dennis Black**  
**BD - Becton, Dickinson and Company**

**GS1 Global Meeting**  
**01 April 2014 - Seoul**





# BD (Becton, Dickinson and Company)

- FORTUNE 500 company (#332)
- Locations in more than 50 countries
- Nearly 30,000 associates worldwide
- Serves healthcare institutions, life science researchers, clinical laboratories and the general public
- Sells a broad range of medical supplies and services, devices, laboratory equipment, diagnostic products, and pharmaceuticals



BD Nexiva™ Closed IV Catheter System



BD Influx™ Flow Cytometry System



BD SurePath™ PAP Collection System



BD PosiFlush™ Flush Syringe



BD Viper™ System with XTR Technology



BD Vacutainer® Push Button Blood Collection Set & Blood Collection Tubes



BD™ Insulin Syringes



BD RX





# Current UDI Efforts Include:

- ❑ Reviewing all applicable UDI data, GTIN assignment, and labels to conduct a gap analysis
- ❑ Internal Education on UDI Requirements
- ❑ Confirming Nuances in FDA UDI Rule
- ❑ Verifying Non-US Requirements & IMDRF Guidance
- ❑ Revising ERP and Other System to Store UDI Data
- ❑ Retooling/Printing Processes/Reassigning GTINs if Necessary
- ❑ Revising Policies, Procedures and Processes to Comply with UDI
- ❑ Label Revision Process
- ❑ Populating UDID
- ❑ Revising Commercial Processes



*Moving from voluntary adoption of data standards to compliance with a regulation.*



# Are We There Yet?

Driving data standards within the  
healthcare supply chain

Jithendra Nair

UDI & Traceability for Medical Devices

Seoul, Korea 1-3 April, 2014



[www.cookmedical.com](http://www.cookmedical.com)

## Improved Patient Safety – using global standards



- Identifies: Right product, right patient, right time
- Is scanned at the bedside
- Helps prevent medication errors
- Combats counterfeit products
- Facilitates recalls

# What is a data standard & What does it all mean?

- Data standard: A common language for trading partners to use about products that pass through the supply chain.

## SAME DATA. DIFFERENT NAMES.

<p style="text-align: center;"><b>UDI</b> Unique Device Identification</p>	<p style="text-align: center;"><b>GS1 Standards</b> Product Identification</p>
<p style="text-align: center;"><b>DI</b> Device Identifier</p>	<p style="text-align: center;"><b>GTIN</b> Global Trade Item Number</p>
<p style="text-align: center;"><b>PI</b> Product Identifier <i>(if applicable)</i></p>	<p style="text-align: center;"><b>AI</b> Application Identifier</p> <ul style="list-style-type: none"> <li>• Expiration Date AI(17) – e.g. 141120</li> <li>• Lot/Batch AI(10) – e.g. 1234AB</li> <li>• Serial Number A(21) – e.g. 12345XYZ</li> </ul>

*Product identifier data will vary by medical device type and manufacturer current practice.*

**DI + PI = UDI**

**GTIN or GTIN + AI(s) = UDI**

# Labeling challenges

## Date format

YYYY-MM-DD for all dates displayed in the labeling

Cook will start using day within the date

## For Cook product, must include DI + PI (at least one)

UDI does not dictate which PI is used

Exceptions for retail and some Class I devices

## AIDC portion of the UDI

DI + PI (include all PI information shown on the label)

Can request FDA exception for some PIs

Must be human and machine readable

## Labeling challenges

UDI is technology-neutral

Linear barcodes, 2D data matrices, RFID, etc.

As technologies evolve, supply chain will drive changes to the standards;

Standards are internationally recognized; GS1 is Cook's Issuing Agency

**GTIN-14 linear barcode is Cook's AIDC format**

# Labels – Current Cook Label

COOK MEDICAL

REF **UNB-6-15**

GPN REF **G46033**



(01)0082700246033 1

GPN REF **G46033**



<http://www.cookmedical.com/ourProducts.do> Rx ONLY

STERILE EO	 2015-02		
LOT X123456	 2012-02		

STERILE EO  
LOT X123456  2012-02  

**COOK** REF UNB-6-15



(01)00827002460331(17)X12345(10)X123456

GPN REF **G46033** LOT **X123456** **6mmX15cm**

**COOK** MEDICAL

Cook Incorporated  
225 Corner 1 Ave  
Bloomington, IL 61710-1100  
MAD010102

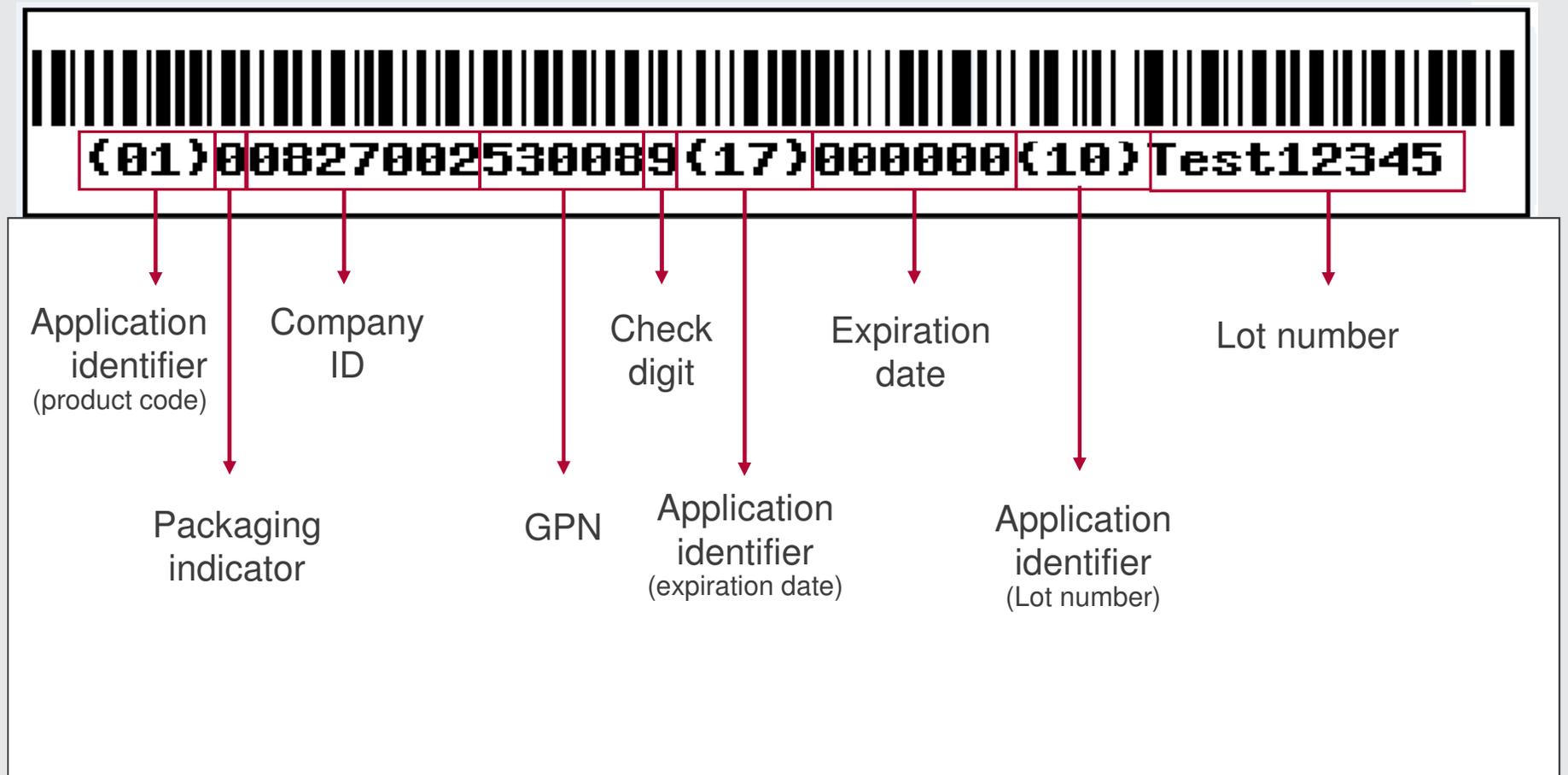
Cook Ireland Ltd.  
National Technology Park  
Limerick Ireland

CE 0382

# Labels – GTIN-14 Requirements

*By complying with GS1 and the GTIN-14 requirements, Cook is already complying, at least in part, with UDI!!!*

# Labels – GTIN-14 Format



# Labels – GTIN-14 Format

- Additional changes moving forward:
  - AI (30) – Box quantity
  - AI (21) – Serial number
  - Which AIDC method(s) is best for customers?
    - Single, linear barcode (current)
    - Split, linear barcodes
    - 2D data matrices
    - RFID
    - Combination

# GTIN-14 Challenges



- Create a global product database
- Manufacturers had to change barcode labeling logic
- Cook distribution systems had to change
- EDI systems had to be altered to pass data through all systems
- Packaging changed, resulting in going from a 1-to-1 relationship to a 1-to-many relationship between product number and packaging
- UOM changed, requiring inventory conversions

# Cook Medical's approach to implementing GS1 Standards

## 1. Assessment

- Identify current systems' capabilities
- Establish core business implementation team

## 2. Setup

- *GLN*
- *GTIN*
- *GDSN*
- *E-commerce*

## 3. Transact

- Use GS1 Standards in all transactions
- Work to achieve perfect order

## 4. Clinical Integration

- *GTIN use at bedside*
- *Integration into electronic health records*

# Start by building a plan and forming a team

## *Milestones*

1. Scope project
2. Assess systems
3. Form implementation team
4. Timelines



1. Assessment

2. Setup

3. Transact

4. Clinical Integration

# Setting up Global Location Numbers (GLNs)

## *Milestone*

1. **GLN**
2. GTIN
3. GDSN
4. E-commerce

## *Milestone Steps*

1. Identify GLN location(s) / entity(ies)
2. Request and assign GLNs from your GPO or GS1
3. Exchange and upload GLN(s) with supplier

[GS1 GLN Quick Start Guide](#)

[GS1 Healthcare Provider GLN Tool Kit](#)

1. Systems  
Assessment

2. Setup

3. Transact

4. Clinical Integration

# Setting Up Global Trade Item Numbers (GTINs)

## *Milestone*

1. GLN
- 2. GTIN**
3. GDSN
4. E-commerce

## *Milestone Steps*

1. Perform an item master cleanup.
2. Upload cleansed item master into the NPC/GS1 Catalogue
- 3. *Optional*:** Request supplier GTIN information through GDSN

1. Systems  
Assessment

2. Setup

3. Transact

4. Clinical Integration

# Setting Up Global Data Synchronization Network (GDSN)

## *Milestone*

1. GLN
2. GTIN
- 3. GDSN**
4. E-commerce

## *Milestone Steps*

1. Choose data pool provider
2. Request Cook publish GTIN attributes from GDSN

1. Systems  
Assessment

2. Setup

3. Transact

4. Clinical Integration

# Setting Up E-commerce

## *Milestone*

1. GLN
2. GTIN
3. GDSN
- 4. *E-commerce***

## *Milestone Steps*

1. Choose e-commerce option
2. Setup e-commerce

1. Systems  
Assessment

2. Setup

3. Transact

4. Clinical Integration

**Thank You**

Jithendra Nair  
Director Information Technology (Asia Pacific)  
Cook Medical



CUSTOMER  
& LOGISTICS  
SERVICES

# Unique Device Identification (UDI) Use Case

Tom Werthwine

GS1 Global Healthcare Conference Spring 2014

# UDI - Objectives

- Develop a clear understanding of the rule
- Establish a common framework to drive consistency, standardization and clear ownership
- Develop an initial comprehensive view of resources, requirements and investments across all work streams – including: UDI data & database, labeling, direct part marking, conforming amendments, steady state organization, etc.



# Required Components for FDA Compliance

Requirement	Description	Challenge
Bar Coding	GTIN and appropriate Application Identifiers	Migrating from HIBCC bar codes to GS1 bar codes
Date Format	YYYY-MM-DD	Many products carry month and year
GUDID Date Submission	GTIN, regulatory and labeling data	Need to associate “primary UDI” with other levels of packaging May need GTINS for unpackaged and DPM units US only product lack Global Medical Device Nomenclature RA data decentralized
Direct Part Marking	Bar code and/or human readable	Technology and space constraints
Conforming Amendments	Usage in Adverse Event Reports, Device Hx files	Change management

# UDI Bar Coding

<b>REF</b> 279751107	YYYY-MM	<b>QTY</b> 1
<b>LOT</b> SAMPLE	<b>MATL</b> SS/RADEL@SILICONE	

**EXPEDIUM® J SPINE SYSTEM  
RATCHETING TEARDROP HANDLE  
FOR EXPORT ONLY.**

POIGNÉE PIRIFORME À CLIQUET  
TROPFENFÖRMIGER RATSCHENGRIF  
DRUPPELVORMIG HANDVAT MET RATEL  
IMPUGNATURA A GOCCIA CON ARPIONISMO  
MANGO TIPO GOTA DE TRINQUETE  
CABO EM FORMA DE LÁGRIMA COM CATRACA  
DRÅBEFORMET SKRALDEHÄNDTAG  
SPÄRRANDE DROPPFORMAT HANDTAG  
RÄIKKÄPISARAKAHVA  
ΔΑΚΡΥΟΣΧΗΜΗ ΛΑΒΗ ΜΕ ΚΑΕΤΑΝΙΑ  
RACSNIS, KÖNNYCSEPP ALAKÜ NYÉL  
OZUBENÁ SLZOVÁ KLIKA  
RĄCZKA ZAPADKOWA W KSZTAŁCIE ŁZY  
TÄREFORMET HÄNDTAK MED SKRALLE

**5.5**

Medos International SARL  
Chemin-Blanc 38  
2400 Le Locle, Switzerland

**DePuy Spine**  
For patent information about this product, go to  
[www.depuy.com/patentmarking](http://www.depuy.com/patentmarking)

**US REP** DePuy Spine, Inc.  
325 Paramount Drive  
Raynham, MA 02767, USA

(01)10705034460581(20)99

(10)SAMPLE

REV. A

GS1 Linear 128 and Datamatrix

Testing Summary	
<b>GS1 General Specifications for Linear Symbols tested environments:</b>	
Not Assessed for Retail, Point of Sale Scanning	
Not Assessed for General Distribution and Logistics scanning	
Approved for Other Scanning Applications - Regulated Healthcare Non-Retail Consumer Trade Items Not Scanned in General Distribution	

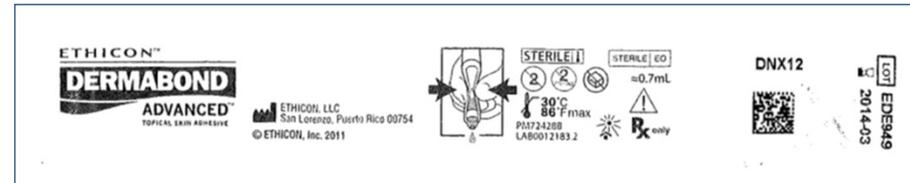
Complies to GS1 Symbol Location Recommendations	In/Out of Spec - <b>Not Assessed</b> (Comment on Business Critical Issue)
GS1 System Grade	<b>PASS</b>
ISO Symbol Grade	<b>ISO 3.1/10/660 (B) - PASS</b> Example: ISO 4.00/06/660 (0.00 - 4.00) PASS/FAIL

Business Critical Comments	
生产日期: 2013-04-17	MODEL NUMBER: 10033-901
序列号: 0033050293	GTIN: 10705037014163
(01) 1 0705037 01416 3 (11) 130417 (21) 0033050293	

GS1 US Verification Report

# GUDID Database Support

Field	Example
Submitter DUNS	TBD
Labeler DUNS	002144145 (ETHICON)
RA Contact	TBD
Customer Contact	1-877-384-4266
UDI Issuing Agency	GS1
Primary UDI	10705031203532
Primary UDI Count	1 EA
Secondary UDI IA	HIBCC
Secondary Primary UDI	H206DNX121
FDA Authorization	K100423
FDA PROCODE	MPN
FDA PROCODE Name	Tissue adhesive



Field	Example
FDA Listing	From FURLS
GMDN Code	TBD
GMDN Term	TBD
Brand Name	DERMABOND ADV
Model/REF	DNX12
Description	Topical Skin Adhesive
Market Status	Active
Combination Product	No
Contains Human Tissue	No

# Sample 2D Bar Code Etches for DePuy Synthes



# UDI and Conforming Amendments

Part	Name
803	Medical Device Reporting
806	Reports of Corrections and Removals
810	Medical Device Recall Authority
814	Premarket Approvals
820	Quality System Regulations
821	Medical Device Tracking Requirements
822	Post market Surveillance

Impacts Device History Records, Complaint Files, and Tracking Records.

# UDI in Medical Device Reporting

§ 803.32 If I am a user facility, importer or manufacturer, what information must I submit in my individual adverse event reports?

\* \* \* \* \*

(c) \* \* \*

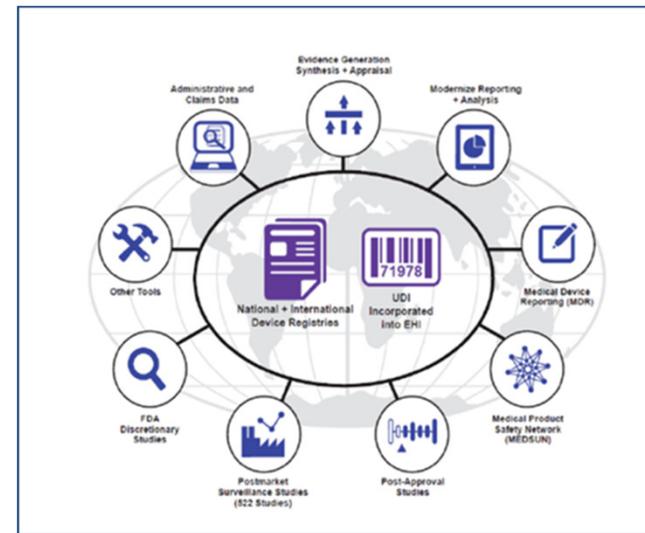
(6) The unique device identifier (UDI) that appears on the device label or on the device package;

\* \* \* \* \*

# UDI Opportunities

For manufacturers:

- Supporting customer need for data
- Globally unique product identification versus product selection by color, package size, etc.
- Support “perfect order”
- Support implant registries
- Support electronic health records
- Increase efficiencies for evidenced-based medicine





# US FDA UDI

**Compliance .....  
some important things to  
think about**

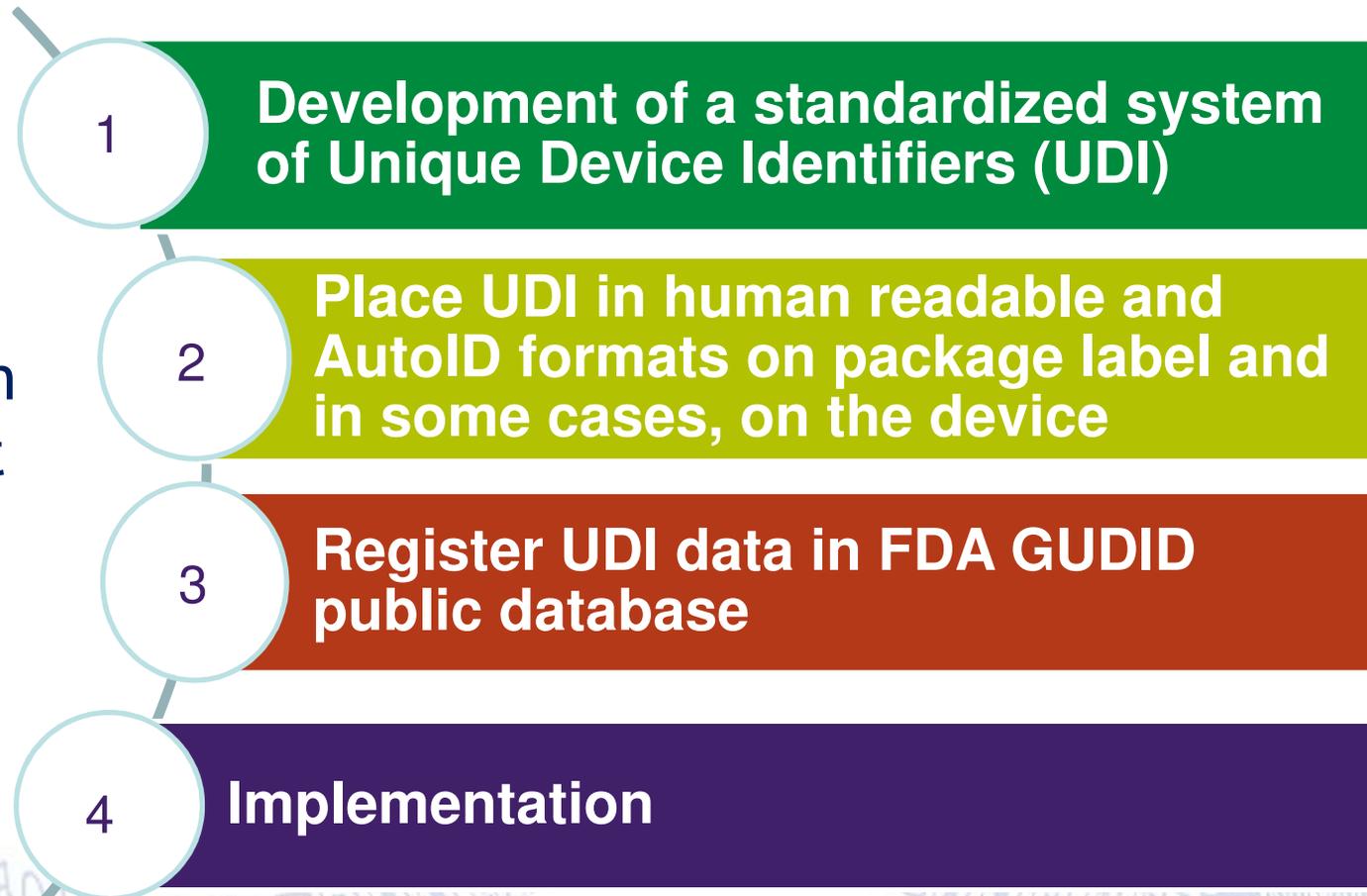


**Jackie Rae Elkin, Medtronic, Inc. Global Regulatory Affairs**



# Unique Device Identification

Combination  
of 4 Distinct  
Ideas





# Development of a standardized system of Unique Device Identifiers (UDI)

*Can you use more than one?*

*You might need to .....*



The global language of business



International Council for Commonality in Blood Banking Automation, Inc.



Health Industry Business Communication Council





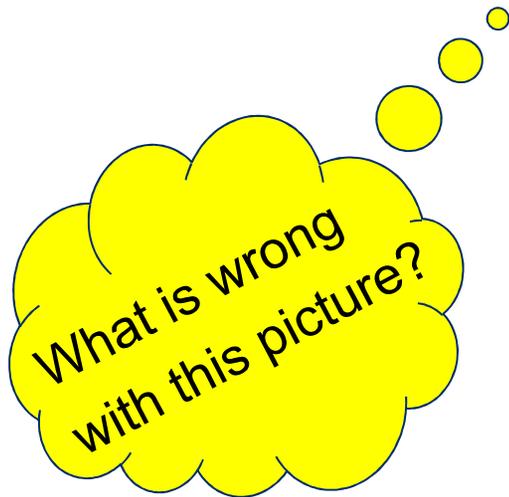
2

Place UDI in human readable and AutoID formats on package label and in some cases, on the device

- The Date Format applies to **All** medical devices (not just those subject to UDI). Compliance timelines follow the classification of the product.
- Bar code quality **must be verified**. Simply scanning for readability is not verification, nor is it sufficient. You must measure and verify the quality of the code to ISO/ANSI standards.
- Medical device **software version** should be captured in the Lot or Batch Production Identifier (AI 10 for GS1).
- **Manufacturing date** on the label. If you want an exception from FDA, the **labeler** needs to request it (industry groups cannot) or wait for the outcome of another labeler to be posted.
- GUDID concept of “**should**” **match** what appears on the product label. UDI and GUDID do not have requirements for the label beyond date format and the UDI itself. But remember the intent to accommodate description to your customer. Should give the customer the “sense” that this is the same product.



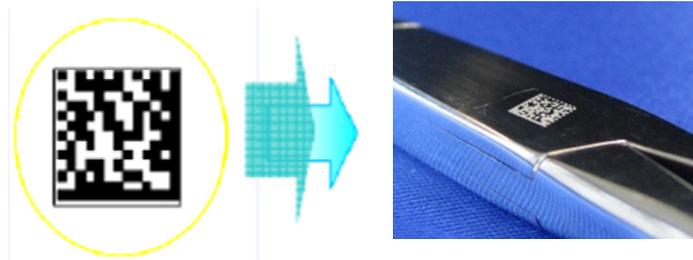
## Take the Opportunity to Fix Other Issues .....



If you must make label changes to be UDI compliant, e.g., date format, take the opportunity to fix other issues that may cause you problems in the future.

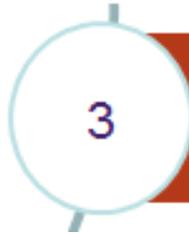


# Direct Marking on the Device



Reusable devices that require reprocessing (sterilization, cleaning) before reuse must have the UDI directly marked on the device.

- Remember the **exceptions** in the rule:
  - ✓ Interfere with safety and efficacy
  - ✓ Not technically feasible
  - ✓ SUD
  - ✓ Previously marked
- **Self exempt** and document in Design History File.
- Consider legacy products placed on market in consignment and remember the 3 years to deplete inventory begins to toll with the classification level for label and direct marking timelines



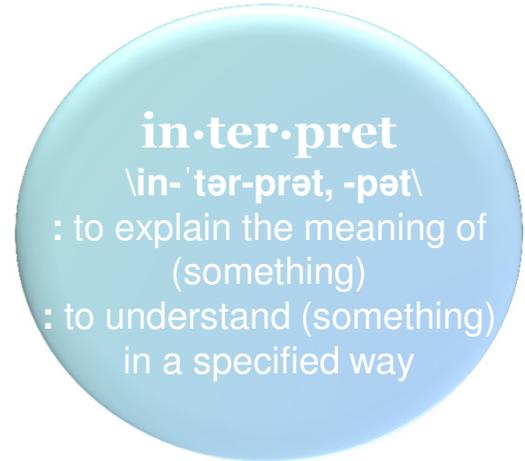
## Register UDI data in FDA GUDID public database

- Who will be **responsible for UDI submission** to FDA?
  - ✓ Using a solution provider to assist?
- **Data Governance** needed - roles and responsibilities to be defined.
  - ✓ Shared responsibility for data maintenance (business units, global/local)
- All UDI data for a medical devices must be submitted to the GUDID **before commercialization** of the product – where is product release trigger?
- **FDA pushing for labelers to publish data now** in order to provide insight to potential issues not anticipated. You can submit your data and push the publish date out 30 – 60 days which will allow you ample time to fix it before actual go-live or compliance dates.
  - \* FDA highly recommend labelers “test the waters” before finishing system and process designs.
- **DUNs conundrum** - it is up to the labeler to determine the responsible entity on the label, s/b the person responsible for interpretation of the rule. Primarily used to provide consistency of the responsible labeler name (trying avoid errors in manual entry).



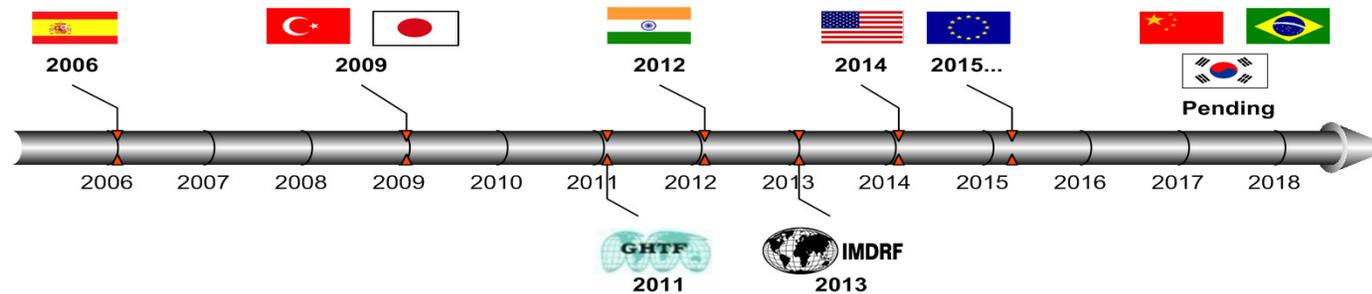
# Interpretation Required !

The **objective** of UDI is to **establish a system to adequately identify devices through distribution and use**. The **purpose** is to **rapidly and definitively identify a device** and it is intended to lead to more **accurate reporting** of adverse events by **making it easier to identify the device** prior to submitting a report.



- Be able to identify a device through a UDI that will appear on the label and package of the device
- UDI, when provided through AIDC technology will allow rapid and accurate data acquisition, recording and retrieval.
- Eliminating the uncertainty concerning the identity of the device subject of an adverse report
- More effective FDA safety communication
- To be used in EHR of a patient implanted with device to strengthen the ability to identify a specific device and improve response to postmarket surveillance activities including adverse event reporting and recalls.

# Global Device Identification Monitoring



Country	Timeline	STD	Label Requirements	Data Reporting
Spain	2006	GS1	Device Identifier, Production Identifiers to Unit of Use Level	Reimbursement SAS - Department of Health Andaluz
Turkey	2009	GS1 HIBC	Device Identifier, Production Identifiers to Unit of Use Level	TITUBB: Reimbursement SGK – Social Security Institute
Japan	2009 - Guideline	GS1	Device Identifier, Production Identifiers to Unit of Use Level	MEDIS: Reimbursement Ministry of Health, Labor and Welfare
India	2012	GS1	Device Identifier, Production Identifiers to Unit of Use Level	Procurement Ministry of Health & Family Welfare
IMDRF	Release 2013	GS1 HIBC	Device Identifier, Production Identifiers to Unit of Use Level	UDI - International Medical Device Regulators Forum (IMDRF)
USA	Implementation Timeline Class III: 2014 LS / LS Implants: 2015 Class II: 2016 Class I: 2018	GS1 HIBC ISBT	Device Identifier, Production Identifiers to Unit of Use Level Class II & III	UDI Database – US FDA
EU	Recommendation Release 2013	GS1 HIBC	Will Align with IMDRF	EUDAMED - European Commission
China	TBD	TBD	TBD	TBD - CFDA
Brazil	TBD	GS1	Will Align with IMDRF	TBD - ANVISA
S. Korea	TBD	GS1	TBD	TBD - KFDA

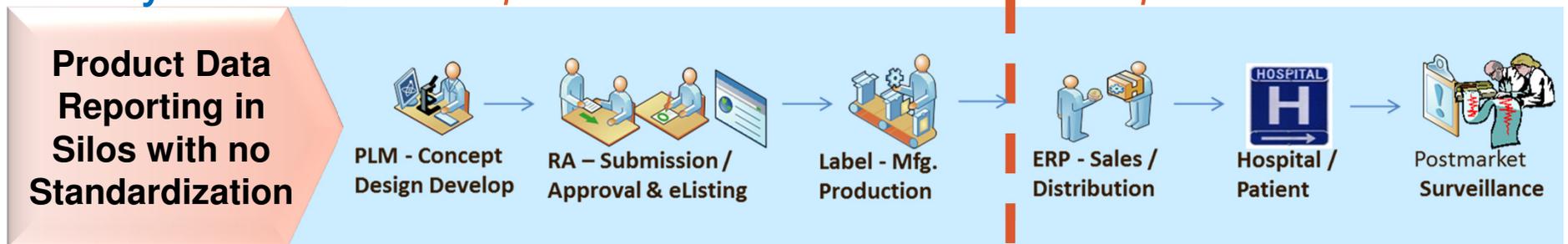


# External Trends Affecting RIM

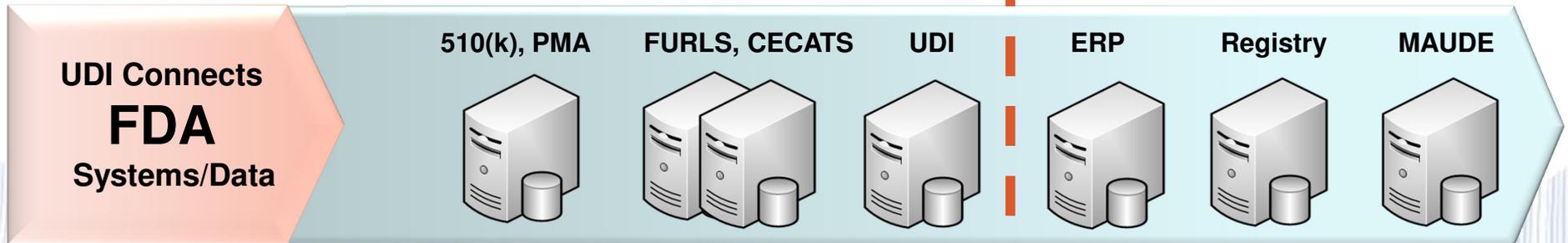
Regulators are Developing Master Data Strategies

- UDI requirements include electronic data about products.
- Regulated Product Submissions (RPS): standards for electronic submissions and electronic data about documents, common data elements for products.

Today



Future





# Contact Details

***Jackie Rae Elkin***

**Global Process Owner - Standard Product Identification**

**Medtronic, Inc. - Global Regulatory Operations  
710 Medtronic Parkway | Minneapolis, MN 55432  
USA**

**Office: 1-763-505-2575    Mobile: 1-612-801-6615**

**[jackie.elkin@medtronic.com](mailto:jackie.elkin@medtronic.com)**







# More questions afterwards... ??

## Check out more FAQ's at:

<http://helpdesk.gs1.org/ArticlesBySubject.aspx?UDI%20-%20Unique%20Device%20Identifier&id=3a55268a-c05a-e311-ba24-00155d644240>

## Or if you have additional questions:

### UDI Regulations / Public Policy

Géraldine Lissalde-Bonnet [g.lissalde@gs1.org](mailto:g.lissalde@gs1.org)

### UDI AIDC

Chuck Biss [chuck.biss@gs1.org](mailto:chuck.biss@gs1.org)

### UDI GUDID

Pete Alvarez [peter.alvarez@gs1.org](mailto:peter.alvarez@gs1.org)

### UDI Marketing & Collateral

Anouk Chavel [anouk.chavel@gs1.org](mailto:anouk.chavel@gs1.org)

### GS1 Healthcare UDI web page at:

<http://www.gs1.org/healthcare/udi>

### GS1 US Healthcare UDI web page:

<http://www.gs1us.org/industries/healthcare/gs1-healthcare-us/fda-udi>

### FDA Helpdesk Direct

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/ucm368904.htm>



# Contact Details

Chuck Biss

Senior Director, AIDC Healthcare

GS1 Global Office

T +1 (315) 252-5941

M +1 (315) 480-2034

Email: [chuck.biss@gs1.org](mailto:chuck.biss@gs1.org)

## REMEMBER TO CHECK OUT:

...GS1 Healthcare UDI web page at: <http://www.gs1.org/healthcare/udi>

...GS1 US Healthcare UDI web page at: <http://www.gs1us.org/industries/healthcare/gs1-healthcare-us/fda-udi>

...U.S. FDA UDI general web page at:

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/default.htm>

